

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 September 30, 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**

(State or other jurisdiction of incorporation or organization)

**47-2389984**

(IRS Employer Identification No.)

**P.O. Box 130235, Ann Arbor, MI**  
(Address of principal executive offices)

**48113**  
(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)

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

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

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

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of November 6, 2019 was 14,872,411.

**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)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,855	\$ 18,954
Restricted cash	15	—
Prepaid expenses	140	715
Other assets	38	17
Total current assets	<u>2,048</u>	<u>19,686</u>
Deposits	—	8
Total assets	<u>\$ 2,048</u>	<u>\$ 19,694</u>
<b>Liabilities and stockholders' (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$ 2,677	\$ 2,044
Accrued liabilities	396	438
Term loan - current portion	—	9,437
Total current liabilities	<u>3,073</u>	<u>11,919</u>
Long-term liabilities:		
Other liabilities	—	1
Total liabilities	<u>3,073</u>	<u>11,920</u>
Commitments and contingencies (Note 6)		
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized as of September 30, 2019 and December 31, 2018, no shares issued or outstanding as of September 30, 2019 and December 31, 2018.	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized as of September 30, 2019 and December 31, 2018, 14,872,411 and 14,265,411 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively.	23	22
Additional paid-in capital	93,214	91,863
Accumulated deficit	<u>(94,262)</u>	<u>(84,111)</u>
Total stockholders' (deficit) equity	<u>(1,025)</u>	<u>7,774</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 2,048</u>	<u>\$ 19,694</u>

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		For the Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Operating expenses:				
General and administrative	\$ 1,250	\$ 2,364	\$ 3,772	\$ 7,025
Research and development	1,068	3,542	3,695	12,479
Total operating expenses	<u>2,318</u>	<u>5,906</u>	<u>7,467</u>	<u>19,504</u>
Loss from operations	(2,318)	(5,906)	(7,467)	(19,504)
Interest income (expense), net	4	(172)	(816)	(476)
Other expense, net	(1,116)	(1)	(1,868)	(1)
Loss before income taxes	(3,430)	(6,079)	(10,151)	(19,981)
Provision (benefit) for income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Net loss	(3,430)	(6,079)	(10,151)	(19,981)
Other comprehensive loss, net of tax	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Comprehensive loss	<u>\$ (3,430)</u>	<u>\$ (6,079)</u>	<u>\$ (10,151)</u>	<u>\$ (19,981)</u>
Net loss per share:				
Basic and diluted (Note 10)	<u>\$ (0.24)</u>	<u>\$ (0.43)</u>	<u>\$ (0.71)</u>	<u>\$ (1.46)</u>
Number of shares used in per share calculations:				
Basic and diluted	<u>14,265,411</u>	<u>14,259,691</u>	<u>14,265,411</u>	<u>13,650,556</u>

See accompanying notes to condensed financial statements.

**Gemphire Therapeutics Inc.**  
**Condensed Statements of Changes in Stockholders' (Deficit) 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
Share-based compensation — employee	—	—	—	—	908	—	908
Share-based compensation — non-employee	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	(6,678)	(6,678)
Balance at June 30, 2018	—	\$ —	14,232,313	\$ 22	\$ 89,402	\$ (74,376)	\$ 15,048
Issuance of common stock	—	—	—	—	—	—	—
Issuance costs	—	—	—	—	—	—	—
Warrant issuance	—	—	—	—	196	—	196
Exercise of stock options	—	—	33,098	—	61	—	61
Share-based compensation — employee	—	—	—	—	1,626	—	1,626
Share-based compensation — non-employee	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	(6,079)	(6,079)
Balance at September 30, 2018	—	\$ —	14,265,411	\$ 22	\$ 91,286	\$ (80,455)	\$ 10,853
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
Share-based compensation — employee	—	—	—	—	438	—	438
Net loss	—	—	—	—	—	(2,920)	(2,920)
Balance at June 30, 2019	—	\$ —	14,265,411	\$ 22	\$ 92,774	\$ (90,832)	\$ 1,964
Share-based compensation — employee	—	—	—	—	441	—	441
Restricted stock issuance	—	—	607,000	1	(1)	—	—
Net loss	—	—	—	—	—	(3,430)	(3,430)
Balance at September 30, 2019	—	\$ —	14,872,411	\$ 23	\$ 93,214	\$ (94,262)	\$ (1,025)

See accompanying notes to condensed financial statements.

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

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Operating activities</b>		
Net loss	\$ (10,151)	\$ (19,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,352	3,556
Non-cash discount amortization on term loan	822	247
Change in assets and liabilities:		
Prepaid expenses and other assets	562	(520)
Accounts payable	633	(1,674)
Accrued and other liabilities	(43)	574
Net cash used in operating activities	<u>(6,825)</u>	<u>(17,798)</u>
<b>Investing activities</b>		
Net cash provided by (used in) investing activities	<u>—</u>	<u>—</u>
<b>Financing activities</b>		
Repayment of principal	(10,259)	(10)
Exercise of stock options	—	84
Proceeds from sale of common stock	—	25,150
Offering costs	—	(2,093)
Net cash (used in) provided by financing activities	<u>(10,259)</u>	<u>23,131</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(17,084)	5,333
Cash, cash equivalents and restricted cash at beginning of period	18,954	18,473
Cash, cash equivalents and restricted cash at end of period	<u>\$ 1,870</u>	<u>\$ 23,806</u>
<i>Supplemental disclosure of cash flow information:</i>		
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>
Cash paid for interest	<u>\$ 75</u>	<u>\$ 358</u>
<i>Supplemental non-cash financing transactions:</i>		
Issuance of warrants in connection with term loan	<u>\$ —</u>	<u>\$ 196</u>
<i>Reconciliation of cash, cash equivalents and restricted cash:</i>		
Cash and cash equivalents	\$ 1,855	\$ 23,806
Restricted cash	<u>15</u>	<u>—</u>
Total cash, cash equivalents and restricted cash	<u>\$ 1,870</u>	<u>\$ 23,806</u>

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 Ann Arbor, 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. On July 24, 2019, the Company entered into a definitive agreement (the "Original Merger Agreement" and, as amended on October 29, 2019, the "Merger Agreement") with GR Merger Sub Inc., a Delaware corporation and the Company's wholly owned subsidiary ("Merger Sub"), and NeuroBo Pharmaceuticals, Inc., a Delaware corporation ("NeuroBo"), pursuant to which Merger Sub will merge with and into NeuroBo, with NeuroBo surviving as a wholly owned subsidiary of the Company in an all-stock transaction (the "Merger"). See Note 3— *Merger Agreement* for further information.

The Company is subject to certain risks, which include risks related to the proposed Merger and 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' over-allotment 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 or discontinue its operations.

**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.

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

**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 September 30, 2019, the Company had an accumulated deficit of \$94.3 million and a total stockholders' deficit of \$1 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$1.9 million at September 30, 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. The Company has no current source of revenue to sustain its present activities and does not expect to generate revenue until, and unless, the Food and Drug Administration (FDA) or other regulatory authorities approve, and the Company successfully commercializes, gemcabene or any other product candidate it may pursue in the future or unless certain development and commercialization milestones are met under the Beijing SL Agreement (See Note 7 – *License Agreements*). Until such time, if ever, the Company expects to finance its cash needs through a combination of equity and debt financings as well as collaborations, strategic alliances and licensing arrangements. The Company does not have any committed external source of funds beyond the non-refundable upfront gross payment under the Beijing SL Agreement, which was received in October 2019, 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, or the proposed Merger is not consummated, the Company may have to significantly reduce or terminate its operations or delay, further scale back or discontinue the development of gemcabene or the board of directors may elect to dissolve and liquidate the Company's assets. 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.



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

**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 5 – *Debt*).

**Fair Value of Financial Instruments**

The Company's financial instruments include principally cash and cash equivalents, other assets, accounts payable, accrued liabilities and debt. The carrying amounts for these financial instruments reported in the balance sheets approximate their fair values. See Note 11 — *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.

**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 activities, clinical costs and an allocation of overhead expenses. Research and development costs are expensed as incurred.

**Revenue Recognition**

Beginning January 1, 2018, the Company has followed the provisions of Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers. The guidance provides a unified model to determine how revenue is recognized. The Company to date has not recognized any revenue, but has entered into a license transfer and collaboration agreement in July 2019 that will have revenue recognition implications in future reporting periods. See Note 7 – *License Agreements*.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. Performance obligations may include license rights, development services, and services associated with regulatory submission and approval processes. Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations are either completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines,

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

reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. The Company allocates the total transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation.

