



Gemphire Therapeutics Reports Fourth Quarter and Fiscal Year 2018 Financial Results

March 15, 2019

LIVONIA, Mich., March 15, 2019 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), 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, focused on orphan indications, as well as nonalcoholic fatty liver disease (NAFLD/NASH), today announced its financial results for the quarter and fiscal year ended December 31, 2018, and provided a corporate update.

"2018 was a year of progress for Gemphire with our Phase 2 INDIGO-1 trial investigating gemcabene in severe hypertriglyceridemia (SHTG) successfully meeting its primary endpoint," said Steven Gullans, Ph.D., CEO of Gemphire. "In addition, patient enrollment was completed in an investigator-initiated Phase 2 study in familial partial lipodystrophy (FPL). On the other hand, the FDA requested that we provide additional information regarding preclinical toxicology before it will consider lifting our clinical hold and scheduling an End of Phase 2 (EOP2) meeting. We are moving propositiously to achieve this milestone and move into Phase 3."

"In August, we received unexpected news when the pediatric non-alcoholic fatty liver disease (NAFLD) study was halted early by the Data Safety Monitoring Board (DSMB) due to unanticipated problems," added Gullans. "While there were no serious adverse events (SAEs), the first three patients experienced increased circulating liver enzyme levels and increased liver fat content. Unlike prior studies of gemcabene in adults, the pediatric patients gained weight and did not experience a decrease in serum triglycerides (TGs). Moreover patients were poorly compliant in taking the drug as assessed by tablet counts and blood drug levels. Being cautious with regard to the patients, we fully supported the decision to discontinue the trial, and we look forward to seeing how and whether, we can further resolve these findings."

Fourth Quarter and Recent Corporate Highlights

- **Completed patient enrollment in a proof-of-concept (POC) Phase 2 trial investigating gemcabene in FPL**
 - This investigator initiated trial (GEM-IIT-602) is an unblinded, 24 week study being conducted at the University of Michigan.
 - All patients receive 300 mg/day dose for the first 12 weeks, and then are randomized to either the same dose or a higher dose of 600 mg/day for the subsequent 12 weeks.
 - The primary endpoint is TG reduction from baseline after 12 weeks. Secondary endpoints include measurement of liver fat fraction by MRI-PDFF.
 - The trial is on track to report top-line results in the second quarter of 2019.
 - FPL is considered an orphan indication and represents an unmet clinical need.

- **The POC Phase 2 trial in pediatric non-alcoholic fatty liver disease (NAFLD) was halted early**
 - An open-label, 12 week, investigator initiated trial (GEM-IIT-601) was undertaken to assess gemcabene (300 mg/d) in pediatric patients (12-17 years old) with NAFLD.
 - The study enrolled 6 patients and in August 2018, the DSMB halted the trial early due to "unanticipated problems" in the first three patients.
 - The primary efficacy endpoint of alanine amino transferase (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 magnetic resonance imaging—estimated proton density fat fraction (MRI-PDFF).
 - All patients gained weight and had increased serum TGs during study treatment, in contrast to what has been reported in other gemcabene trials.
 - Patient compliance taking gemcabene was compromised as assessed by return of unused tablets and measurement of blood drug levels.
 - No serious adverse events (SAEs) were reported.
 - The risk for increased liver fat with gemcabene treatment is unknown at this time and patients will continue to be monitored for 12 months post-final dose.

- **Engaged Ladenburg Thalmann & Co. as our strategic financial advisor to explore strategic alternatives**
 - We established a transaction committee of independent board members to oversee a review of strategic

alternatives focused on maximizing stockholder value.

- o There can be no assurance that this process will result in any transaction, or the terms and timing of any potential transaction.

- **Term loan facility with Silicon Valley Bank (SVB) was prepaid and terminated in January 2019**

- o In January 2019, we prepaid in full all outstanding indebtedness under our Loan Agreement with SVB.
- o The payment included approximately \$8.9 million in outstanding borrowings and approximately \$1.0 million in outstanding interest and fees under the Loan Agreement.

- **Initiated activities to address FDA requests related to the partial clinical hold**

- o In Q3 2018, our request to the FDA to lift our partial clinical hold was denied and the Agency requested additional information in order to resubmit.
- o The FDA informed us that an End of Phase 2 (EOP2) meeting would not take place until the partial clinical hold is lifted.
- o We expect to submit the additional information to the FDA in the fourth quarter of 2019.
- o Based on the Company's current operating plans, management believes we will need to raise capital to complete additional activities needed to submit our request to the FDA to lift the partial clinical hold.

