UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

(Mark One)

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

For the Quarterly Period Ended March 31, 2019

OR

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

For the transition period from ____ to ____

Commission file number 001-37809

Gemphire Therapeutics Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**47-2389984**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
17199 N. Laurel Park Drive, Suite 401, Livonia, MI	**48152**
(Address of principal executive offices)	(Zip Code)

(734) 245-1700
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange On Which Registered**
Common stock, $0.001 par value	GEMP	The Nasdaq Stock Market LLC

The number of outstanding shares of the registrant's common stock, $0.001 par value, as of May 8, 2019 was 14,265,411.

Gemphire Therapeutics Inc.
FORM 10-Q
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PART I – FINANCIAL INFORMATION
ITEM 1 – FINANCIAL STATEMENTS

Gemphire Therapeutics Inc.
Condensed Balance Sheets
(in thousands, except share amounts and par value)

	March 31, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 5,510	$ 18,954
Restricted cash	15	—
Prepaid expenses	513	715
Other assets	68	17
Total current assets	6,106	19,686
Right-of-use assets and deposits	52	8
Total assets	$ 6,158	$ 19,694
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,234	$ 2,044
Accrued liabilities	478	438
Term loan - current portion	—	9,437
Total current liabilities	1,712	11,919
Long-term liabilities:		
Other liabilities	—	1
Total liabilities	1,712	11,920
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of March 31, 2019 and December 31, 2018, no shares issued or outstanding as of March 31, 2019 and December 31, 2018.	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2019 and December 31, 2018, 14,265,411 and 14,265,411 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively.	22	22
Additional paid–in capital	92,336	91,863
Accumulated deficit	(87,912)	(84,111)
Total stockholders' equity	4,446	7,774
Total liabilities and stockholders' equity	$ 6,158	$ 19,694

See accompanying notes to condensed financial statements.

Gemphire Therapeutics Inc.
Condensed Statements of Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	For the Three Months Ended March 31,	
	2019	2018
Operating expenses:		
General and administrative	$ 1,407	$ 2,087
Research and development	1,393	4,977
Total operating expenses	2,800	7,064
Loss from operations	(2,800)	(7,064)
Interest expense, net	(830)	(160)
Other expense	(171)	—
Loss before income taxes	(3,801)	(7,224)
Provision (benefit) for income taxes	—	—
Net loss	(3,801)	(7,224)
Other comprehensive loss, net of tax	—	—
Comprehensive loss	$ (3,801)	$ (7,224)
Net loss per share:		
Basic and diluted (Note 9)	$ (0.27)	$ (0.58)
Number of shares used in per share calculations:		
Basic and diluted	14,265,411	12,439,591

See accompanying notes to condensed financial statements.

Gemphire Therapeutics Inc.
Condensed Statements of Changes in Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid–In Capital	Accumulated Deficit	Total Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at January 1, 2018	—	$ —	10,633,042	$ 18	$ 64,397	$ (60,474)	$ 3,941
Issuance of common stock	—	—	3,592,858	4	25,146	—	25,150
Issuance costs	—	—	—	—	(2,093)	—	(2,093)
Exercise of stock options	—	—	6,413	—	23	—	23
Share–based compensation — employee	—	—	—	—	1,019	—	1,019
Share–based compensation — non–employee	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	(7,224)	(7,224)
Balance at March 31, 2018	—	$ —	14,232,313	$ 22	$ 88,493	$ (67,698)	$ 20,817
Balance at January 1, 2019	—	$ —	14,265,411	$ 22	$ 91,863	$ (84,111)	$ 7,774
Share–based compensation — employee	—	—	—	—	473	—	473
Net loss	—	—	—	—	—	(3,801)	(3,801)
Balance at March 31, 2019	—	$ —	14,265,411	$ 22	$ 92,336	$ (87,912)	$ 4,446

See accompanying notes to condensed financial statements.

Gemphire Therapeutics Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2019	**2018**
Operating activities		
Net loss	$ (3,801)	$ (7,224)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	473	1,020
Non-cash discount amortization on term loan	822	77
Change in assets and liabilities:		
Prepaid expenses and other assets	107	168
Accounts payable	(810)	(1,304)
Accrued and other liabilities	39	27
Net cash used in operating activities	(3,170)	(7,236)
Investing activities		
Net cash provided by (used in) investing activities	—	—
Financing activities		
Repayment of principal	(10,259)	—
Exercise of stock options	—	23
Proceeds from sale of common stock	—	25,150
Offering costs	—	(1,949)
Net cash (used in) provided by financing activities	(10,259)	23,224
Net (decrease) increase in cash, cash equivalents and restricted cash	(13,429)	15,988
Cash, cash equivalents and restricted cash at beginning of period	18,954	18,473
Cash, cash equivalents and restricted cash at end of period	$ 5,525	$ 34,461
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 75	$ 112
Supplemental non-cash financing transactions:		
Issuance costs in accounts payable and accrued liabilities	$ —	$ 144
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and equivalents	$ 5,510	$ 34,461
Restricted cash	15	—
Total cash, cash equivalents and restricted cash	$ 5,525	$ 34,461

See accompanying notes to condensed financial statements.

Gemphire Therapeutics Inc.
Notes to Condensed Financial Statements (unaudited), continued

1. The Company and Basis of Presentation

The Company, headquartered in Livonia Michigan, is a clinical-stage biopharmaceutical entity focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease, particularly orphan indications as well as NAFLD/NASH (nonalcoholic fatty liver disease/non-alcoholic steatohepatitis). The Company's primary activities to date have been conducting research and development activities, planning and conducting clinical trials, performing business and financial planning, recruiting personnel and raising capital. The Company is subject to certain risks, which include the need to research, develop, and clinically test potentially therapeutic products, initially one product candidate gemcabene (also known as CI-1027); obtain regulatory approval for its products and commercialize them around the world, if approved; expand its management scientific staff; finance its operations; and find collaboration partners to further advance development and commercial efforts.

Follow-On Public Offering

On February 12, 2018, the Company completed an underwritten public offering (the Follow-On Offering) of 3,142,858 shares of common stock at the public offering price of $7.00 per share. As part of such offering, the Company issued 450,000 additional shares of common stock representing partial exercise of the underwriters' overallotment option. The Company received net proceeds of approximately $23.1 million after deducting underwriting discounts and commissions and offering expenses.

Capital Requirements

The Company has sustained operating losses since inception and expects such losses to continue over the next several years. Management plans to continue financing the Company's operations with equity and/or debt issuances. The Company's management believes the Company's cash and cash equivalents on hand, are not adequate to fund the Company's operations for at least the next 12 months (see *Going Concern* section below). If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate part or all of its research and development programs.

Basis of Presentation

The accompanying condensed financial statements have been prepared by the Company, without audit, pursuant to the rules and regulations of the SEC. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles (GAAP) have been condensed or omitted pursuant to such rules and regulations. The condensed financial statements may not include all disclosures required by U.S. GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2019. The condensed balance sheet at December 31, 2018 was derived from the audited financial statements.

In the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, have been made. The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

Going Concern

The accompanying condensed financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In accordance with Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements - Going Concern* (Subtopic 205-40), the Company has disclosed its

conclusions regarding whether there is substantial doubt about the entity's ability to continue as a going concern within one year from the date of the issuance of these financial statements.

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of March 31, 2019, the Company had an accumulated deficit of $87.9 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $5.5 million at March 31, 2019 are not sufficient to fund the Company's current operating plan for at least twelve months after the date the condensed financial statements are issued. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the Food and Drug Administration (FDA) or other regulatory authorities approve gemcabene and we successfully commercialize gemcabene. Until such time, if ever, we expect to finance our cash needs through a combination of equity and debt financings as well as collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds and there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of gemcabene. The condensed financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of deposit to be cash equivalents. The Company invests excess cash in readily available checking and savings accounts and invests in highly liquid investments in money market accounts.