*Licenses of intellectual property:* If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

*Milestone payments:* At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. When our assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in license, collaboration, and other revenues based upon when the customer obtains control of each element.

*Royalties:* For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

#### **Income Taxes**

The Company utilizes the liability method of accounting for income taxes as required by 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

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

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**

***Recent Accounting Pronouncements Adopted***

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.

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, July 2018 and March 2019. 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 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

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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. Merger Agreement**

***Merger Agreement with NeuroBo***

On July 24, 2019, the Company entered into the Merger Agreement with NeuroBo pursuant to which, the Company's wholly owned subsidiary, Merger Sub, will merge with and into NeuroBo, with NeuroBo surviving as a wholly owned subsidiary of the Company, in an all-stock transaction. Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), (a) each share of NeuroBo common stock outstanding immediately prior to the Effective Time (excluding shares held as treasury stock, held by NeuroBo and dissenting shares) will be converted into the right to receive shares of Gemphire common stock equal to the Exchange Ratio described below; and (b) each outstanding NeuroBo stock option that has not previously been exercised prior to the Effective Time will be assumed by the Company.

For accounting purposes, NeuroBo is considered to be acquiring the Company even though the Company will be the issuer of the common stock in the merger due to various considerations, including the expected ownership positions of Gemphire and NeuroBo post-merger. Substantially all the fair value of the Company is concentrated in one asset, in-

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process research and development IP, and therefore the merger is expected to be accounted for as an asset acquisition by NeuroBo.

Under the exchange ratio formula in the Merger Agreement (the “Exchange Ratio”), upon the closing of the Merger, on a pro forma basis and based upon the number of shares of common stock expected to be issued in the Merger, former Company security holders immediately prior to the Merger are expected to own, or hold rights to acquire, approximately 3.74% of the combined company and former NeuroBo security holders immediately prior to the Merger are expected to own, or hold rights to acquire, approximately 96.26% of the combined company, on a fully-diluted basis and assuming that the Company has a net cash amount of negative \$3,400,000 at closing and that NeuroBo raises the minimum required amount of \$24,240,000 in its Series B Preferred Stock financing described below. The ownership percentages are subject to adjustment to the extent that the Company’s net cash at the Effective Time is negative or to reflect aggregate gross proceeds received by NeuroBo in its financing before the closing of the Merger above the minimum required amount and up to and including \$50 million.

Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the Company’s stockholders and NeuroBo’s stockholders, the continued listing of the common stock on the Nasdaq Capital Market, the conversion of all NeuroBo preferred stock and NeuroBo convertible notes into NeuroBo common stock and satisfaction by the Company of a minimum parent cash amount of negative \$3.75 million at closing.

Prior to signing the Merger Agreement, NeuroBo entered into subscription agreements with investors for a Series B Preferred Stock financing for approximate gross proceeds of \$24,240,000, the minimum required amount under the Merger Agreement, and may enter into additional subscription agreements and receive additional proceeds between signing and closing of the Merger.

The Merger Agreement contains certain termination rights for both the Company and NeuroBo, and further provides that, upon termination of the Merger Agreement under specified circumstances, either party may be required to pay the other party a termination fee of \$1,000,000, or in some circumstances reimburse the other party’s expenses up to a maximum of \$500,000.

Following the closing of the Merger, it is expected that NeuroBo’s Chief Executive Officer, John L. Brooks III, will serve as Chief Executive Officer of the Company and the board of directors of the Company will be comprised of ten directors, consisting of nine directors designated by NeuroBo and Steven Gullans, the Company’s current President and Chief Executive Officer. In addition, upon completion of the merger, Gemphire will change its name to NeuroBo Pharmaceuticals, Inc., and plans to change its ticker symbol on the Nasdaq Capital Market to “NRBO”. The merged company will focus on the development of NeuroBo’s clinical-stage drug candidates for the treatment of neurodegenerative diseases.

The Merger is expected to close in the fourth quarter of 2019, subject to approval by the Company’s stockholders at an annual meeting to be held on December 6, 2019 and other closing conditions.

***Contingent Value Rights Agreement***

At the Effective Time, the Company will enter into a Contingent Value Rights Agreement (the “CVR Agreement”). Pursuant to the Merger Agreement and the CVR Agreement, for each share of the Company’s common stock held, stockholders of record as of immediately prior to the Effective Time will receive one contingent value right (“CVR”) entitling such holders to receive in the aggregate, 80% of the Gross Consideration (as defined in the CVR Agreement which contemplates the post-Merger combined company’s prior retention of an aggregate of \$500,000) less other Permitted Deductions (each as defined in the CVR Agreement) received during the 15-year period after the closing of the Merger (the “CVR Term”) from the grant, sale or transfer of rights to the Company’s product candidate gemcabene (other than a grant, sale or transfer of rights involving a sale or disposition of the post-Merger combined company) that is entered into during the 10-year period after the closing of the Merger or pursuant to the Beijing SL Agreement, but not

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including the \$2.5 million non-refundable upfront gross payment pursuant to the Beijing SL Agreement, which was paid in October 2019. Under the CVR Agreement, the combined company agreed to commit \$1 million to support the further development of gemcabene through the quarter ending March 31, 2020, the funding of which was conditioned on receipt by the Company of the \$2.5 million non-refundable upfront gross payment payable under the Beijing SL Agreement. The CVRs are not transferable, except in certain limited circumstances, will not be certificated or evidenced by any instrument, will not accrue interest and will not be registered with the SEC or listed for trading on any exchange. The CVR Agreement will be effective prior to the closing of the Merger and will continue in effect until the later of the end of the CVR Term and the payment of all amounts payable thereunder, unless and until earlier terminated upon termination of the Merger Agreement.

***Change in Control Payments and Severance Awards***

On July 24, 2019, the Company entered into amendments to the employment agreements (the “Amendments”) of Dr. Steven Gullans, Chief Executive Officer and President, Dr. Charles Bisgaier, Chief Scientific Officer and Chairman of the board of directors, and Seth Reno, Chief Commercial Officer (the “Executives”) to reduce the cash severance obligation owed to each Executive in connection with the termination of their employment upon the closing of the Merger. Pursuant to the Amendments, if the Merger is completed, each of Dr. Gullans, Dr. Bisgaier and Mr. Reno will receive a lump sum cash payment within thirty days after the effective date of the Merger in an amount equal to \$75,000, \$330,000 and \$297,536, respectively, subject to a reduction for withholding tax, in lieu of the cash compensation such Executives would otherwise be entitled to receive in connection with a termination following a change in control pursuant to such Executives’ employment agreements.

In connection with the Executives agreeing to the Amendments, on July 24, 2019, the Company issued each of Dr. Gullans, Dr. Bisgaier and Mr. Reno a restricted stock award representing 300,000, 100,000 and 100,000 shares, respectively, of common stock. The restricted stock awards were made pursuant to Restricted Stock Grant Notices and Restricted Stock Agreements (the “Award Agreements”). Such Award Agreements provide that such shares shall fully vest immediately prior to the Effective Time, provided that the Executive has executed and delivered to the Company a release and waiver of claims and such release is not subsequently revoked. The Company shall automatically reacquire for no consideration all unvested shares upon the earliest to occur of (i) the Executive’s termination of continuous service (unless such termination results from the completion of the Merger prior to March 31, 2020) or (ii) March 31, 2020 if the Merger has not been completed. The Award Agreements provide that the holders shall have all rights and privileges of a holder of common stock, including for purposes of voting and receiving dividends.

Grants were also made to the Company’s non-employee directors (45,000 shares of restricted stock in the aggregate) and employees (62,000 shares of restricted stock in the aggregate) pursuant to Award Agreements on July 24, 2019. The non-employee director Award Agreements do not require the execution and delivery of a release and waiver of claims.

On July 23, 2019, the Company’s non-employee directors agreed to waive payment of the cash retainer for the remainder of 2019 otherwise payable to such directors pursuant to the Company’s non-employee director compensation policy.

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**Notes to Condensed Financial Statements (unaudited), continued**

**4. Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued compensation and other payroll liabilities	\$ 92	\$ 137
Legal costs	52	106
Accrued interest	—	43
Non-operating transactional costs	176	—
Other research and development expenses	66	135
Other general and administrative expenses	10	17
Total	<u>\$ 396</u>	<u>\$ 438</u>

**5. 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. The Merger, upon completion, will trigger a success fee of \$350,000 (See Note 3 – *Merger Agreement*). 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 remains 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.