Fourth Quarter and Fiscal 2018 Financial Update

General and administrative expense for the fourth quarter and fiscal year ended December 31, 2018 was \$1.5 million and \$8.5 million, respectively, compared to \$1.5 million and \$10.4 million for the fourth quarter and fiscal year ended December 31, 2017, respectively. The decrease for the year was primarily attributable to lower separation costs in the 2018 period when compared to 2017.

Research and development expense for the fourth quarter and fiscal year ended December 31, 2018 was \$1.8 million and \$14.3 million, respectively, compared to \$5.1 million and \$22.7 million for the fourth quarter and fiscal year ended December 31, 2017, respectively. The decrease for the year was primarily attributable to reduced clinical trial activities in 2018 compared to 2017, partially offset by separation costs recorded as research and development expenses in connection with the September 2018 reduction-in-workforce.

Net loss for the fourth quarter and fiscal year ended December 31, 2018 was \$3.7 million, or (\$0.26) per share, and \$23.6 million, or (\$1.71) per share, respectively, compared to \$6.7 million, or (\$0.63) per share, and \$33.4 million, or (\$3.23) per share, for the fourth quarter and fiscal year ended December 31, 2017, respectively.

At December 31, 2018, the company had cash and cash equivalents of approximately \$19 million. Based on the Company's current operating plans, management believes the current cash on hand (net of our SVB Term Loan prepayment in January 2019) will be sufficient to fund operations into the third quarter of 2019. Management believes we will need to raise additional capital to continue to fund the further development of gemcabene and our operations thereafter, including submission of the additional information requested by the FDA to lift the partial clinical hold.

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, hypertriglyceridemia and fatty liver disease, including FH, SHTG, 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, such as statements about the plan of the Board of Directors to conduct a review of strategic alternatives to maximize stockholder value, the clinical development of Gemphire's product candidate, gemcabene, expectations regarding clinical trials, expected timing of top-line results of such trials, timing and expectations for pre-clinical studies, regulatory submissions and meetings, future expectations and plans and prospects for gemcabene, 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: the ability of the Company to successfully and timely negotiate and consummate a possible transaction on terms that are favorable to the Company; whether desirable products and combinations can be identified; risks related to cost reduction efforts; Gemphire's ability to analyze the results and understand the reasons for the unexpected events in the Phase 2a pediatric NAFLD trial; that MRI-PDF scans or other follow-up tests of patients show similar increases in liver fat content or other undesirable side effects; uncertainties inherent in the clinical drug development process and the regulatory approval process, including the risk that gemcabene may have 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:

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

	Year Ended		Three Months Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Operating expenses:				
General and administrative	\$ 8,493	\$ 10,438	\$ 1,468	\$ 1,487
Research and development	14,312	22,686	1,833	5,080
Total operating expenses	22,805	33,124	3,301	6,567
Loss from operations	(22,805)	(33,124)	(3,301)	(6,567)
Interest expense	(654)	(286)	(178)	(179)
Other expense	(178)	(5)	(177)	—
Net loss	\$(23,637)	\$(33,415)	\$(3,656)	\$(6,746)
Other comprehensive loss, net of tax	—	—	—	—
Comprehensive loss	\$(23,637)	\$(33,415)	\$(3,656)	\$(6,746)
Net loss per share:				
Basic and diluted	\$(1.71)	\$(3.23)	\$(0.26)	\$(0.63)
Number of shares used in per share calculations:				
Basic and diluted	13,805,552	10,349,136	14,265,411	10,633,042

Gemphire Therapeutics Inc.
Balance Sheet Data
(in thousands)

	Year Ended	
	December 31,	
	2018	2017
	(unaudited)	
Cash and cash equivalents	\$ 18,954	\$ 18,473
Total assets	19,694	19,017
Term loan (short-term portion)	9,437	1,355
Term loan (long-term portion)	—	8,683
Total liabilities	11,920	15,076
Accumulated deficit	(84,111)	(60,474)
Total stockholders' equity	7,774	3,941



Source: Gemphire Therapeutics Inc.