Restricted Cash

The Company considers the cash security requirement related to a commercial credit card arrangement with Silicon Valley Bank as restricted cash (See Note 4 – *Debt*).

Fair Value of Financial Instruments

The Company's condensed financial instruments include principally cash and cash equivalents, other assets, accounts payable, accrued liabilities and debt. The carrying amounts for these condensed financial instruments reported in the balance sheets approximate their fair values. See Note 10 — *Fair Value Measurements*, for further discussion of fair values.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries and share-based compensation costs, for personnel in functions not directly associated with research and development activities. Other significant costs include legal fees related to intellectual property and corporate matters and professional fees for accounting and other services.

Gemphire Therapeutics Inc.
Notes to Condensed Financial Statements (unaudited), continued

Research and Development Expenses

Research and development expenses consist of costs incurred in performing research and development activities, including compensation for research and development employees, costs associated with preclinical studies and trials, regulatory activities, manufacturing activities to support clinical activities, license fees, non-legal patent costs, fees paid to external service providers that conduct certain research and development, clinical costs and an allocation of overhead expenses. Research and development costs are expensed as incurred.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by Accounting Standards Codification (ASC) 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. Currently, there is no provision for income taxes, as the Company has incurred operating losses to date, and a full valuation allowance has been provided on the net deferred tax assets.

Share-Based Compensation

The Company accounts for share-based compensation in accordance with the provisions of ASC 718, *Compensation — Stock Compensation* (ASC 718). Accordingly, compensation costs related to equity instruments granted are recognized at the grant-date fair value. The Company records forfeitures when they occur. Share-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718 and ASC 505, *Equity*, using a fair value approach.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of development and commercialization of therapeutics for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease particularly orphan indications. Accordingly, the Company has a single reportable segment.

Jumpstart Our Business Startups Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act), the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company has irrevocably elected not to avail itself of this exemption and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments — Overall: Recognition and Measurement of Financial Assets and Financial Liabilities.* The guidance affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. This pronouncement is effective for annual and interim reporting periods beginning after December 15, 2018, with early adoption permitted for the accounting guidance on financial liabilities under the fair value option. The Company adopted this standard on January 1, 2019 and it did not have a material impact on the Company's financial statements.

Gemphire Therapeutics Inc.
Notes to Condensed Financial Statements (unaudited), continued

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* and subsequently amended the guidance relating largely to transition considerations under the standard in January 2017 and July 2018. The objective of this update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods. The Company adopted the standard on January 1, 2019, and applied the modified retrospective approach to each lease in existence at the adoption date. As such, the Company did not restate comparative periods and did not recognize any cumulative adjustment to retained earnings on the date of the adoption given that no difference in operating expense resulted upon adoption. The Company elected the package of practical expedients provided under the standard. The Company recognized approximately $0.1 million of lease assets and liabilities on the balance sheet as of January 1, 2019. The new standard did not have an impact on the Company's statements of comprehensive loss or statements of cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. The objective of this ASU is to eliminate the diversity in practice related to the classification of restricted cash or restricted cash equivalents in the statement of cash flows. For public business entities, this ASU is effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted. The amendments in this update should be applied retrospectively to all periods presented. The Company adopted this standard on January 1, 2018 and it did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting* (ASU 2016-09), which provides guidance about which changes to the terms or conditions of a share-based payment awards require an entity to apply modification accounting in Topic 718. This pronouncement is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard on January 1, 2018 and it did not have a material impact on the Company's financial statements.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share, Distinguishing Liabilities from Equity and Derivatives and Hedging*, which changes the accounting and earnings per share for certain instruments with down round features. The amendments in this ASU should be applied using a cumulative-effect adjustment as of the beginning of the fiscal year or retrospective adjustment to each period presented and is effective for annual periods beginning after December 15, 2018, and interim periods within those periods. The Company adopted this standard on January 1, 2019 and it did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018-07)*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should generally apply the requirements of Topic 718 to nonemployee awards except in circumstances where there is specific guidance on inputs to an option pricing model and the attribution of cost. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The guidance also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. This guidance is effective for annual reporting periods beginning after December 15, 2018, with early adoption permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted this standard on January 1, 2019 and it did not have an impact on the Company's financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (ASU 2018-13)*. The new guidance modifies the disclosure requirements in Topic 820 as follows:

- Removals: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements.

- Modifications: for investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly; and the amendments clarify that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date.

- Additions: the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements.

This guidance is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should all be applied prospectively for only the most recent interim or annual period presented in the initial year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is currently evaluating the impact of the new guidance on its financial statements.

3. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued compensation and other payroll liabilities	$ 24	$ 137
Legal costs	172	106
Accrued interest	—	43
Lease liability	44	—
Other research and development expenses	177	135
Other general and administrative expenses	61	17
Total	$ 478	$ 438

4. Debt

Term Loan

On January 25, 2019, the Company agreed to prepay in full all outstanding indebtedness under the Loan and Security Agreement (the "Original Loan Agreement") with Silicon Valley Bank (SVB) dated July 24, 2017 (the "Initial Effective Date"), as amended by the First Amendment, dated July 31, 2018 (the "First Amendment" and, the Original Loan Agreement, as amended by the First Amendment, the "Loan Agreement"). Effective January 28, 2019, the Company prepaid in full all outstanding indebtedness under the Term Loan. As of the date of repayment, the Company had approximately $8.9 million in principal and interest outstanding as well as a final payment fee due of $1.0 million. Upon repayment, approximately $0.8 million of unamortized note discounts were recognized as interest expense.

The obligations, liabilities, covenants, and terms that are expressly specified in the Loan Agreement and any other related loan and collateral security documents issued by the Company to SVB in connection with the transaction evidenced by the Loan Agreement as surviving termination shall continue to survive notwithstanding the payment, including without limitation, the Company's indemnity obligations and the Company's obligation to pay to SVB a success fee of 3.5% of the funded principal amount of the Term Loan in the event any of the following occur on or before 5:00 PM, Eastern time, on July 24, 2024: (a) the Company receives FDA approval for any new drug application for gemcabene, (b) a sale or other transfer of all or substantially all of the assets of the Company occurs, (c) a merger or consolidation of the Company with or into another person or entity occurs where the holders of the Company's outstanding voting equity securities immediately prior to such merger or consolidation hold less than a majority of the issued and outstanding voting equity securities of the successor immediately following such transaction or (d) any sale by the holders of the Company's outstanding voting equity securities where such holders do not continue to hold at least a majority of the Company's issued and outstanding voting equity securities immediately following the consummation of such transaction. No event requiring payment of the success fee has occurred, or is probable of occurring, through the filing date of this Quarterly Report on Form 10-Q. The Warrant to purchase 36,000 shares (subject to adjustment) of the Company's common stock dated as of July 31, 2018 between the Company and SVB will remain outstanding and exercisable in accordance with its terms.

The Company was required to reserve $15,000 in cash related to a SVB commercial credit card arrangement in February 2019 upon the prepayment of the Term Loan. The cash reserve is reflected as restricted cash in the accompanying condensed balance sheets.