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**6. 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 7 — *License Agreements*). As of September 30, 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 was 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 \$17,000 and \$26,000 during the three month periods ended September 30, 2019 and 2018, respectively, and \$69,000 and \$78,000 during the nine month periods ended September 30, 2019 and 2018, respectively. The lease expired in August 2019, and no office space is currently being leased as of September 30, 2019.

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

	<u>Nine months ended September 30, 2019</u>	<u>Nine months ended September 30, 2018</u>
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating leases	\$ 71	\$ 78
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):

	<u>As of September 30, 2019</u>	<u>As of December 31, 2018</u>
Right-of-use assets	\$ —	\$ 68
Lease liability	\$ —	\$ 70
Weighted average remaining lease term	—	0.7 years
Weighted average discount rate	—	5.5%



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***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.

**7. License Agreements**

***Pfizer***

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 September 30, 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 sublicensees 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-

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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.

***Beijing SL License and Collaboration Agreement***

On July 23, 2019, the Company entered into a License and Collaboration Agreement (the "Beijing SL Agreement") with Beijing SL Pharmaceutical Co., Ltd. ("Beijing SL"), pursuant to which the Company granted Beijing SL an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, gemcabene in mainland China, Hong Kong, Macau and Taiwan (each, a "region," and collectively, the "Territory"). The terms of the agreement include non-refundable upfront fees, payments based upon achievement of milestones and royalties on net product sales. Under the Beijing SL Agreement, the Company has both fixed and variable consideration. Non-refundable upfront fees are considered fixed, while milestone payments are identified as variable consideration. As of September 30, 2019, no revenue under the Beijing SL Agreement has been recognized as the performance obligation related to the non-refundable upfront fees was not satisfied. For additional detail on the Company's accounting policy regarding revenue recognition, refer to Note 2 –*Summary of Accounting Policies*.

Under the terms of the Beijing SL Agreement, Beijing SL will be responsible, at its expense, for developing and commercializing products containing gemcabene (each, a "Licensed Product") in the Territory, with certain assistance from the Company. To the extent mutually agreed to in writing, the Company and Beijing SL will collaborate on the Phase 3 clinical trial for homozygous familial hypercholesterolemia or other clinical trials with the Company as the sponsor designed to enroll patients both inside and outside the Territory (a "Global Study"), but Beijing SL will be responsible, at its expense, for the conduct of any Global Study to the extent solely in the Territory, subject to the Company's final decision making authority, and the Company will be responsible, at its expense, for the conduct of any Global Study to the extent solely outside of the Territory. Under a territory development plan, the parties shall develop Licensed Products with respect to the Territory. Beijing SL will be responsible for development activities, including non-clinical and clinical studies directed at obtaining regulatory approval of the Licensed Product in the Territory. Beijing SL has agreed to use commercially reasonable efforts to commercialize the Licensed Products for each indication that receives regulatory approval in the Territory and shall prepare and present a commercialization plan that shall be subject to approval by the joint steering committee.

Pursuant to the Beijing SL Agreement, Beijing SL will make a non-refundable upfront gross payment of \$2.5 million to the Company within 45 days of the effective date of the Beijing SL Agreement; the upfront payment was received in October 2019. Additionally, with respect to each Licensed Product, the Company will be eligible to receive (i) payments for specified developmental and regulatory milestones (including submission of a new drug application to China's National Medical Product Administration, dosing of the first patient in a phase 3 clinical trial in mainland China and regulatory approval for the first and each additional indication of a Licensed Product in the Territory) totaling up to \$6 million in the aggregate and (ii) payments for specified global net sales milestones of up to \$20 million in the aggregate multiplied by the ratio of the net sales of a Licensed Product sold by Beijing SL in the Territory divided by the global net sales of a Licensed Product, which net sales milestone payments are payable once, upon the first achievement of such milestone.

Beijing SL will also be obligated to pay the Company tiered royalties ranging from the mid-teens to twenty percent on the net sales of all Licensed Products in the Territory until the latest of (a) the date on which any applicable regulatory exclusivity with respect to such Licensed Product expires in such region, (b) the expiration or abandonment of the last valid patent claim or joint patent claim covering such Licensed Product in each region and (c) the fifth anniversary of the first commercial sale of such Licensed Product in such region (the "Royalty Term"). Future milestone payments under the Beijing SL Agreement, if any, are not expected to begin for at least one year and will extend over a number of subsequent years. The Company cannot determine the date on which Beijing SL's potential royalty payment obligations to the Company would expire because Beijing SL has not yet developed any Licensed Products under the Beijing SL

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Agreement and therefore the Company cannot at this time identify the date of the first commercial sale or the periods of any regulatory exclusivity or patent claims with respect to any Licensed Product.

On a Licensed Product-by-Licensed Product and region-by-region basis upon the expiration of the Royalty Term, the license granted to Beijing SL shall be deemed perpetual, fully paid-up and royalty free with respect to such Licensed Product in such region. Either party may terminate the Agreement (x) with written notice for the other party's material breach following a cure period or (y) if the other party becomes subject to certain insolvency proceedings. In addition, the Company may terminate the agreement in its entirety if Beijing SL or its affiliates or sublicensees commence a proceeding challenging the validity, enforceability or scope of any of the Company's patents.

To the extent rights granted to Beijing SL under the Beijing SL Agreement are controlled by the Company pursuant to the Pfizer Agreement between Gemphire and Pfizer, such rights are subject to the terms and conditions of such agreement with Pfizer, and Beijing SL has agreed to comply with such terms and conditions.

The Beijing SL Agreement contemplates that Beijing SL and the Company shall, no later than 60 days following the effective date of the Beijing SL Agreement, negotiate in good faith and execute a clinical supply agreement and, no later than twelve months prior to the anticipated date of the first commercial sale of a Licensed Product, if any, negotiate in good faith and execute a commercial supply agreement, pursuant to which Beijing SL shall purchase from the Company, and the Company shall use commercially reasonable efforts to supply, gemcabene or Licensed Product for clinical or commercial purposes, as applicable, until manufacturing and regulatory transfers are complete.

Each of the Company and Beijing SL has agreed to indemnify the other party against certain losses and expenses relating to the development or commercialization of a Licensed Product by the indemnifying party, the negligence or willful misconduct of the indemnifying party or its directors, officers, employees or agents or a breach of the indemnifying party's representations, warranties or covenants.

## **8. Stockholders' (Deficit) Equity**

### ***Common Stock***

The Company had 14,872,411 and 14,265,411 shares of its common stock issued and outstanding as of September 30, 2019 and December 31, 2018, respectively. 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 and nine month periods ending September 30, 2019 and 2018, no warrants were exercised. As of September 30, 2019 and December 31, 2018, warrants to purchase 1,014,204 shares of common stock were outstanding.

### ***Dividend Rights***

Common stockholders 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 September 30, 2019.

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**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.

**9. 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		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
General and administrative	\$ 276	\$ 861	\$ 835	\$ 2,008
Research and development	165	766	517	1,548
Total share-based compensation	<u>\$ 441</u>	<u>\$ 1,627</u>	<u>\$ 1,352</u>	<u>\$ 3,556</u>

In April 2015, the Company adopted the 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 581,100 shares as of September 30, 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

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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 268,667 shares as of September 30, 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 September 30, 2019, no shares have been purchased under the ESPP.

***Restricted Stock Awards***

During the three and nine months ended September 30, 2019, the Company granted 607,000 restricted stock awards (RSAs) to officers, directors and employees. The RSAs vest immediately upon the close of that merger (See Note 3 – *Merger Agreement*). The grant date fair value of the RSAs was \$0.72 per share. As of September 30, 2019, all 607,000 RSAs remain unvested and none were forfeited. The Company did not grant any RSAs during the comparable periods in the prior year.

***Stock Options***

During the three months ended September 30, 2019 and 2018, the Company did not grant any stock options. During the nine months ended September 30, 2019 and 2018, zero and 822,000 stock options were granted, 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 and nine months ended September 30, 2018 was zero and \$5.07 per share, respectively.

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.

