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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2018

GEMPHIRE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37809
(Commission
File No.)

47-2389984
(IRS Employer
Identification No.)

17199 N. Laurel Park Drive, Suite 401
Livonia, Michigan 48152
(Address of principal executive offices) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2018, Gemphire Therapeutics Inc. (the “*Company*”) issued a press release reporting its financial results for the third quarter ended September 30, 2018. The press release is furnished as Exhibit 99.1 and incorporated by reference herein.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Current Report on Form 8-K (including Exhibit 99.1) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	<u>Press Release dated November 8, 2018 reporting financial results for the third quarter ended September 30, 2018.</u>

SIGNATURE

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 hereunto duly authorized.

GEMPHIRE THERAPEUTICS INC.

Dated: November 8, 2018

By: /s/ Dr. Steven Gullans

Dr. Steven Gullans

President and Chief Executive Officer

Gemphire Therapeutics Reports Third Quarter 2018 Financial Results and Provides Corporate Update

LIVONIA, Mich., November 8, 2018 -- Gemphire Therapeutics Inc. (NASDAQ: GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and nonalcoholic steatohepatitis (NASH), today announced financial results for the quarter and nine months ended September 30, 2018, and provided a corporate update.

“During the third quarter we had several accomplishments that are important to the continued development of gemcabene,” said Steven Gullans, Ph.D., CEO of Gemphire. “We negotiated our license agreement with Pfizer to extend the timeline to commercialization of gemcabene and we renegotiated the terms of our debt facility with Silicon Valley Bank (SVB) to provide additional flexibility. We also made significant adjustments to our headcount and cash burn to extend our cash runway into at least the fourth quarter of 2019.”

“Our immediate priority is to work closely with the FDA to release the partial clinical hold on gemcabene, with the goal of proceeding to an End of Phase 2 meeting in 2019 and reaching agreement on the design of a Phase 3 clinical program. We continue to believe that gemcabene is a differentiated, late stage candidate for cardiometabolic disease, and has successfully shown clinical benefits in both orphan and broader dyslipidemia indications,” concluded Dr. Gullans.

Third quarter 2018 Corporate Highlights

- Gemcabene is on partial clinical hold with respect to clinical trials of longer than six months in duration. The Company plans to conduct a sub-chronic (13-week) toxicology study that has been requested by the FDA and expects to submit the additional results in the second quarter of 2019. The Company continues to be free to conduct clinical trials with gemcabene that are six months or less in duration.
 - In the ongoing 24 week open-label Phase 2a trial investigating gemcabene in adult patients with familial partial lipodystrophy (FPL), an interim safety review by the Data Safety and Monitoring Board (DSMB) of the first three patients, on a dose of 300 mg/dL, did not uncover safety or tolerability concerns nor was there a change in biomarkers that would indicate concerns about liver function. The principal investigator in the trial intends to closely monitor these patients while including MRI-PDFF scans to be reviewed at interim time points. Following the DSMB interim review, additional patients have been enrolled and top-line data, including MRI-PDFF, is expected in Q2 2019.
 - The investigator-led open label Phase 2a proof-of-concept trial evaluating gemcabene in pediatric patients with non-alcoholic fatty liver disease (NAFLD) was terminated due to lack of efficacy and liver signals observed in the patients that underwent 12-week MRI-PDFF imaging scans. In cooperation with the principal investigator, the Company is continuing to gather information to determine whether the unanticipated problems could be related to variables such as diet, age, compliance, or other factors.
 - The Company amended the license agreement with Pfizer to extend the period of first commercial sale of gemcabene to April 2024.
 - The Company amended the debt facility agreement with SVB to provide additional flexibility.
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- The Company conducted a workforce reduction totaling five employees, or approximately 33% of the Company's workforce, in order to reduce costs and conserve cash resources, until the partial clinical hold on gemcabene has been lifted.

Third Quarter Ended September 30, 2018 Financial Results

General and administrative expenses for the three months ended September 30, 2018 were \$2.4 million compared to \$2.1 million for the three months ended September 30, 2017. The \$0.3 million increase year over year was largely attributed to separation costs in connection with the September 2018 reduction-in-force. Timing of costs related to infrastructure supporting the Company's ongoing clinical trials and public company requirements, focused primarily on personnel costs and professional services, were the other primary drivers of the activity during both quarterly periods in 2018 and 2017.

Research and development expenses for the three months ended September 30, 2018 were \$3.5 million compared to \$6.5 million for the three months ended September 30, 2017. The year over year decrease was primarily attributable to reduced clinical trial activities in the third quarter of 2018. This was partially offset by separation costs in connection with the September 2018 reduction-in-force.

Net loss attributable to common stockholders for the third quarter ended September 30, 2018 was \$6.1 million, or (\$0.43) per share, compared to \$8.7 million, or (\$0.82) per share, for the third quarter ended September 30, 2017.

At September 30, 2018, the company had cash and cash equivalents of approximately \$23.8 million. The Company believes that the cash on hand will be sufficient to fund operations into at least the fourth quarter of 2019.

Nine Months Ended September 30, 2018 Financial Results

General and administrative expenses for the nine months ended September 30, 2018 were \$7.0 million compared to \$9.0 million for the nine months ended September 30, 2017. The decrease in expenses from the comparable period in 2017 was largely the result of separation costs for the Company's former chief executive officer in 2017, offset partially by separation costs in connection with the reduction-in-force in September 2018. Timing of costs related to infrastructure supporting our ongoing clinical trials and public company requirements, focused primarily on personnel costs and professional services, were the other primary drivers of the activity during both nine-month periods in 2018 and 2017.