5. Commitments and Contingencies

Pfizer License Agreement

In April 2011, the Company and Pfizer Inc. (Pfizer) entered into an exclusive license agreement for the clinical product candidate gemcabene, which was subsequently amended and restated in August 2018 (as so amended, the Pfizer Agreement). In exchange for this worldwide exclusive license to certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene, the Company agreed to certain milestone and royalty payments on future sales (See Note 6 — *License Agreement)*. As of March 31, 2019, there was sufficient uncertainty with regard to both the outcome of the clinical trials and the ability to obtain sufficient funding to support any of the cash milestone payments under the Pfizer Agreement, and as such, no liabilities were recorded related to the Pfizer Agreement.

Other Agreements

In May 2016, the Company entered into a non-cancellable lease agreement for its headquarters location, commencing in the third quarter of 2016. The initial term of the agreement is 3 years with an initial monthly base rent of approximately $8,400 and increasing to approximately $8,900 during the last year of the lease term. The total rent expense under this operating classified lease was $25,000 and $26,000 during the three month periods ended March 31, 2019 and 2018, respectively.

Supplemental cash flow information related to the operating lease was as follows (in thousands):

Gemphire Therapeutics Inc.
Notes to Condensed Financial Statements (unaudited), continued

	Three months ended March 31, 2019	Three months ended March 31, 2018
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating leases	$ 27	$ 26
Right-of -use assets obtained in exchange for lease obligations:		
Operating leases	$ 70	$ -

Supplemental balance sheet information related to the operating lease was as follows (in thousands, except weighted average data):

	As of March 31, 2019	As of December 31, 2018
Right-of-use assets	$ 44	$ 68
Lease liability	$ 44	$ 70
Weighted average remaining lease term	0.4 years	0.7 years
Weighted average discount rate	5.5%	5.5%

Maturity of the lease liability was as follows (in thousands):

	As of March 31, 2019
2019 (period from April 1, 2019 to December 31, 2019)	$ 45
Total lease payments	$ 45
Less imputed interest	(1)
Total	$ 44

Other Commitments and Contingencies

In the ordinary course of business, from time to time, the Company may be subject to a broad range of claims and legal proceedings that relate to contractual allegations, patent infringement, employment-related matters and other claims. The Company establishes accruals for matters which it believes that losses are probable and can be reasonably estimated. Although it is not possible to predict with certainty the outcome of these matters, the Company is of the opinion that the ultimate resolution of these matters will not have a material adverse effect on its results of operations or financial position.

6. License Agreement

The Company is party to the Pfizer Agreement, as amended on August 2, 2018, for a worldwide exclusive license to certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Pfizer retains the right to make, use and import gemcabene solely for internal research purposes.

In partial exchange for the rights granted by Pfizer, the Company agreed to issue shares of its common stock to Pfizer representing 15% of the Company's fully diluted capital at the close of its first arms-length Series A financing, which occurred on March 31, 2015.

The Company agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first new drug application (or its foreign equivalent) in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

The Company also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales, as specified in the Pfizer Agreement, until the later of: (a) five (5) years after the first commercial sale in such country; (b) the expiration of all regulatory or data exclusivity for gemcabene in such country; and (c) the expiration or abandonment of the last valid claim of the licensed patents, including any patent term extensions or supplemental protection certificates in such country (collectively, the Royalty Term). Under the Pfizer Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

On March 31, 2015, upon the closing of the Series A preferred stock financing, the Company issued 675,250 shares of its common stock, at a fair market value of $0.9 million, to Pfizer in connection with the first equity payment, pursuant to which Pfizer became the owner of more than 5% of the Company's capital stock. The transaction was recorded as acquired in-process research and development expenses based on the fair value of the common shares issued since no processes or activities that would constitute a "business" were acquired and none of the rights and underlying assets acquired had alternative future uses or reached a stage of technological feasibility. None of the other milestone or royalty payments were triggered as of March 31, 2019.

The Pfizer Agreement will expire upon expiration of the last Royalty Term. On expiration (but not earlier termination), the Company will have a perpetual, exclusive, fully paid-up, royalty-free license under the licensed patent rights and related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Either party may terminate the Pfizer Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the Pfizer Agreement in the event that (i) the Company or any of its affiliates or sublicenses contests or challenges, or supports or assists any third party to contest or challenge, Pfizer's ownership of or rights in, or the validity, enforceability or scope of any of the patents licensed under the Pfizer Agreement or (ii) the Company or any of its affiliates or sublicensees fails to achieve the first commercial sale in at least one country by April 16, 2024. Furthermore, upon termination of the Pfizer Agreement by Pfizer for any of the foregoing reasons, the Company grants Pfizer a non-exclusive, fully paid-up, royalty free, worldwide, transferrable, perpetual and irrevocable license to use any intellectual property rights arising from the development or commercialization of gemcabene by the Company and any trademarks identifying gemcabene and agrees to transfer regulatory filings and approvals to Pfizer or permit Pfizer to cross-reference and rely on such regulatory filings and approvals for gemcabene. The Company may terminate the License Agreement for convenience upon 90 days' written notice and payment of an early termination fee.

7. Stockholders' Equity

Common Stock

The Company had 14,265,411 shares of its common stock issued and outstanding as of March 31, 2019 and December 31, 2018. Voting, dividend and liquidation rights of the holders of the common stock are subject to the Company's articles of incorporation, corporate bylaws and underlying shareholder agreements.

In the first quarter of 2018, the Company completed the Follow-On Offering of 3,592,858 shares of common stock which includes 450,000 shares of common stock purchased by the underwriters upon the partial exercise of their overallotment option, at the public offering price of $7.00 per share. The Company received net proceeds of

approximately $23.1 million after deducting underwriting discounts and commissions and offering expenses. The costs incurred related to the Follow-On Offering were $2.1 million.

Warrants

During the three month periods ending March 31, 2019 and 2018, no warrants were exercised. As of March 31, 2019 and December 31, 2018, warrants to purchase 1,014,204 shares of common stock were outstanding.

Dividend Rights

Common stock holders are entitled to receive dividends at the sole discretion of the board of directors of the Company. There have been no dividends declared on common stock as of March 31, 2019.

Voting Rights

The holders of common stock are entitled to one vote for each share of common stock along with all other classes and series of stock of the Company on all actions to be taken by the stockholders of the Company, including actions that would amend the certificate of incorporation of the Company to increase the number of authorized shares of the common stock.

Liquidation Rights

In the event of any liquidation, dissolution, or winding-up of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution post preferential distributions made to preferred stockholders, if any.

8. Share-Based Compensation

Share-based compensation expense was included in general and administrative and research and development expenses as follows in the accompanying condensed statements of comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2019	2018
General and administrative	$ 284	$ 711
Research and development	189	309
Total share-based compensation	$ 473	$ 1,020

Stock Options

In April 2015, the Company adopted a 2015 Equity Incentive Plan (the 2015 Plan) under which 320,615 shares of the Company's common stock were reserved for issuance to employees, directors and consultants. The 2015 Plan permits the grant of incentive and non-statutory stock options, appreciation rights, restricted stock, restricted stock units, performance stock and cash awards, and other stock-based awards.

Amended and Restated 2015 Equity Incentive Plan

In April 2016, the Company's board of directors approved the Company's amended and restated 2015 Plan (the A&R 2015 Plan). The Company's stockholders also approved the A&R 2015 Plan in April 2016 and the A&R 2015 Plan became effective immediately upon the execution and delivery of the underwriting agreement related to the IPO. The A&R 2015 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity awards, as well as performance cash awards.

Under the A&R 2015 Plan, the number of shares of common stock reserved for issuance thereunder automatically increases on January 1st of each year, for a period of 10 years commencing on January 1, 2017 and ending on (and including) January 1, 2026, to an amount equal to 20% of the Company's fully-diluted shares as of December 31st of the preceding calendar year. Notwithstanding the foregoing, the Company's board of directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the shares reserved for such year, or that the increase in shares reserved for such year will be less than would have otherwise been allowed under the provision. Effective January 1, 2019, 501,001 shares were added to the A&R 2015 Plan under the share reserve provision. As a result, the total shares available under the A&R 2015 Plan for future issuance was 959,783 shares as of March 31, 2019.