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**Notes to Condensed Financial Statements (unaudited), continued**

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

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Expected stock price volatility	—	—	—	66.3%
Expected life of options (years)	—	—	—	5.8
Expected dividend yield	—	—	—	0%
Risk free interest rate	—	—	—	2.7%

During the three months ended September 30, 2019 and 2018, 76,818 and 279,924 stock options vested, respectively, and 242,952 and 587,334 stock options vested during the nine months ended September 30, 2019 and 2018, respectively. During the three months ended September 30, 2019 and 2018, 176,705 and 307,121 stock options were forfeited, respectively, and 254,505 and 422,010 stock options were forfeited during the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, 2,546,268 stock options were outstanding, 1,994,357 stock options were vested and 849,767 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 \$2.3 million for the stock options and \$0.4 million for the RSAs as of September 30, 2019. The unrecognized share-based expense is expected to be recognized over a weighted average period of 0.2 years for both the stock options and RSAs taking into account the anticipated accounting treatment of such awards upon the closing of the Merger.

**10. 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, restricted stock awards and warrants are considered common stock equivalents while outstanding for this purpose. Diluted earnings are computed utilizing the treasury method for stock options, restricted stock awards 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 and nine months ended September 30, 2019 and 2018. The following table sets forth the computation of basic and diluted loss per share for the three and nine months ended September 30, 2019 and 2018 (in thousands, except share and per share amounts):

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
<b>Numerator:</b>				
Net loss attributed to common stockholders	\$ (3,430)	\$ (6,079)	\$ (10,151)	\$ (19,981)
<b>Denominator:</b>				
Basic and diluted weighted average common shares outstanding	14,265,411	14,259,691	14,265,411	13,650,556
Basic and diluted net loss per share	\$ (0.24)	\$ (0.43)	\$ (0.71)	\$ (1.46)

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**Notes to Condensed Financial Statements (unaudited), continued**

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 and nine months ended September 30, 2019 and 2018:

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Stock options	2,546,268	2,823,732	2,546,268	2,823,732
Warrants	1,014,204	1,014,204	1,014,204	1,014,204
Restricted stock awards	607,000	—	607,000	—

### 11. 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, whether 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 September 30, 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 and nine months ended September 30, 2019 and 2018.

There were no instruments measured on a recurring fair value basis as of September 30, 2019 and December 31, 2018. In addition, no financial instruments were measured on a non-recurring basis for any of the periods presented.

### 12. Income Taxes

The effective tax rate for the three and nine month periods ended September 30, 2019 and 2018 was zero percent. As a result of the analysis of all available evidence as of September 30, 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 and nine month periods ended September 30, 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.

### 13. 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

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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 nine-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 September 30, 2019 and 2018 was \$13,000 and \$30,000, respectively, and \$60,000 and \$84,000 during the nine month periods ended September 30, 2019 and 2018, respectively.

**14. 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.

**15. Subsequent Events**

The Company has evaluated all events or transactions that occurred after September 30, 2019 up through the date the condensed financial statements were issued. Other than as set forth below, there were no material recognizable or nonrecognizable subsequent events during the period evaluated.

***The Merger***

On October 29, 2019, the Company entered into an amendment to the Original Merger Agreement with NeuroBo and Merger Sub. See Note 3—*Merger Agreement*. The amendment amended certain of the terms of the Original Merger Agreement by, among other things, (i) reducing the minimum net cash amount the Company is required to have at the closing of the Merger (the "Parent Cash Amount") from negative \$3,000,000 to negative \$3,750,000; (ii) clarifying that the Parent Cash Amount will not be reduced for pre-closing payments by the Company of certain amounts related to the development of gemcabene that the parties previously expected would be incurred post-closing pursuant to the CVR Agreement; (iii) providing for an increase in the size of the combined company's board of directors to ten; and (iv) extending the date after which either the Company or NeuroBo may terminate the Merger Agreement from December 24, 2019 to February 22, 2020.

The annual meeting of stockholders of the Company, where stockholders will be asked to vote, among other things, on the issuance of the Company's common stock to NeuroBo's stockholders pursuant to the Merger Agreement and the change of control of the Company resulting from the Merger, has been scheduled for December 6, 2019 pursuant to a notice of annual meeting dated November 6, 2019.

***Beijing SL Agreement***

A non-refundable upfront payment of \$2.5 million was received by the Company in October 2019 under the Beijing SL Agreement. The Company has not yet met its performance obligations related to this payment. As such, the upfront non-refundable payment collected was recorded as a deferred revenue liability upon receipt.

***Nasdaq Compliance***

As previously disclosed, on August 12, 2019, the Company received written notice from Nasdaq stating that the Company no longer complied with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing on The Nasdaq Capital Market because the Company's stockholders' equity, as reported in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, had fallen below \$2.5 million. On September 26, 2019, the Company submitted its compliance plan to Nasdaq, explaining how the Company believes that the completion of its proposed merger with NeuroBo will address the stockholders' equity deficiency.

On October 4, 2019, Nasdaq notified the Company that it had determined to grant the Company an extension until February 10, 2020 to regain compliance. Under the terms of the extension, NeuroBo must receive approval of its initial



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**Notes to Condensed Financial Statements (unaudited), continued**

listing application and the Company must consummate the Merger on or before February 10, 2020. If NeuroBo fails to receive approval of its initial listing application or the Company fails to consummate the Merger prior to February 10, 2020, Nasdaq will provide written notification to the Company that its securities will be delisted. At that time, the Company may appeal the Staff's determination to a Listing Qualifications Panel.

There can be no assurance that the Company will be successful in implementing its plan to regain compliance with the minimum stockholders' equity requirement, will regain compliance with the Minimum Bid Price Rule, or will otherwise be in compliance with other Nasdaq Listing Rules. See Part II "Other Information," Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q.

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**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.

As described below, on July 24, 2019, we entered into a Merger Agreement with NeuroBo, as amended on October 29, 2019, pursuant to which our wholly owned subsidiary, Merger Sub, will merge with and into NeuroBo, with NeuroBo surviving as a wholly owned subsidiary of the Company in an all-stock transaction.

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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, and we successfully commercialize, gemcabene or any other product candidate we may pursue in the future or unless certain obligations, including development and commercialization milestones, are met under the Beijing SL Agreement. Refer to Note 7— *License Agreements* to our condensed financial statements included in Part I “Financial Information”, Item 1 “Financial Statements” of this Quarterly Report on Form 10-Q for further information. 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 \$3.4 million and \$6.1 million during the three month periods ended September 30, 2019 and 2018, respectively, and our net losses were \$10.2 million and \$20.0 million during the nine month periods ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of \$94.3 million and a total stockholders’ deficit of \$1.0 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 September 30, 2019, we had cash and cash equivalents of \$1.9 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 and no Suspected Unexpected Serious Adverse Reaction

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(SUSAR) report was filed with the FDA by the Primary Investigator. The risk for increased liver fat with gemcabene treatment is unknown at this time. The patients were monitored for 12 months post-final dose and final results are pending. 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.

Top-line data was reported in June 2019 from a Phase 2a proof-of-concept trial treating familial partial lipodystrophy disease (FPLD) patients with gemcabene. This study was an investigator-initiated study at the University of Michigan and was initiated in early 2018. Five FPLD patients were enrolled in this open-label study with two patients having lamin A (LMNA) gene mutations and three patients with unknown causes of the condition. Average baseline serum triglyceride levels were 587.3 mg/dL and average MRI-PDFF liver fat fraction was 14.1%. All patients received a 300 mg/day dose of gemcabene for the first 12 weeks, with randomization to either the same dose (n=3) or a higher dose of 600 mg/day (n=2) for the subsequent 12 weeks.

Gemcabene treatment resulted in a median change in serum triglycerides (TG) of -19.6% for the five patients at twelve weeks (the primary endpoint). The range of TG responses was +40.4% to -52.9%, with three patients showing decreases. Secondary endpoints included measurement of liver fat fraction by MRI-PDFF which showed reduction in 2 of the 3 responding patients. Four patients completed treatment and a fifth one discontinued at 22 weeks (with data carried forward as 24 weeks). Gemcabene appeared to be generally safe and well-tolerated in these five patients. There was one serious adverse event of benign paroxysmal positional vertigo, considered unrelated to gemcabene.

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 PPAR $\alpha$  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 January of 2020. 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 can only take place once the partial clinical hold is lifted. See “—Liquidity and Capital Resources” below regarding our need to raise additional capital to continue to fund the further development of gemcabene, including submission of the additional information requested by the FDA to make a decision regarding lifting the partial clinical hold, if the proposed Merger is not consummated in a timely fashion.