Research and development expenses for the nine months ended September 30, 2018 were \$12.5 million compared to \$17.6 million for the nine months ended September 30, 2017. The decrease was primarily attributable to reduced clinical trial activities through the third quarter in 2018 versus the comparable period in 2017. The overall decrease period over period, was partially offset by separation costs in connection with the September 2018 reduction-in-force.

Net loss attributable to common stockholders for the nine months ended September 30, 2018 was \$20.0 million, or (\$1.46) per share, compared to \$26.7 million, or (\$2.60) per share, for the nine months ended September 30, 2017.

For further details on Gemphire's financial statements, refer to our Quarterly Report on Form 10-Q filed with the SEC.

About Gemphire

Gemphire is a clinical-stage biopharmaceutical company that is committed to helping patients with cardiometabolic disorders, including dyslipidemia and NASH. The Company is focused on providing

new treatment options for cardiometabolic diseases through its complementary, convenient, cost-effective product candidate gemcabene as add-on to the standard of care, especially statins that will benefit patients, physicians, and payors. Gemphire's Phase 2 clinical program is evaluating the efficacy and safety of gemcabene in hypercholesterolemia, including FH and SHTG, as well as NASH/NAFLD and ASCVD. Two trials supporting hypercholesterolemia and one trial in SHTG have been completed under NCT02722408, NCT02634151 and NCT02944383, respectively. Please visit www.gemphire.com for more information.

Forward Looking Statements

Any statements in this press release that are not statements of historical fact, including statements about Gemphire's future expectations, milestones, goals, plans and prospects, including statements about the estimated amount and timing of severance payments and charges and the financial impact of the workforce reduction, Gemphire's financial prospects, future operations and sufficiency of funds for future operations, clinical development of Gemphire's product candidate, expectations regarding future clinical trials, expected timing of top-line results of such trials, timing and expectations for regulatory submissions and meetings and future expectations and plans and prospects for gemcabene, expectations for the future competitive environment for gemcabene, expectations regarding operating expenses and cash used in operations, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "promising," "targets," "may," "potential," "will," "would," "could," "should," "continue," "scheduled," "goal" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks related to cost reduction efforts, including that the Company's workforce reduction costs may be greater than anticipated and that the workforce reduction may have an adverse impact on the Company's drug development activities; Gemphire's ability to analyze the results and understand the reasons for the unexpected events in the Phase 2a pediatric NAFLD trial; the impact of the unexpected events on the Phase 2a study in FPL or the enrollment of patients; that MRI-PDFF scans or other follow-up tests of patients in the pediatric NAFLD, FPL or other trials may show similar increases in liver fat content or ALT or other undesirable side effects; uncertainties inherent in the clinical drug development process and the regulatory approval process, including the risk that gemcabene may cause undesirable side effects or have other properties that could delay or prevent regulatory approval; Gemphire's substantial dependence on its product candidate, gemcabene; developments in the capital markets, the success and timing of Gemphire's regulatory submissions and pre-clinical and clinical trials; regulatory requirements or developments; changes to Gemphire's clinical trial designs and regulatory pathways; changes in Gemphire's capital resource requirements; the actions of Gemphire's competitors; Gemphire's ability to obtain additional financing; Gemphire's ability to successfully market and distribute its product candidate, if approved; Gemphire's ability to obtain and maintain its intellectual property protection; and other factors discussed in the "Risk Factors" section of Gemphire's most recent annual report, subsequent quarterly reports and in other filings Gemphire makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Gemphire's views as of the date hereof. Gemphire anticipates that subsequent events and developments will cause Gemphire's views to change. However, while Gemphire may elect to update these forward-looking statements at some point in the future, Gemphire specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Gemphire's views as of any date subsequent to the date hereof.

Contact:

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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,	
	2018	2017	2018	2017
Operating expenses:				
General and administrative	\$ 2,364	\$ 2,050	\$ 7,025	\$ 8,951
Research and development	3,542	6,489	12,479	17,606
Total operating expenses	5,906	8,539	19,504	26,557
Loss from operations	(5,906)	(8,539)	(19,504)	(26,557)
Interest expense, net	(172)	(132)	(476)	(107)
Other expense	(1)	—	(1)	(5)
Loss before income taxes	(6,079)	(8,671)	(19,981)	(26,669)
Provision (benefit) for income taxes	—	—	—	—
Net loss	(6,079)	(8,671)	(19,981)	(26,669)
Other comprehensive loss, net of tax	—	—	—	—
Comprehensive loss	\$ (6,079)	\$ (8,671)	\$ (19,981)	\$ (26,669)
Net loss per share:				
Basic and diluted	\$ (0.43)	\$ (0.82)	\$ (1.46)	\$ (2.60)
Number of shares used in per share calculations:				
Basic and diluted	14,259,691	10,623,601	13,650,556	10,253,437

Gemphire Therapeutics Inc.
Balance Sheet Data
(in thousands)

	September 30, 2018 (unaudited)	December 31, 2017
Cash and cash equivalents	\$ 23,806	\$ 18,473
Total current assets	24,862	19,009
Term loan (Long-term Portion)	6,398	8,683
Total liabilities	14,017	15,076
Accumulated deficit	(80,455)	(60,474)
Total stockholders' equity	10,853	3,941