Inducement Plan

In September 2016, the Company's board of directors approved the Company's Inducement Plan (the Inducement Plan). The Company initially reserved 300,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. The Plan was approved by the Company's board of directors without stockholder approval pursuant to Rule 5635(c)(4), and the terms and conditions of the Plan are substantially similar to the Company's stockholder-approved A&R 2015 Plan. The total shares available under the Inducement Plan for future issuance was 249,479 shares as of March 31, 2019.

2016 Employee Stock Purchase Plan

In April 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (the ESPP) in order to enable eligible employees to purchase shares of the Company's common stock at a discount following the effective date of the IPO. The Company's stockholders also approved the ESPP in April 2016 and the ESPP became effective immediately upon the execution and delivery of the underwriting agreement related to the IPO. The Company initially reserved 150,000 shares of common stock for issuance under the ESPP. As of March 31, 2019, no shares have been purchased under the ESPP.

During the three months ended March 31, 2019 and 2018, the Company granted an aggregate of zero and 472,000 stock options, respectively, under the A&R 2015 Plan and the Inducement Plan to its officers, directors, employees and consultants, generally vesting over a four-year period. The weighted average grant date fair value for option shares granted during the three months ended March 31, 2018 was $10.18 per share.

The Company measures the fair value of stock options to employees, consultants and directors on the date of grant with service-based and performance-based vesting criteria using the Black-Scholes option pricing model and market-based vesting criteria using a Monte Carlo simulation model. The Company does not have sufficient history to support a calculation of volatility and expected term. As such, the Company has used a weighted-average volatility considering the volatilities of several guideline companies.

For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, and stage of life cycle. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The average expected life of the options was determined based on the mid-point between the vesting date and the end of the contractual term according to the "simplified method" as described in Staff Accounting Bulletin 110. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. The Company records forfeitures when they occur.

The weighted-average assumptions used in the Black-Scholes option-pricing and Monte Carlo simulation models are as follows:

Gemphire Therapeutics Inc.
Notes to Condensed Financial Statements (unaudited), continued

	Three Months Ended March 31,	
	2019	2018
Expected stock price volatility	—	66.5%
Expected life of options (years)	—	5.8
Expected dividend yield	—	0%
Risk free interest rate	—	2.5%

During the three months ended March 31, 2019 and 2018, 79,113 and 180,348 stock options vested, respectively. During the three months ended March 31, 2019 and 2018, 7,000 and 3,500 stock options were forfeited, respectively. As of March 31, 2019, 2,793,773 stock options were outstanding, 1,891,293 stock options were vested and 1,209,262 shares in the aggregate were available for future issuance under the A&R 2015 and Inducement Plans.

Unrecognized share-based compensation cost for stock options issued under the A&R 2015 Plan and the Inducement Plan was $3.4 million as of March 31, 2019. The unrecognized share-based expense is expected to be recognized over a weighted average period of 1.3 years.

9. Net Loss Per Common Share

Basic earnings or loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted earnings or loss per share of common stock is computed similarly to basic earnings or loss per share except the weighted average shares outstanding are increased to include additional shares from the assumed exercise of any common stock equivalents, if dilutive. The Company's stock options and warrants are considered common stock equivalents while outstanding for this purpose. Diluted earnings are computed utilizing the treasury method for stock options and warrants. No incremental common stock equivalents were included in calculating diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the three months ended March 31, 2019 and 2018. The following table sets forth the computation of basic and diluted loss per share for the three months ended March 31, 2019 and 2018 (in thousands, except share and per share amounts):

	Three Months Ended	
	2019	2018
Numerator:		
Net loss attributed to common stock holders	$ (3,801)	$ (7,224)
Denominator:		
Basic and diluted weighted average common shares outstanding	14,265,411	12,439,591
Basic and diluted net loss per share	$ (0.27)	$ (0.58)

The following potential common shares were not considered in the computation of diluted net loss per share as their effect would have been anti-dilutive during the three months ended March 31, 2019 and 2018:

	Three Months Ended	
	2019	2018
Stock options	2,793,773	2,926,227
Warrants	1,014,204	978,204

10. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity specific measurement. Fair value is defined as "the price that would be received to sell an asset or paid to transfer a

liability in an orderly transaction between market participants at the measurement date." Fair value measurements are defined on a three level hierarchy:

Level 1 inputs: Unadjusted quoted prices for identical assets or liabilities in active markets;

Level 2 inputs: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, weather directly or indirectly, for substantially the full term of the asset or liability;

Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

As of March 31, 2019 and December 31, 2018, the fair values of cash and cash equivalents, restricted cash, other assets, accounts payable, accrued liabilities and other liabilities approximated their carrying values because of the short-term nature of these assets or liabilities. The estimated fair value of the Company's Term Loan while outstanding was based on amortized cost which was deemed to approximate fair value. There were no transfers between fair value hierarchy levels during the three months ended March 31, 2019 and 2018.

There were no instruments measured on a recurring fair value basis as of March 31, 2019 and December 31, 2018. In addition, no financial instruments were measured on a non-recurring basis for any of the periods presented.

11. Income Taxes

The effective tax rate for the three month periods ended March 31, 2019 and 2018 was zero percent. As a result of the analysis of all available evidence as of March 31, 2019 and December 31, 2018, the Company recorded a full valuation allowance on its net deferred tax assets. Consequently, the Company reported no income tax benefit for the three month periods ended March 31, 2019 and 2018. If the Company's assumptions change and the Company believes that it will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be recognized as a reduction of future income tax expense. If the assumptions do not change, each period the Company could record an additional valuation allowance on any increases in the deferred tax assets.

12. Defined Contribution Plan

The Company adopted a 401(k) defined contribution plan on September 5, 2017, effective as of January 1, 2017, for all employees over age 21. Employees can defer up to 100% of their compensation through payroll withholdings into the plan subject to federal law limits. Effective January 1, 2018, the Company began matching contributions on deferrals at 100% of deferrals up to 3% of one's contributions and 50% on deferrals over 3%, but not exceeding 5% of one's contributions in order to satisfy certain non-discrimination tests required by the Internal Revenue Code. Employee contributions and any employer matching contributions made to satisfy certain non-discrimination tests required by the Internal Revenue Code are 100% vested upon contribution. Discretionary employer matches vest over a six-year period beginning on the second anniversary of an employee's date of hire. The amount of matching contributions made during the three month periods ended March 31, 2019 and 2018 was $28,000 and $25,000, respectively.

13. Related Party Transactions

In the first quarter of 2018, in connection with an underwritten public offering of 3,592,858 shares of common stock, the offering included 14,286 shares sold to 1 officer, for aggregate proceeds totaling approximately $0.1 million and 71,429 shares sold to 1 investor who is an affiliate of 1 officer and board member, for proceeds totaling approximately $0.5 million.

14. Subsequent Events

Gemphire Therapeutics Inc.
Notes to Condensed Financial Statements (unaudited), continued

Nasdaq Compliance

On March 20, 2019, the Company received written notice from the Nasdaq Stock Market (Nasdaq) stating that the Company no longer complies with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5450(b)(1)(A) for continued listing on the Nasdaq Global Market because its stockholders' equity, as reported in its Annual Report on Form 10-K for the year ended December 31, 2018, had fallen below $10 million. The notification letter also indicated that the Company does not meet the alternative compliance standards set forth in Nasdaq Listing Rule 5450(b).