***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.

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***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 for the Nasdaq Global Market 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 our common stock to the Nasdaq Capital Market. On May 10, 2019, we received approval from Nasdaq to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market. The transfer was effective at the opening of business on May 14, 2019.

On August 8, 2019, we received a notice from Nasdaq stating that, for the last 30 consecutive business days, the closing bid price for our common stock was below the \$1.00 requirement for continued listing under the Minimum Bid Price Rule. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until February 4, 2020, to regain compliance with the Minimum Bid Price Rule. To regain compliance with the Minimum Bid Price Rule, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of 10 consecutive business days at any time during this 180-day period. If we regain compliance with the Minimum Bid Price Rule, Nasdaq will provide us with written confirmation and will close the matter.

If we do not regain compliance with the rule by February 4, 2020, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to meet the continued listing requirement for market value of publicly held shares and all other applicable standards for initial listing on The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not eligible for a second compliance period, Nasdaq will notify us that our common stock will be subject to delisting. In the event of such a notification, we may appeal the determination, but there can be no assurance Nasdaq would grant our request for continued listing.

On August 12, 2019, we received written notice from Nasdaq stating that we no longer complied with the minimum stockholders’ equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing on The Nasdaq Capital Market because our stockholders’ equity, as reported in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, had fallen below \$2.5 million. The notice also indicated that we did not meet the alternative compliance standards.

On September 26, 2019, we submitted our compliance plan to Nasdaq, explaining how we believe that the completion of our proposed merger with NeuroBo will address the stockholders’ equity deficiency.

On October 4, 2019, Nasdaq notified us that it had determined to grant us an extension until February 10, 2020 to regain compliance. Under the terms of the extension, NeuroBo must receive approval of its initial listing application and we must consummate the Merger on or before February 10, 2020. If NeuroBo fails to receive approval of its initial listing application or we fail to consummate the Merger prior to February 10, 2020, Nasdaq will provide written notification that our securities will be delisted. At that time, we may appeal the Staff’s determination to a Listing Qualifications Panel.

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There can be no assurance that we will be successful in implementing our plan to regain compliance with the minimum stockholders' equity requirement, will regain compliance with the Minimum Bid Price Rule, or will otherwise be in compliance with other Nasdaq Listing Rules.

See Part II "Other Information," Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q.

***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.

***License and Collaboration Agreement***

On July 23, 2019, we entered into the Beijing SL Agreement, pursuant to which we granted Beijing SL an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, gemcabene in the Territory. We retained all rights to gemcabene outside of the Territory. Refer to Note 7—*License Agreements* to our condensed financial statements included in Part I "Financial Information", Item 1 "Financial Statements" of this Quarterly Report on Form 10-Q for further information.

***Merger Agreement with NeuroBo***

On July 24, 2019, we entered into the Merger Agreement with NeuroBo, as amended on October 29, 2019, pursuant to which our wholly owned subsidiary, Merger Sub, will merge with and into NeuroBo, with NeuroBo surviving as our wholly owned subsidiary in an all-stock transaction. Pursuant to the Merger Agreement, at the Effective Time, we will enter into the CVR Agreement, pursuant to which, for each share of our common stock held, stockholders of record as of immediately prior to the Effective Time will receive one CVR. Refer to Note 3—*Merger Agreement* to our condensed financial statements included in Part I "Financial Information", Item 1 "Financial Statements" of this Quarterly Report on Form 10-Q for further information. The discussion below excludes any impact that may result from the proposed Merger. The proposed Merger has been approved by the boards of directors of both companies and is expected to close in the fourth quarter of 2019, subject to approval by the stockholders of the Company and NeuroBo as well as other certain other closing conditions. The total fees and costs of the proposed Merger are expected to be material to our results of operations in 2019 and possibly 2020.

Despite undertaking this process, we may not be successful in completing the Merger, and, even if the Merger is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value. If, for any reason, the Merger does not close, our board of directors may elect to dissolve and liquidate the Company's assets. If we were able to secure additional capital to provide us with necessary financial resources, it may alternatively attempt to pursue another strategic transaction like the Merger, sell or otherwise dispose of the various assets of the Company or continue to operate the business of the Company. We expect that it would be difficult to secure financing in a timely manner, on favorable terms or at all. If our board of directors were to decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left, if any, to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

**Financial Operations Overview**

**Revenue**

Other than revenue expected to be recognized from the non-refundable upfront payment under the Beijing SL Agreement, which was received in October 2019, we do not expect to generate revenue unless or until we obtain

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regulatory approval of and commercialize gemcabene or any other product candidate we may pursue in the future or unless certain development and commercialization milestones are met under the Beijing SL Agreement. Refer to Note 7—*License Agreement* to our condensed financial statements included in Part I “Financial Information”, Item 1 “Financial Statements” of this Quarterly Report on Form 10-Q for further information. 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 or any other product candidate we may pursue in the future 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 research and development expenses to continue to trend significantly above comparable prior period levels as development of any product candidates we may pursue progresses. However, it is difficult to determine with certainty the duration, costs and timing to complete our current or future preclinical programs and clinical trials. The duration, costs and timing of clinical trials and development 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;

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- 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 Income (Expense), net*

Interest income (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 largely to non-operating transaction costs associated with our previously-announced review of strategic alternatives. In addition, this category includes de minimis other income stemming from the disposal proceeds received from the sale of excess office supply and non-capital items. Lastly, other expense, net includes foreign currency exchange gains and losses related 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 September 30, 2019 and December 31, 2018.



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**Results of Operations**

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

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Operating expenses:						
General and administrative	\$ 1,250	\$ 2,364	\$ (1,114)	\$ 3,772	\$ 7,025	\$ (3,253)
Research and development	1,068	3,542	(2,474)	3,695	12,479	(8,784)
Total operating expenses	<u>2,318</u>	<u>5,906</u>	<u>(3,588)</u>	<u>7,467</u>	<u>19,504</u>	<u>(12,037)</u>
Loss from operations	(2,318)	(5,906)	3,588	(7,467)	(19,504)	12,037
Interest income (expense), net	4	(172)	176	(816)	(476)	(340)
Other expense, net	(1,116)	(1)	(1,115)	(1,868)	(1)	(1,867)
Loss before income taxes	(3,430)	(6,079)	2,649	(10,151)	(19,981)	9,830
Provision (benefit) for income taxes	—	—	—	—	—	—
Net loss	<u>\$ (3,430)</u>	<u>\$ (6,079)</u>	<u>\$ 2,649</u>	<u>\$ (10,151)</u>	<u>\$ (19,981)</u>	<u>\$ 9,830</u>

**Comparison of Three Months Ended September 30, 2019 and 2018**

*General and Administrative*

General and administrative expenses for the three months ended September 30, 2019 decreased to \$1.3 million compared to \$2.4 million for the three months ended September 30, 2018. The \$1.1 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 September 30, 2019 were \$1.1 million compared to \$3.5 million for the three months ended September 30, 2018. The \$2.5 million decrease was primarily attributable to reduced clinical trial activities in the third quarter of 2019 versus the comparable period in 2018.

*Interest Income (Expense), net*

Interest income (expense), net for the three months ended September 30, 2019 was \$4,000 compared to \$(0.2) million for the three months ended September 30, 2018. Interest income (expense), net during the three months ended September 30, 2019 was comprised of interest earned on our cash and cash equivalents. Interest income (expense), net during the three months ended September 30, 2018 was comprised primarily of interest expense in connection with our Term Loan offset in part by interest income of \$47,000. The decrease in interest expense period over period was the result of the Term Loan not being outstanding during the third quarter of 2019. The decrease in interest income period over period was largely the result of the decrease in our cash and cash equivalents.

*Other Expense, net*

Other expense, net for the three months ended September 30, 2019 comprised substantially of non-operating transaction costs associated with our previously announced review of strategic alternatives, including transaction costs associated with the Merger in the amount of \$1.1 million. There was a de minimis amount of other income related to the disposal of office related items in the amount of \$3,000 during the three month period ending September 30, 2019. There was

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minimal other expense, net activity during the three months ended September 30, 2018 and was limited to net foreign currency exchange losses.

***Comparison of Nine Months Ended September 30, 2019 and 2018***

*General and Administrative*

General and administrative expenses for the nine months ended September 30, 2019 decreased to \$3.8 million compared to \$7.0 million for the nine months ended September 30, 2018. The \$3.3 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 nine months ended September 30, 2019 were \$3.7 million compared to \$12.5 million for the nine months ended September 30, 2018. The \$8.8 million decrease was primarily attributable to reduced clinical trial activities through the third quarter in 2019 versus the comparable period in 2018.

