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

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LIVONIA, Mich., Aug. 13, 2018 (GLOBE NEWSWIRE) -- 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 six months ended June 30, 2018, and provided a corporate update.

“We capped off our second quarter by announcing that our INDIGO-1 trial investigating gemcabene in severe hypertriglyceridemia (SHTG) patients achieved its primary endpoint,” said Steven Gullans, Ph.D., CEO of Gemphire. “We were pleased to successfully complete our third Phase 2b trial in dyslipidemia and look forward to finalizing our Phase 3 program once we are able to provide the FDA with the additional information they recently requested.”

“While last week’s decision by the Data and Safety Monitoring Board of our primary investigator to terminate the Phase 2a pediatric NAFLD trial will cause us to put our plans to develop gemcabene in this particular population on hold, we remain confident that gemcabene has the potential to be an effective therapy for a host of cardiometabolic patients and we intend to continue to develop gemcabene to address multiple indications.”

Second Quarter 2018 Corporate Highlights

- Announced gemcabene achieved its primary endpoint in the Phase 2 INDIGO-1 study of severe hypertriglyceridemia (SHTG) patients (> 500 mg/dL)
    - Primary endpoint met with median triglycerides (TG) significantly decreased by 47% in gemcabene 600 mg group compared to 27% for placebo (P=0.0063; ranked ANCOVA).
    - The clinical target for SHTG patients is to reach a serum TG level of less than 500 mg/dL. The 600 mg gemcabene group attained a significantly lower median level of serum TGs of 333 mg/dL compared to placebo of 538 mg/dL (P=0.0137) at the end of the study.
    - Multiple secondary endpoints achieved with 600 mg gemcabene, including placebo-corrected median decreases in LDL-C, non-HDL-C, VLDL-C, apoB, apoE, apoCIII and SAA.
    - Adverse events (AEs) were generally mild to moderate, occurring less frequently with gemcabene than placebo. No severe adverse events (SAEs) were observed with gemcabene.
- Appointed Steven Gullans, Ph.D., as President and Chief Executive Officer. Dr. Gullans served as Interim President and Chief Executive Officer of Gemphire from May 2017 to May 2018.

Recent Corporate Developments

- U.S. Food and Drug Administration (FDA) requested that the Company produce data from a sub-chronic toxicology study to support lifting the partial clinical hold on gemcabene with respect to clinical trials of longer than six months in duration.
    - The Company is working with the FDA to release the partial hold, with the goal of proceeding to an End of Phase 2 meeting and reaching an agreement on the design of a Phase 3 clinical program in dyslipidemia. It plans to conduct the studies required 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 do not extend beyond six months in duration.
- The investigator-led open label Phase 2a proof-of-concept trial evaluating gemcabene in pediatric NAFLD was terminated due to unexpected liver problems observed in the patients that underwent 12-week MRI-PDFF imaging scans.
- In the ongoing Phase 2a trial in familial partial lipodystrophy, the initial safety review of the first three patients, on a dose of 300 mg/day has not uncovered any 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 waiting for MRI-PDFF scans to be reviewed at an interim time point in the near future before dosing additional patients.

- Amended and restated the gemcabene License Agreement with Pfizer Inc.
  - The amended and restated agreement contains a number of changes to the license, including extending the date of the agreed deadline for the first commercial sale to April 2024.
- Amended loan agreement with Silicon Valley Bank (SVB) to provide additional financial flexibility.

Second Quarter 2018 Financial Update

General and administrative expenses for the three and six months ended June 30, 2018 were $2.6 million and $4.7 million, respectively, compared to $4.7 million and $6.9 million, respectively, for the comparable periods of the prior year. The decrease in expenses from the comparable period in 2017 was primarily attributed to $2.1 million of non-cash share-based compensation expense resulting from the acceleration of stock option vesting that occurred in the second quarter of 2017. Timing of costs related to infrastructure supporting our ongoing clinical trials and expenses associated with being a public company were the other primary drivers of the activity during both quarterly periods in 2018 and 2017.

Research and development expenses for the three and six months ended June 30, 2018 were $4.0 million and $8.9 million, respectively, compared to $5.8 million and $11.1 million for the three and six-month periods ended June 30, 2017, respectively. The decrease year over year was primarily attributable to reduced clinical trial activities in the second quarter and first six months of 2018 versus the comparable periods in 2017.

Net loss attributable to common stockholders for the second quarter ended June 30, 2018 was $6.7 million, or ($0.47) per share, compared to $10.5 million, or ($0.99) per share, for the second quarter ended June 30, 2017. Net loss attributable to common stockholders for the six months ended June 30, 2018 was $13.9 million, or ($1.04) per share, compared to $18.0 million, or ($1.79) per share, for the six months ended June 30, 2017.

At June 30, 2018, the company had cash and cash equivalents of approximately $28.0 million. Based on current projections, taking into account the delay of significant cash expenditures for clinical trials and manufacturing and the amended terms of the loan agreement with SVB, the Company believes it has sufficient resources to fund operations into the fourth quarter of 2019.

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 ASCVD, SHTG and NASH/NAFLD. 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 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" 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: 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 annual report 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.

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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 June 30,		For the Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
General and administrative	$ 2,574	$ 4,678	$ 4,661	$ 6,901
Research and development	3,960	5,837	8,937	11,117
Total operating expenses	6,534	10,515	13,598	18,018
Loss from operations	(6,534)	(10,515)	(13,598)	(18,018)
Interest (expense) income	(144)	13	(304)	25
Other expense	—	—	—	(5)
Loss before income taxes	(6,678)	(10,502)	(13,902)	(17,998)
Provision (benefit) for income taxes	—	—	—	—

Net loss	(6,678)	(10,502)	(13,902)	(17,998)
Other comprehensive loss, net of tax	—	—	—	—
Comprehensive loss	$ (6,678)	$ (10,502)	$ (13,902)	$ (17,998)
Net loss per share:				
Basic and diluted	$ (0.47)	$ (0.99)	$ (1.04)	$ (1.79)
Number of shares used in per share calculations:				
Basic and diluted	14,232,313	10,603,371	13,340,941	10,065,287

Gemphire Therapeutics Inc.
Balance Sheet Data
(in thousands)

	June 30, 2018 (unaudited)	**December 31, 2017**
Cash and cash equivalents	$ 28,039	$ 18,473
Total current assets	28,798	19,009
Term loan (long-term portion)	7,540	8,683
Total liabilities	13,758	15,076
Accumulated deficit	(74,376)	(60,474)
Total stockholders' equity	15,048	3,941

Primary Logo

Gemphire Therapeutics Inc.