Under applicable Nasdaq rules, the Company had 45 calendar days from the date of the notification letter, or until May 6, 2019, to submit a plan to regain compliance. On May 6, 2019, our Board approved an application to transfer the Company's common stock to The Nasdaq Capital Market, which has a minimum stockholders' equity requirement of $2.5 million for continued listing, and we timely submitted our plan and application to transfer the Company's common stock to The Nasdaq Capital Market. If our plan is accepted and application is approved, our common stock will be listed on the Nasdaq Capital Market and will continue to be listed on the Nasdaq Capital Market provided we meet the continued listing standards. See Part II "Other Information," Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q.

Gemphire Therapeutics Inc.
Form 10-Q

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed financial statements and related notes included in Part I "Financial Information", Item I "Financial Statements" of this Quarterly Report on Form 10-Q and the audited financial statements and related notes for the fiscal year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 18, 2019.

Forward-Looking Statements

Certain statements contained in this Quarterly Report on Form 10-Q are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements give current expectations or forecasts of future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "target," "contemplate," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements.

These forward-looking statements reflect our management's beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this report and are subject to known and unknown risks and uncertainties, many of which are beyond our control, that could cause our actual results to differ materially from those in these forward-looking statements. We discuss many of these risks in greater detail under Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K filed on March 18, 2019 and under Part II "Other Information," Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q and in subsequent reports filed with or furnished to the SEC. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Any forward-looking statement made by us in this report speaks only as of the date hereof or as of the date specified herein. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments, changed circumstances or otherwise, except as may be required by applicable laws or regulations.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life threatening cardiovascular disease, particularly orphan indications such as homozygous familial hypercholesterolemia (HoFH), as well as NAFLD/NASH. Our therapeutic compound, gemcabene, has been tested as monotherapy and in combination with statins and other drugs in over 1,100 subjects, which we define as healthy volunteers and patients, across 25 Phase 1 and Phase 2 clinical trials and has demonstrated promising evidence of efficacy, safety and tolerability.

Our Company was co-founded in November 2008 as a limited liability company under the name Michigan Life Therapeutics, LLC (MLT) by former Pfizer Inc. employees, including Dr. Charles Bisgaier, who were responsible for licensing exclusive worldwide rights to gemcabene from Pfizer in April 2011. In October 2014, we incorporated a new entity under the name Gemphire Therapeutics Inc. in Delaware. In November 2014, we entered into a merger agreement with Gemphire whereby MLT was merged with and into Gemphire, with Gemphire as the surviving entity and all

outstanding units of membership interest in MLT were exchanged for shares of common stock of Gemphire. The purpose of the merger was to change the jurisdiction of our incorporation from Michigan to Delaware and to convert from a limited liability company to a corporation.

To date, our primary activities have been conducting research and development activities, planning and conducting clinical trials, performing business and financial planning, recruiting personnel and raising capital. We do not have any products approved for sale and have not generated any revenue. We do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve gemcabene and we successfully commercialize gemcabene. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings as well as collaborations, strategic alliances and licensing arrangements. Our net losses were $3.8 million and $7.2 million during the three month periods ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had an accumulated deficit of $87.9 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies, clinical trials and our expenditures on other research and development activities.

We have funded our operations to date primarily through the issuance and sale of common stock and warrants in public offerings and a private placement, the proceeds of our term loan facility with Silicon Valley Bank (the “Term Loan”) which we prepaid in full on January 28, 2019, and, prior to our IPO, the issuance of preferred stock and convertible notes. As of March 31, 2019, we had cash and cash equivalents of $5.5 million.

Key Developments

Clinical and Research Program Updates

During 2016 to 2018, we initiated and completed three Phase 2b clinical trials for gemcabene in HoFH, hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) and atherosclerotic cardiovascular disease (ASCVD) patients on maximally tolerated statins, and SHTG. We reported top line data from our 8 patient trial for HoFH (COBALT-1 trial) in the second quarter of 2017, top line data from our 105 patient trial for hypercholesterolemia on high-intensity statin therapy including HeFH and ASCVD patients (ROYAL-1 trial) in the third quarter of 2017, and top line data from our 91 patient trial in severe hypertriglyceridemia (SHTG) patients (INDIGO-1 trial) in the second quarter of 2018. As previously announced, all three of these trials achieved statistical significance for their primary endpoints.

An investigator initiated Phase 2a pediatric NAFLD trial was begun in the fourth quarter of 2017 to study gemcabene in adolescents 12-17 years old. The study enrolled six patients and in August 2018, the Data Safety Monitoring Board (DSMB) halted the trial early due to “unanticipated problems” in the first three patients. Specifically, the primary efficacy endpoint of ALT increased beyond baseline levels in two of these three patients. In addition, all three patients had an increase in the secondary endpoint of liver fat fraction as measured by MRI-PDFF. All patients gained weight and had increased TGs during study treatment, in contrast to data in other gemcabene trials. Patient compliance was compromised as assessed by unused tablets and blood drug levels. Three observations were reported as AEs considered related to gemcabene. No events were reported as SAEs. The risk for increased liver fat with gemcabene treatment is unknown at this time. The patients are being monitored for 12 months post-final dose. We intend to work closely with the trial site physicians and other KOLs to identify potential reasons for the unanticipated problems in the pediatric NAFLD study but cannot assure you that it will be possible to determine the reasons for the unexpected problems.

A Phase 2a proof-of-concept trial treating familial partial lipodystrophy (FPL) patients for 24 weeks is being conducted in an investigator-initiated study at the University of Michigan and was initiated in early 2018. In the third quarter, the primary investigator and DSMB for this trial reviewed the data from the pediatric trial as well interim data from the FPL trial and decided to continue the FPL trial. The trial was fully enrolled in the fourth quarter of 2018 and top-line data, including MRI-PDFF, is expected in the second quarter of 2019.

As announced in the third quarter of 2018, we completed and submitted to the FDA the results from our two year rodent carcinogenicity studies. These studies were submitted as part of a request for the FDA to remove the partial clinical hold that prevents us from conducting human studies of gemcabene that are greater than six months in duration. In response to our submission, the FDA did not lift the hold and requested that we provide additional data, including two preclinical studies, namely, a subchronic (13 week) study of gemcabene in PPARα knock-out mice and a study of gemcabene in *in vitro* PPAR transactivation assays using monkey and canine PPAR isoforms. We are working to complete studies requested by the FDA and expect to submit this additional data to the FDA in the fourth quarter of 2019. In addition, the FDA informed us that an End of Phase 2 (EOP2) meeting to reach an agreement on the design of Phase 3 registration and long term safety exposure trials for our target indications in dyslipidemia would not take place until the partial clinical hold is lifted.

Pfizer License Agreement

In the third quarter of 2018, we announced that our gemcabene in-licensing agreement with Pfizer was renegotiated providing three additional years to for us to achieve our first commercial sale, by April 2024. See "—Pfizer Agreement" below.

Workforce Reduction

In September 2018, our board of directors approved a workforce reduction to reduce costs and conserve cash resources in light of the FDA's request for additional data described above and the resulting delay in our Phase 3 trials. The workforce reduction included 5 employees, which represented approximately 33% of our workforce at such time, and was completed in the fourth quarter of 2018. We recorded severance related charges totaling approximately $1.6 million, which included cash severance payments of approximately $0.5 million, a non-cash charge of approximately $1.1 million related to the accelerated vesting of outstanding stock options for certain affected employees, and $30,000 for continued health insurance coverage. We may incur additional costs not currently contemplated due to events associated with or resulting from the workforce reduction.