*Interest Income (Expense), net*

Interest income (expense), net for the nine months ended September 30, 2019 was \$(0.8) million, compared to \$(0.5) million for the comparable period in 2018. Interest income (expense), net for the nine months ended September 30, 2019 included interest expense in connection with our Term Loan offset in part by interest income of \$39,000. Interest income (expense), net for the nine months ended September 30, 2018 included interest expense in connection with our Term Loan offset in part by interest income of \$0.1 million. The increase in net interest (expense), net through the third 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, net*

Other expense for the nine months ended September 30, 2019 comprised substantially of non-operating transaction costs associated with our previously announced review of strategic alternatives, including transaction costs associated with the Merger in the amount of \$1.9 million. There was a de minimis amount of other income related to the disposal of office related items in the amount of \$3,000 during the nine month period ending September 30, 2019. There was minimal other expense, net activity during the three months ended September 30, 2018 and was limited to net foreign currency exchange losses.

***Cash Flows***

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

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>(in thousands)</b>	
Net cash used in operating activities	\$ (6,825)	\$ (17,798)
Net cash provided by (used in) investing activities	—	—
Net cash (used in) provided by financing activities	(10,259)	23,131
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (17,084)	\$ 5,333

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***Cash Flow from Operating Activities***

For the nine months ended September 30, 2019, cash used in operating activities of \$6.8 million was attributable to a net loss of \$10.2 million as adjusted by \$1.4 million in share-based compensation and non-cash interest expense of \$0.8 million offset by a net change of \$1.2 million in our operating assets and liabilities. The change in operating assets and liabilities was primarily attributable to a net increase in our accounts payable and accrued liabilities and to a decrease in our prepaid expenses associated with fluctuations in our operating activities.

For the nine months ended September 30, 2018, cash used in operating activities of \$17.8 million was attributable to a net loss of \$20.0 million as adjusted by \$3.6 million in share-based compensation and non-cash interest expense of \$0.2 million offset by a net change of \$1.6 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 increase in our prepaid expenses, offset in part by an increase in accrued liabilities, 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 nine months ended September 30, 2019 of \$10.3 million related the repayment of our Term Loan.

Net cash provided by financing activities during the nine months ended September 30, 2018 of \$23.1 million related primarily to proceeds received from our Follow-On Offering, net of discounts, commissions and other costs totaling \$2.1 million paid through September 30, 2018.

***Liquidity and Capital Resources***

As of September 30, 2019, our principal sources of liquidity consisted of cash and cash equivalents of approximately \$1.9 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 net losses for the foreseeable future despite the revenue expected to be recognized from the non-refundable up-front payment in connection with the Beijing SL Agreement. 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 over-allotment 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

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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.

We have no current source of revenue to sustain our present activities, and, other than revenue expected to be recognized from the non-refundable upfront payment under the Beijing SL Agreement, we do not expect to generate revenue until and unless, the FDA or other regulatory authorities approve, and we successfully commercialize, gemcabene or any other product candidate we may pursue in the future or unless certain development and commercialization milestones are met under the Beijing SL Agreement. Refer to Note 7— *License Agreements* to our condensed financial statements included in Part I “Financial Information”, Item 1 “Financial Statements” of this Quarterly Report on Form 10-Q for further information. 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. Other than the non-refundable upfront payment under the Beijing SL Agreement, which was received in October 2019, we do not have any committed external source of funds.

Our ability to raise additional funds and the terms upon which we are able to raise funds have been severely harmed by the FDA’s decision not to lift the partial clinical hold on gemcabene and request that we provide additional data and the termination of the investigator initiated Phase 2a pediatric NAFLD trial, each in August 2018. To the extent that we seek and are able to 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 previously in place 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 or if the proposed Merger is not consummated, we may be required to significantly reduce or terminate our operations, delay, further scale back or discontinue the development of gemcabene, or grant rights to develop and market gemcabene that we would otherwise prefer to develop and market ourselves. The condensed financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We believe our cash on hand, including amounts received from Beijing SL pursuant to the non-refundable upfront payment, will be sufficient to fund operations through the fourth quarter of 2019, excluding transaction costs associated with the Merger (which we expect to pay upon the closing), and if for any reason the Merger does not close, we would 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 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 may need additional financing sooner than we expect. Additionally, the process of advancing early-stage product candidates and testing product candidates in clinical

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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 or if the proposed Merger is not consummated in a timely manner would require us to delay or abandon clinical development plans and our board of directors may determine to cease our operations. If our board of directors were to decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left, if any, to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.

We do not believe that our current expenses are indicative of the costs we may incur in the future in connection with the development and commercialization of any product candidate if we consummate the Merger or raise additional capital to continue our operations. Our future funding requirements will depend on many factors, including:

- our ability to consummate the Merger with NeuroBo;
- the level of development and commercialization efforts of Beijing SL with respect to gemcabene and the receipt of milestone and other payments, if any, from Beijing SL under the Beijing SL Agreement;
- the scope, rate of progress and cost of our preclinical and clinical trials for any product candidate in our future pipeline and results of future clinical trials;
- the cost and timing of regulatory filings and approvals for any product candidates that successfully complete clinical trials;
- the timing and nature of any strategic transactions that we undertake, including potential partnerships;
- the effect of competing technological and market developments;
- the cost incurred in responding to actions by activist stockholders; and
- the cost of filing, prosecuting, defending and enforcing our intellectual property rights.

We currently have an effective shelf registration statement on Form S-3 on file with the SEC which expires in September 2020. The shelf registration statement permits the offering, issuance and sale of up to an aggregate offering price of \$175 million of common stock, preferred stock, debt securities, warrants and subscription rights, of which \$50 million may be offered, issued and sold under an “at-the-market” (ATM) equity distribution agreement with Piper Jaffray & Co. However, the amounts available under the shelf registration statement, including the ATM program, will be significantly limited as long as our public float remains below \$75 million, which, given our currently depressed stock price, limits our ability to obtain meaningful funding through the ATM program or the shelf registration statement at this time, although we could still raise funds through a registration statement on Form S-1 or through private placements.

***Beijing SL Agreement***

On July 23, 2019, the Company entered into the Beijing SL Agreement, pursuant to which the Company granted Beijing SL an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, gemcabene in the Territory and Beijing SL agreed to make a non-refundable upfront gross payment of \$2.5 million, which was received in October 2019, and to pay certain milestone and royalty payments if certain development and commercialization milestones are met. Refer to Note 7—*License Agreements* to

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our condensed financial statements included in Part I “Financial Information”, Item 1 “Financial Statements” of this Quarterly Report on Form 10-Q for further information.

***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. The Merger, upon completion, will trigger a success fee of \$350,000. 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 remains outstanding and exercisable in accordance with its terms.

***Facility Lease***

In May 2016, we entered into a non-cancellable facility lease. The term of the agreement was September 1, 2016 to August 31, 2019 and monthly base rent was approximately \$8,900 during the last year of the lease agreement. The facility lease expired in August 2019 and no replacement facility lease was executed.

***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

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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). The royalty rates range from the high single digits to the mid-teens depending on the level of net sales. The royalty rates are subject to reduction during certain periods when therapeutically-equivalent generic products represent a certain market share of prescription volume in the country. 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 sublicensees 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 September 30, 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.

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**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 September 30, 2019. Based on this evaluation, our Chief Executive Officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 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 September 30, 2019, that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.



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**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 factors 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 Capital 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 of directors 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. On May 10, 2019, we received approval from Nasdaq to transfer the listing of our common stock to the Nasdaq Capital Market, which was effective at the opening of business on May 14, 2019.

On August 8, 2019, we received a notice from Nasdaq stating that, for the last 30 consecutive business days, the closing bid price for our common stock was below the \$1.00 requirement for continued listing under the Minimum Bid Price Rule. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until February 4, 2020, to regain compliance with the Minimum Bid Price Rule. To regain compliance with the Minimum Bid Price Rule, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of 10 consecutive business days at any time during this 180-day period. If we regain compliance with the Minimum Bid Price Rule, Nasdaq will provide us with written confirmation and will close the matter.

If we do not regain compliance with the rule by February 4, 2020, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to meet the continued listing requirement for market value of publicly held shares and all other applicable standards for initial listing on The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second

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compliance period by effecting a reverse stock split, if necessary. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not eligible for a second compliance period, Nasdaq will notify us that our common stock will be subject to delisting. In the event of such a notification, we may appeal the determination, but there can be no assurance Nasdaq would grant our request for continued listing.

On August 12, 2019, we received written notice from Nasdaq stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing on the Nasdaq Capital Market because our stockholder's equity, as reported in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, had fallen below \$2.5 million. The notice also indicated that we do not meet the alternative compliance standards.

On September 26, 2019, we submitted our compliance plan to Nasdaq, explaining how we believe that the completion of its proposed merger will address the stockholders' equity deficiency.

On October 4, 2019, Nasdaq notified us that it had determined to grant us an extension until February 10, 2020 to regain compliance. Under the terms of the extension, NeuroBo must receive approval of its initial listing application and we must consummate the merger on or before February 10, 2020. If NeuroBo fails to receive approval of its initial listing application or we fail to consummate the merger prior to February 10, 2020, Nasdaq will provide written notification to us that our securities will be delisted. At that time, we may appeal Nasdaq's determination to a Listing Qualifications Panel.

If we are unable to regain compliance, Nasdaq may make a determination to delist our common stock. Continued listing of our common stock on the Nasdaq Capital Market is a condition to the closing of the Merger. Furthermore, 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.

***If the conditions to the Merger are not met, the Merger will not occur.***

Before the proposed Merger can be completed, the stockholders of each of the Company and NeuroBo must approve the Merger Agreement. There can be no assurances that the necessary stockholder approvals will be obtained. Failure to obtain stockholder approval may result in a material delay in, or the abandonment of, the Merger. Even if the Merger is approved by our stockholders and NeuroBo's stockholders, certain other specified conditions set forth in the Merger Agreement must be satisfied or waived to complete the Merger. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed, and we may lose some or all of the intended benefits of the Merger.

***If the Merger is not completed, we may not be able to otherwise source adequate liquidity to fund our operations, meet our obligations, and continue as a going concern. Our board of directors may decide to pursue a dissolution and liquidation of the Company. In such an event, there can be no assurances as to the amount or timing of available cash left, if any, to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves.***

While we have entered into the Merger Agreement with NeuroBo, the closing of the Merger may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits we expect or enhance stockholder value. If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, we may be required to pay NeuroBo a termination fee of \$1.0 million. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, we will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

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We believe our cash on hand, including amounts received from Beijing SL pursuant to the non-refundable upfront payment, will be sufficient to fund operations through the fourth quarter of 2019, excluding transaction costs associated with the Merger (which we expect to pay upon the closing), and if for any reason the Merger does not close, we would 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. We have based our cash sufficiency estimates on our current business plan and our assumptions may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding sooner than currently anticipated. 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. Even if Gemphire raises sufficient funds and decides to continue the development of gemcabene, its ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support its cost structure. Gemphire cannot assure you that it 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 or the failure of the proposed Merger to be consummated in a timely manner would require us to delay or abandon clinical development plans. If, for any reason, the Merger does not close, our board of directors may elect to dissolve and liquidate our assets. Alternatively, if we were able to secure additional capital to provide us with necessary financial resources to pursue other options, we may attempt to pursue another strategic transaction like the Merger, sell or otherwise dispose of the various assets of the Company or continue to operate the business of the Company. Any of these alternatives would be costly and time-consuming and would require that we obtain additional funding. We expect that it would be difficult to secure financing in a timely manner, on favorable terms or at all. We can make no assurances that we would be able to obtain additional financing or find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement or that any such alternatives are possible or would be successful, if pursued. To the extent that we seek and are able to raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing or preferred equity 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 funds through strategic transactions or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, even if we were able to pursue such alternatives, the failure to complete the Merger may result in negative publicity and/or a negative impression of us in the investment community, could significantly harm the market price of our common stock and may affect our relationship with employees and other partners in the business community.

If our board of directors were to decide to dissolve and liquidate our assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left, if any, to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, the board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock would likely lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the Company.

We do not believe that our current expenses are indicative of the costs we may incur in the future in connection with the development and commercialization of any product candidate if we consummate the merger or raise additional capital to continue our operations. Our future funding requirements will depend on many factors, including:

- our ability to consummate the merger with NeuroBo;
- the level of development and commercialization efforts of Beijing SL with respect to gemcabene and the receipt of milestone and other payments, if any, from Beijing SL under the Beijing SL License Agreement;

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- the scope, rate of progress and cost of our preclinical and clinical trials for any product candidate in our future pipeline and results of future clinical trials;
- the cost and timing of regulatory filings and approvals for any product candidates that successfully complete clinical trials;
- the timing and nature of any strategic transaction that we undertake, including potential partnerships;
- the effect of competing technological and market developments;
- the cost incurred in responding to actions by activist stockholders; and
- the cost of filing, prosecuting, defending and enforcing our intellectual property rights.

We currently have an effective shelf registration statement on Form S-3 on file with the SEC which expires in September 2020. The shelf registration statement permits the offering, issuance and sale of up to an aggregate offering price of \$175 million of common stock, preferred stock, debt securities, warrants and subscription rights, of which \$50 million may be offered, issued and sold under an "at-the-market" (ATM) equity distribution agreement with Piper Jaffray & Co. However, the amounts available under the shelf registration statement, including the ATM program, will be significantly limited as long as our public float remains below \$75 million, which, given our currently depressed stock price, limits our ability to obtain meaningful funding through the ATM program or the shelf registration statement at this time, although we could still raise funds through a registration statement on Form S-1 or through private placements.

***The issuance of shares of our common stock to NeuroBo's stockholders in the proposed Merger will substantially dilute the voting power of our current stockholders.***

If the proposed Merger is completed, each share of NeuroBo common stock outstanding immediately prior to the Effective Time will be converted into the right to receive shares of our common stock equal to the Exchange Ratio. Applying the Exchange Ratio in the Merger Agreement, our former security holders immediately prior to the Merger are expected to own, or hold rights to acquire, approximately 3.74% of the combined company and former NeuroBo security holders immediately prior to the Merger are expected to own approximately 96.26% of the combined company, in each case, immediately following the Merger, on a fully-diluted basis and assuming we have a net cash amount of negative \$3,400,000 and that NeuroBo raises the minimum required amount of \$24,240,000 in its pre-closing financing. The ownership percentages are subject to adjustment to the extent our net cash at the Effective Time is negative or to reflect aggregate gross proceeds received by NeuroBo in its pre-closing financing before the closing of the Merger above the minimum required amount and up to and including \$50 million. Accordingly, the issuance of shares of our common stock to NeuroBo's stockholders in the Merger will reduce significantly the relative voting power of each share of our common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and policies of the combined company after the Merger than prior to the Merger. These estimates are based on the anticipated Exchange Ratio and are subject to adjustment as provided in the Merger Agreement.

In addition, the ten member board of directors of the combined company will initially include nine individuals with prior NeuroBo affiliations and one individual with a prior Company affiliation. Consequently, security holders of the Company will be able to exercise less influence over the management and policies of the combined organization following the closing of the Merger than they currently exercise over the management and policies of the Company.

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***The Merger may be completed even though certain events occur prior to the closing that materially and adversely affect us or NeuroBo.***

The Merger Agreement provides that either the Company or NeuroBo can refuse to complete the Merger if there is a material adverse change affecting the other party between July 24, 2019, the date of the Merger Agreement, and the closing of the Merger. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on us or NeuroBo, including:

- general business or economic conditions affecting the industry in which we or NeuroBo, as applicable, operate;
- any acts of war, armed hostilities or terrorism;
- any changes in financial, banking or securities markets;
- with respect to us, any change in our stock price or trading volume excluding any underlying effect that may have caused such change, unless such effect is otherwise exempt from causing a material adverse effect under the Merger Agreement;
- failure to meet internal or analysts' expectations or projections or the results of operations;
- any clinical trial programs or studies, including any adverse data, event or outcome arising out of or related to any such programs or studies;
- any change in, or any compliance with or action taken for the purpose of complying with, applicable laws or GAAP, or interpretations thereof;
- any effect resulting from the announcement or pendency of the Merger or any related transactions;
- continued losses from operations or decreases in cash balances of us or NeuroBo; and
- the taking of any action by us or NeuroBo required to comply with the terms of the Merger Agreement.

If adverse changes occur and the Company and NeuroBo still complete the Merger, the market price of our common stock may suffer. This in turn may reduce the value of the Merger to our stockholders.