Review of Strategic Alternatives

In December 2018, we announced that our Board of Directors established a committee to oversee a review of strategic alternatives focused on maximizing stockholder value and that we had engaged Ladenburg Thalmann & Co. Inc. to act as our strategic financial advisor in this process. Despite undertaking this process, we may not be successful in completing a transaction, and, even if a strategic transaction is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value.

SVB Loan Repayment

In January 2019, we prepaid in full all outstanding indebtedness under our Loan Agreement with SVB. See "—Term Loan" below.

Nasdaq Compliance

On March 20, 2019, we received written notice from the Nasdaq Stock Market (Nasdaq) stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5450(b)(1)(A) for continued listing on the Nasdaq Global Market because our stockholders' equity, as reported in our Annual Report on Form 10-K for the year ended December 31, 2018, had fallen below $10 million. The notification letter also indicated that we do not meet the alternative compliance standards set forth in Nasdaq Listing Rule 5450(b).

Under applicable Nasdaq rules, the Company had 45 calendar days from the date of the notification letter, or until May 6, 2019, to submit a plan to regain compliance. On May 6, 2019, our Board approved an application to transfer the Company's common stock to The Nasdaq Capital Market, which has a minimum stockholders' equity requirement of $2.5 million for

continued listing, and we timely submitted our plan and application to transfer the Company's common stock to The Nasdaq Capital Market. If our plan is accepted and application is approved, our common stock will be listed on the Nasdaq Capital Market and will continue to be listed on the Nasdaq Capital Market provided we meet the continued listing standards. See Part II “Other Information,” Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. We do not expect to generate revenue unless or until we obtain regulatory approval of and commercialize gemcabene. If we fail to complete the development of gemcabene, or any other product candidate we may pursue in the future, in a timely manner, or fail to obtain regulatory approval, our ability to generate future revenue would be compromised.

Operating Expenses

Our operating expenses are classified into two categories: general and administrative and research and development.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, including salaries and share-based compensation costs, for personnel in functions not directly associated with research and administrative activities. Other significant costs include legal fees relating to intellectual property and corporate matters and professional fees for accounting and other services. We anticipate our general and administrative expenses will continue to trend below comparable prior period levels in the near future as a result of reduced research and development activities, as we work to resolve the six-month clinical hold by the FDA.

Research and Development

To date, our research and development expenses have related primarily to the clinical stage development of gemcabene. Research and development expenses consist of costs incurred in performing research and development activities, including compensation for research and development employees, costs associated with preclinical studies and trials, regulatory activities, manufacturing activities to support clinical activities, license fees, nonlegal patent costs, fees paid to external service providers that conduct certain research and development, clinical costs and an allocation of overhead expenses. Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the study or project, and the invoices received from our external service providers. We adjust our accrual as actual costs become known. Research and development activities are central to our business model.

We anticipate our research and development expenses will continue to trend below comparable prior period levels in the near future as a result of reduced research and development activities, as we work to resolve the six-month clinical hold by the FDA. We expect that gemcabene will have higher development costs during its later stages of clinical development, as compared to costs incurred during its earlier stages of development, primarily due to the increased size and duration of the later-stage clinical trials, so we expect our research and development expenses to continue to trend significantly above comparable prior period levels in the future as we continue to conduct preclinical studies and clinical trials for gemcabene and potentially develop other product candidates. However, it is difficult to determine with certainty the duration, costs and timing to complete our current or future preclinical programs and clinical trials of gemcabene. The duration, costs and timing of clinical trials and development of gemcabene will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;

- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidate;
- arrangements with contract research organizations and other service providers; and
- the efficacy and safety profile of the product candidates.

Interest Expense, net

Interest expense, net consists of cash and non-cash interest expense attributed to our Term Loan while outstanding based on the prime rate in effect, as well as cash interest income from our cash and cash equivalents. We continued to incur cash and non-cash interest expense related to our Term Loan through the prepayment of the Term Loan on January 28, 2019. We also expect to earn interest income from the investment of our cash and cash equivalents in future periods.

Other Expense, net

Other expense, net relates to non-operating transaction costs associated with our previously-announced review of strategic alternatives and foreign currency exchange gains and losses. Foreign currency exchange gains and losses relate to transactions and monetary asset and liability balances denominated in currencies other than the U.S. dollar. Foreign currency gains and losses may continue to fluctuate in the future due to changes in foreign currency exchange rates.

Provision for Income Taxes

Provision for income taxes consists of federal and state income taxes in the United States, as well as deferred income taxes and changes in related valuation allowance reflecting the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Currently, there is no provision for income taxes, as we have incurred operating losses to date, and a full valuation allowance has been provided on the net deferred tax assets as of March 31, 2019 and December 31, 2018.

Results of Operations

The following table summarizes our operating results for the periods indicated:

	For the Three Months Ended March 31,		
	2019	2018	Change
	(in thousands)		
Operating expenses:			
General and administrative	$ 1,407	$ 2,087	$ (680)
Research and development	1,393	4,977	(3,584)
Total operating expenses	2,800	7,064	(4,264)
Loss from operations	(2,800)	(7,064)	4,264
Interest expense, net	(830)	(160)	(670)
Other expense	(171)	—	(171)
Loss before income taxes	(3,801)	(7,224)	3,423
Provision (benefit) for income taxes	—	—	—
Net loss	$ (3,801)	$ (7,224)	$ 3,423

Comparison of Three Months Ended March 31, 2019 and 2018

General and Administrative

General and administrative expenses for the three months ended March 31, 2019 decreased to $1.4 million compared to $2.1 million for the three months ended March 31, 2018. The $0.7 million decrease in expenses from the comparable period in 2018 was largely due to a reduction in support activities, focused primarily on personnel costs and professional services, related to our ongoing clinical trials.

Research and Development

Research and development expenses for the three months ended March 31, 2019 were $1.4 million compared to $5.0 million for the three months ended March 31, 2018. The $3.6 million decrease was primarily attributable to reduced clinical trial activities in the first quarter of 2019 versus the comparable period in 2018.

Interest Expense, net

Interest expense, net for the three months ended March 31, 2019 was $0.8 million compared to $0.2 million for the three months ended March 31, 2018. Interest expense, net was comprised primarily of interest expense in connection with our Term Loan offset in part by interest income of $25,000 and $30,000 during the three month periods ended March 31, 2019 and 2018, respectively. The increase in net interest expense in the first quarter of 2019 over the comparable period in the prior year was largely the result of non-cash acceleration of debt discount amortization attributed to the prepayment of the Term Loan in January 2019.

Other Expense

Other expense for the three months ended March 31, 2019 comprises non-operating transaction costs associated with our previously announced review of strategic alternatives in the amount of $0.2 million. There was no other expense activity during the three months ended March 31, 2018.

Liquidity and Capital Resources

Capital Resources

As of March 31, 2019, our principal sources of liquidity consisted of cash and cash equivalents of approximately $5.5 million. Our cash and cash equivalents are invested in cash deposits and money market accounts. We have not generated any revenue, and we anticipate that we will continue to incur losses for the foreseeable future. We have funded our operations to date primarily through the issuance and sale of common stock and warrants in public offerings and a private placement, proceeds from our term loan facility with Silicon Valley Bank, which we prepaid in full on January 28, 2019, and, prior to our IPO, the issuance of preferred stock and convertible notes in private placements.

- In the first quarter of 2018, we completed an underwritten public offering of 3,592,858 shares of our common stock, including 450,000 shares of our common stock purchased by the underwriters upon the partial exercise of their overallotment option, at the public offering price of $7.00 per share. We received net proceeds of approximately $23.0 million after deducting underwriting discounts and commissions and offering expenses.

- On July 24, 2017, we entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB). The Loan Agreement established a term loan facility in the aggregate principal amount of up to $15.0 million (the Term Loan) to be funded in several tranches. We drew $10.0 million under the Loan Agreement on July 24, 2017. The Term loan was repaid effective January 28, 2019. See “—Term Loan” below for a description of the repayment terms and certain other material terms of the Loan Agreement.

- On March 15, 2017, we completed a private placement of 1,324,256 units at a price of $9.47 per unit for net proceeds of approximately $11.3 million after deducting offering expenses. Each unit consisted of one share of our common stock and a warrant to purchase 0.75 shares of common stock. The warrants have an exercise price of $10.40 per share and are exercisable for a period of five years from the date of issuance. On April 20, 2017, the registration statement on Form S-1 (File No 333-217296) for the resale of the shares of common stock issued in the private placement and the shares of common stock to be issued upon exercise of the warrants issued in the private placement was declared effective by the SEC, and on September 1, 2017, we filed a post-effective amendment to convert the registration statement into Form S-3 for the registration of any unsold private placement shares, which included an updated prospectus relating to such unsold shares.

- In August 2016, we closed our IPO. We sold an aggregate of 3,027,755 shares of our common stock, including 27,755 shares of our common stock purchased by the underwriters upon the partial exercise of their overallotment option, at a public offering price of $10.00 per share. We received net proceeds of approximately $26.1 million after deducting underwriting discounts and commissions and offering expenses. All of our outstanding preferred stock and convertible notes outstanding prior to our IPO converted into shares of our common stock immediately prior to the closing of the IPO.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	For the Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (3,170)	$ (7,236)
Net cash provided by (used in) investing activities	—	—
Net cash (used in) provided by financing activities	(10,259)	23,224
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (13,429)	$ 15,988

Cash Flow from Operating Activities

For the three months ended March 31, 2019, cash used in operating activities of $3.2 million was attributable to a net loss of $3.8 million as adjusted by $0.5 million in share-based compensation and non-cash interest expense of $0.8 million offset by a net change of $(0.7) million in our operating assets and liabilities. The change in operating assets and liabilities was primarily attributable to a decrease in our accounts payable and our prepaid expenses associated with fluctuations in our operating activities.

For the three months ended March 31, 2018, cash used in operating activities of $7.2 million was attributable to a net loss of $7.2 million offset by $1.0 million in share-based compensation and non-cash interest expense of $0.1 million offset by a net change of $1.1 million in our operating assets and liabilities and was primarily attributable to a decrease in accounts payable. The change in operating assets and liabilities was primarily attributable to a net decrease in our accounts payable offset in part by an increase in other liabilities and prepaid expenses associated with fluctuations in our operating activities.

Cash Flow from Investing Activities

There were no sources or uses of funds from investing activities for all periods presented.

Cash Flow from Financing Activities

Net cash used in financing activities during the three months ended March 31, 2019 of $10.3 million related the repayment of our Term Loan.

Net cash provided by financing activities during the three months ended March 31, 2018 of $23.2 million related to proceeds received from our Follow-On Offering, net of discounts, commissions and other costs totaling $1.9 million paid through March 31, 2018.

Liquidity and Capital Resource Requirements

We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve gemcabene and we successfully commercialize gemcabene. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings as well as collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Similar to the restrictions described below under our Loan

Agreement, additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development, future commercialization efforts, or grant rights to develop and market gemcabene that we would otherwise prefer to develop and market ourselves.

We believe our cash on hand will be sufficient to fund operations into the third quarter of 2019, but we will need to raise additional capital to continue to fund the further development of gemcabene and our operations thereafter, including submission of the additional information requested by the FDA to make a decision regarding lifting the partial clinical hold. Our business and the development of gemcabene is subject to numerous uncertainties, and we have based these estimates on assumptions that may prove to be substantially different than we currently anticipate and could use our cash resources sooner than we expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical trials is costly, and the timing of progress in these clinical trials is uncertain. Our ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans.

We anticipate that our near-term expenses will continue to be below comparable period levels as we work to have the six-month partial clinical hold by the FDA removed, then if successful, expect our expenses will increase substantially as we:

- continue clinical trials for gemcabene and for any other product candidate in our future pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- contract to manufacture our product candidates;
- establish on our own or with partners, a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, operational and financial personnel, to execute our business plan;
- add operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- continue to pursue strategic alternatives to maximize stockholder value; and
- continue to operate as a public company.

Term Loan

On January 25, 2019, we agreed to prepay in full all outstanding indebtedness under Loan Agreement which prepayment was effective January 28, 2019. Upon payoff, any unfunded commitments to make credit extensions or financial accommodations to us terminated, and all security interests and other liens granted to or held by SVB as security for the obligations were terminated and automatically released, except those that were specified as surviving termination. As of the date of payment, we had approximately $8.9 million in outstanding borrowings and approximately $1.0 million in outstanding interest and fees under the Loan Agreement, including the final payment fee equal to 10% of the original aggregate principal amount of the Term Loan funded by SVB and drawn by us, which were repaid in full at the time of payment.

The obligations, liabilities, covenants, and terms that are expressly specified in the Loan Agreement and any other related loan and collateral security documents issued by us to SVB in connection with the transaction evidenced by the Loan Agreement as surviving termination shall continue to survive notwithstanding the payment, including without limitation, our indemnity obligations and our obligation to pay to SVB a success fee of 3.5% of the funded principal amount of the Term Loan in the event any of the following occur on or before 5:00 PM, Eastern time, on July 24, 2024: (a) we receive FDA approval for any new drug application for gemcabene, (b) a sale or other transfer of all or substantially all of our assets occurs, (c) a merger or consolidation of the Company with or into another person or entity occurs where the holders of the Company's outstanding voting equity securities immediately prior to such merger or consolidation hold less than a majority of the issued and outstanding voting equity securities of the successor immediately following such transaction or (d) any sale by the holders of our outstanding voting equity securities where such holders do not continue to hold at least a majority of our issued and outstanding voting equity securities immediately following the consummation of such transaction. In addition, the warrant to purchase 36,000 shares (subject to adjustment) our common stock dated as of July 31, 2018 between us and SVB will remain outstanding and exercisable in accordance with its terms.

Facility Lease

In May 2016, we entered into a non-cancellable facility lease commencing August 1, 2016. The term of the agreement is three years with an initial monthly base rent of approximately $8,400 and increasing to approximately $8,900 during the last year of the lease agreement.

Pfizer Agreement

We entered into an exclusive license agreement for the clinical product candidate gemcabene with Pfizer Inc. (Pfizer) in April 2011, which was subsequently amended and restated in August 2018 (as so amended, the "Pfizer Agreement"). The Pfizer Agreement grants us certain patent rights and a non-exclusive royalty bearing right and license to certain related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Pfizer retains the right to make, use and import gemcabene solely for internal research purposes.

In partial exchange for the rights granted by Pfizer, we agreed to issue shares of our common stock to Pfizer representing 15% of our fully diluted capital at the close of its first arms-length Series A financing, which occurred on March 31, 2015.

We also agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first new drug application (or its foreign equivalent) in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

In addition, we agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales, as specified in the Pfizer Agreement, until the later of: (a) five (5) years after the first commercial sale in such

country; (b) the expiration of all regulatory or data exclusivity for gemcabene in such country; and (c) the expiration or abandonment of the last valid claim of the licensed patents, including any patent term extensions or supplemental protection certificates in such country (collectively, the Royalty Term). Under the Pfizer Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize gemcabene.