***The market price of our common stock following the Merger may decline as a result of the Merger.***

The market price of our common stock may decline as a result of the Merger for a number of reasons, including if:

- investors react negatively to the prospects of the combined organization's product candidates, business and financial condition following the Merger;
- the effect of the Merger on the combined organization's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined organization does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts.

***Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.***

If the combined organization is unable to realize the strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving the expected commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined organization is able to realize only part of the expected strategic and financial benefits currently anticipated from the Merger.

***Our stockholders may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.***

The right of our stockholders to receive any future payment on or derive any value from the CVRs will be contingent solely upon the achievement of the events specified in the CVR Agreement within the time periods specified in the CVR

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Agreement and the consideration received being greater than the amounts permitted to be retained or deducted by us under the CVR Agreement. We may not be able to grant, sell or transfer our rights to gemcabene during the 10-year period after the closing of the Merger, and we may not receive any future payments pursuant to the Beijing SL Agreement after the closing of the Merger. If these events are not achieved for any reason within the time periods specified in the CVR Agreement, or the consideration received is not greater than the amounts permitted to be retained or deducted by us, no payments will be made under the CVRs, and the CVRs will expire valueless. NeuroBo (as successor in interest to the Company) has agreed to commit \$1 million to support the further development of gemcabene through the quarter ending March 31, 2020 (the “*Covenant End Date*”), the funding of which was conditioned on receipt by the Company of the \$2.5 million non-refundable upfront gross payment payable under the Beijing SL Agreement, which was received in October 2019. Following the Effective Time, neither the Company nor NeuroBo will have any obligation to develop gemcabene, or to expend any funds or efforts with respect to gemcabene, other than the \$1 million payment, to fund, (i) a toxicity study, (ii) a related FDA submission designed to result in the release of the partial clinical hold with respect to gemcabene, (iii) preparation for an end-of-phase 2 meeting with the FDA, and (iv) consulting costs for up to four (4) of our employees to support such activities. The expected cost of such activities is based on estimates and assumptions that may prove to be inaccurate. If \$1 million is insufficient to fund the matters set forth above, neither the Company nor NeuroBo will have any obligation to provide further funding. We have no other obligation to support the development of gemcabene or to undertake any effort or expend any resource to divest or otherwise monetize gemcabene or to otherwise maximize the likelihood or amount of any CVR payment. Following the Covenant End Date, we may, at any time and in our sole and absolute discretion, discontinue any and all further efforts to develop, divest or otherwise monetize gemcabene.

Furthermore, the CVRs will be unsecured obligations of the combined company and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto will be subordinated in right of payment to the prior payment in full of all current or future senior obligations of the combined company. Finally, the U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments on, the CVRs, and there can be no assurance that the Internal Revenue Service, would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

***Beijing SL has exclusive rights for the development and commercialization of gemcabene in the Territory. Beijing SL’s failure to timely develop or commercialize gemcabene would have a material adverse effect on our business and operating results.***

We granted Beijing SL an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, gemcabene, in the Territory, subject to certain rights that we retained in the Territory. The collaboration with Beijing SL may not be successful due to several factors, including the following:

- gemcabene may fail to demonstrate in clinical trials sufficient efficacy with an acceptable safety profile to support regulatory approval;
- Beijing SL may not be able to obtain from us or manufacture gemcabene in a timely or cost-effective manner;
- Beijing SL may be unable to obtain regulatory approval to commercialize gemcabene even if preclinical and clinical testing is successful;
- Beijing SL may not succeed in obtaining sufficient reimbursement for gemcabene if approved; and
- existing or future products developed by competitors may be less expensive, safer or more effective than gemcabene.

In addition, we could be adversely affected by:

- Beijing SL’s failure to timely perform its obligations under the Beijing SL Agreement;
- Beijing SL’s failure to timely or fully develop or effectively commercialize gemcabene; or

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- contractual disputes or other disagreements between us and Beijing SL, including those regarding the development, manufacture, and commercialization of gemcabene, interpretation of the Beijing SL Agreement, and ownership of proprietary rights.

Any of the foregoing could adversely impact the likelihood and timing of any milestone or royalty payments we are eligible to receive under the Beijing SL Agreement and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

***During the pendency of the Merger, we may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect our business.***

Covenants in the Merger Agreement impede our ability to make acquisitions, subject to certain exceptions relating to fiduciary duties, as set forth below, or to complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors during such period. In addition, while the Merger Agreement is in effect, we are generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to our stockholders.

***Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.***

The terms of the Merger Agreement prohibit us from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when the board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the proposal would be reasonably likely to be inconsistent with the board of director's fiduciary duties. Any such transactions could be favorable to such party's stockholders.

***We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.***

As of September 30, 2019, we had only 7 full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

***Litigation relating to the Merger could require us to incur significant costs and suffer management distraction, and could delay or enjoin the Merger.***

The Company and NeuroBo could be subject to demands or litigation related to the Merger, whether or not the Merger is consummated. Such actions may create uncertainty relating to the Merger, delay or enjoin the Merger, result in substantial costs to us and divert management time and resources.

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

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

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**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.



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<b>ITEM 6.</b>	<b>EXHIBITS</b>
<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF DOCUMENT</b>
2.1*	<a href="#">Agreement and Plan of Merger, dated as of July 24, 2019, by and among Gemphire, Merger Sub and NeuroBo (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
2.2	<a href="#">First Amendment to Agreement and Plan of Merger and Reorganization, dated as of October 29, 2019, by and among Gemphire, Merger Sub and NeuroBo (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on October 29, 2019).</a>
2.3*	<a href="#">Form of CVR Agreement by and among Gemphire, Grand Rapids Holders' Representative, LLC, as Holders' Representative, and Computershare Inc., as Rights Agent (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
2.4	<a href="#">Form of Gemphire Voting Agreement, by and between NeuroBo, Gemphire and certain stockholders of Gemphire (incorporated by reference to Exhibit 2.3 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
2.5*	<a href="#">Form of NeuroBo Voting Agreement, by and between Gemphire, NeuroBo and certain stockholders of NeuroBo (incorporated by reference to Exhibit 2.4 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
2.6	<a href="#">Form of Lock-Up Agreement, by and between Gemphire, NeuroBo and certain stockholders of Gemphire and NeuroBo (incorporated by reference to Exhibit 2.5 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
3.1	<a href="#">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).</a>
3.2	<a href="#">Second Amended and Restated Bylaws 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 October 29, 2019).</a>
10.1+	<a href="#">First Amendment to Employment Agreement dated as of July 24, 2019 by and between Gemphire and Steve Gullans (incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to Current Report on Form 8-K/A, filed on August 13, 2019).</a>
10.2+	<a href="#">First Amendment to Employment Agreement dated as of July 24, 2019 by and between Gemphire and Charles L. Bisgaier (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
10.3+	<a href="#">First Amendment to Employment Agreement dated as of July 24, 2019 by and between Gemphire and Seth Reno (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
10.4+	<a href="#">Form of Restricted Stock Grant Notice and Restricted Stock Agreement under the Amended and Restated 2015 Equity Incentive Plan (Employees) (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
10.5+	<a href="#">Form of Restricted Stock Grant Notice and Restricted Stock Agreement under the Amended and Restated 2015 Equity Incentive Plan (Directors) (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>
10.6**	<a href="#">License and Collaboration Agreement dated as of July 23, 2019 by and between Gemphire and Beijing SL (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on July 25, 2019).</a>

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10.7+	<a href="#">Second Amendment to Employment Agreement dated September 30, 2019 by and between Gemphire and Steven Gullans (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on October 3, 2019).</a>
10.8+	<a href="#">Second Amendment to Employment Agreement dated September 30, 2019 by and between Gemphire and Charles L. Bisgaier (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on October 3, 2019).</a>
10.9+	<a href="#">Second Amendment to Employment Agreement dated September 30, 2019 by and between Gemphire and Seth Reno (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, File No. 001-37809, filed on October 3, 2019).</a>
31.1	<a href="#">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.</a>
32.1	<a href="#">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.</a>
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

\* Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

\*\* Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the License Agreement that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of the unredacted License Agreement will be furnished to the SEC upon request.

+ Management compensation plan or arrangement.

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**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.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ STEVEN GULLANS</u> Steven Gullans	President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)	November 8, 2019

**Exhibit 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**

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 September 30, 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: November 8, 2019

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

**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 September 30, 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: November 8, 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.
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