The Pfizer Agreement will expire upon expiration of the last Royalty Term. On expiration (but not earlier termination), we will have a perpetual, exclusive, fully paid-up, royalty-free license under the licensed patent rights and related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate gemcabene. Either party may terminate the Pfizer Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the Pfizer Agreement in the event that (i) we or any of our affiliates or sublicenses contest or challenge, or support or assist any third party to contest or challenge, Pfizer's ownership of or rights in, or the validity, enforceability or scope of any of the patents licensed under the Pfizer Agreement or (ii) we or any of our affiliates or sublicensees fail to achieve the first commercial sale in at least one country by April 16, 2024. Furthermore, upon termination of the Pfizer Agreement by Pfizer for any of the foregoing reasons, we grant Pfizer a non-exclusive, fully paid-up, royalty free, worldwide, transferrable, perpetual and irrevocable license to use any intellectual property rights arising from the development or commercialization of gemcabene by us and any trademarks identifying gemcabene and agree to transfer regulatory filings and approvals to Pfizer or permit Pfizer to cross-reference and rely on such regulatory filings and approvals for gemcabene. We may terminate the License Agreement for convenience upon 90 days' written notice and payment of an early termination fee.

Other Commitments

In the course of our normal operations, we have entered into cancellable purchase commitments with our suppliers for various key research and clinical services and raw materials. The purchase commitments covered by these arrangements are subject to change based on our research and development efforts.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with GAAP. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonably based upon information available to us at the time that we make these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. The accounting policies that reflect our more significant estimates and judgments and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results are described in Note 2 — "Summary of Significant Accounting Policies" to our condensed financial statements included in Part I "Financial Information", Item 1 "Financial Statements" of this Quarterly Report on Form 10-Q.

During the three months ended March 31, 2019, there were no material changes to our critical accounting policies or estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K filed on March 18, 2019.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under the rules and regulations of the Securities and Exchange Commission.

Recent Accounting Pronouncements

Refer to Note 2— "Summary of Significant Accounting Policies" to our condensed financial statements included in Part I "Financial Information", Item 1 "Financial Statements" of this Quarterly Report on Form 10-Q for a discussion of

recently issued accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information we are required to disclose in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and financial officer, as appropriate, to allow timely decisions regarding required disclosure.

We designed and evaluate our disclosure controls and procedures recognizing that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance and not absolute assurance of achieving the desired control objectives. Also, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls 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.

Under the supervision of and with the participation of our management, including our principal executive and financial officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15(d)- 15(e) promulgated under the Exchange Act as of March 31, 2019. Based on this evaluation, our Chief Executive Officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2019.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company may be subject to claims and lawsuits that arise primarily in the ordinary course of business. The Company believes that the disposition or ultimate resolution of any such claims and lawsuits will not have a material adverse effect on the financial position, results of operations or cash flows of the Company.

ITEM 1A. RISK FACTORS

In addition to the other information set forth elsewhere in this Quarterly Report on Form 10-Q, you should carefully consider the factor set forth below and the other factors discussed in Part I, Item 1A "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2018. Those factors, if they were to occur, could cause our actual results to differ materially from those expressed in our forward-looking statements in this report, and materially adversely affect our financial condition or future results. Although we are not aware of any other factors that we currently anticipate will cause our forward-looking statements to differ materially from our future actual results, or materially affect the Company's financial condition or future results, additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results.

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

Our common stock is currently listed on the Nasdaq Global Market. Nasdaq imposes, among other requirements, continued listing standards including minimum bid, public float and stockholders' equity requirements.

On March 20, 2019, we received written notice from the Nasdaq stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5450(b)(1)(A) for continued listing on the Nasdaq Global Market because our stockholders' equity, as reported in our Annual Report on Form 10-K for the year ended December 31, 2018, had fallen below $10 million. The notification letter also indicated that we do not meet the alternative compliance standards set forth in Nasdaq Listing Rule 5450(b).

Under applicable Nasdaq rules, we had 45 calendar days from the date of the notification letter, or until May 6, 2019, to submit a plan to regain compliance. On May 6, 2019, our Board approved an application to transfer our common stock to The Nasdaq Capital Market, which has a minimum stockholders' equity requirement of $2.5 million for continued listing, and we timely submitted our plan and application to transfer the Company's common stock to The Nasdaq Capital Market. If our plan is accepted and application approved, our common stock will be listed on the Nasdaq Capital Market and will continue to be listed on the Nasdaq Capital Market provided we meet the continued listing standards. If our plan and application are not approved, we expect to have the opportunity to appeal to a Nasdaq Hearings Panel. There can be no assurance that our application will be approved or, if it is approved, that we will maintain compliance or, if it is not approved and we appeal, that such appeal would be successful.

Recently, our common stock has traded at closing bid prices below Nasdaq's minimum closing bid price of $1.00. If the closing bid price of our common stock fails to meet Nasdaq's minimum closing bid price requirement for a period in excess of 30 consecutive days, or if we otherwise fail to meet any other applicable requirement of the Nasdaq Global Market, Nasdaq could send another deficiency notice.

If we are unable to regain compliance, Nasdaq may make a determination to delist our common stock. If our common stock is delisted, it will trade, if at all, only on an over-the-counter market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. Upon any such delisting, our common stock could become subject to the regulations of the SEC relating to the market for penny stocks. Generally, any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share may be deemed a penny stock. Any delisting of our common stock could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. Furthermore, if our common stock were delisted it could adversely affect our ability to obtain financing for the continuation of our operations and our ability to attract and retain employees by means of equity compensation and/or result in the loss of confidence by investors.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Nasdaq Compliance

On March 20, 2019, we received written notice from the Nasdaq Stock Market (Nasdaq) stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5450(b)(1)(A) for continued listing on the Nasdaq Global Market because our stockholders' equity, as reported in our Annual Report on Form 10-K for the year ended December 31, 2018, had fallen below $10 million. The notification letter also indicated that we do not meet the alternative compliance standards set forth in Nasdaq Listing Rule 5450(b).

Under applicable Nasdaq rules, the Company had 45 calendar days from the date of the notification letter, or until May 6, 2019, to submit a plan to regain compliance. On May 6, 2019, our Board approved an application to transfer the Company's common stock to The Nasdaq Capital Market, which has a minimum stockholders' equity requirement of $2.5 million for continued listing, and we timely submitted our plan and application to transfer the Company's common stock to The Nasdaq Capital Market. If our plan is accepted and application is approved, our common stock will be listed on the Nasdaq Capital Market and will continue to be listed on the Nasdaq Capital Market provided we meet the continued listing standards. See Part II "Other Information," Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q.

Gemphire Therapeutics Inc.
Form 10-Q

ITEM 6. EXHIBITS

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
3.1	Third Amended and Restated Certificate of Incorporation of Gemphire Therapeutics Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on August 10, 2016).
3.2	Amended and Restated Bylaws of Gemphire Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on August 10, 2016).
31.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of The Sarbanes Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal 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

Gemphire Therapeutics Inc.
Form 10-Q

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.

Registrant: Gemphire Therapeutics Inc.

SIGNATURE	TITLE	DATE
/s/ STEVEN GULLANS Steven Gullans	President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)	May 9, 2019

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Steven Gullans, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gemphire Therapeutics Inc. for the quarterly period ended March 31, 2019;

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. I am 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. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

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

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

Date: May 9, 2019

/s/ STEVEN GULLANS
Name: Steven Gullans
Title: President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER, PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002*

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, Steven Gullans, President and Chief Executive Officer of Gemphire Therapeutics Inc. (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and results of operations of the Company for the period covered by the Quarterly Report.

/s/ STEVEN GULLANS
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Dated: May 9, 2019

* This certification accompanies the report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Gemphire Therapeutics Inc. under the Securities Act of 1933, as amended, or the Exchange Act made before or after the date of the report, irrespective of any general incorporation language contained in such filing.