

## **Gemphire Announces Third Quarter 2016 Financial Results and Provides Corporate Update**

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LIVONIA, Mich., Nov. 02, 2016 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for the treatment of dyslipidemia and NAFLD/NASH, today announced its financial results for the third quarter and nine months ended September 30, 2016 and provided a corporate update.

"Since the successful closing of our initial public offering in August, we continued to make excellent progress in the development of gemcabene, our once-daily oral drug candidate for the treatment of multiple unmet needs in dyslipidemia and NASH," said Mina Sooch, President and CEO of Gemphire Therapeutics. "We were proud to announce the publication of the Phase 2 gemcabene clinical results in the Journal of Clinical Lipidology and begin patient enrollment in the Phase 2b COBALT-1 trial investigating gemcabene for homozygous familial hypercholesterolemia (HoFH). We remain on track with our plans to initiate two further Phase 2b studies, ROYAL-1 and INDIGO-1, in the fourth quarter of this year, which will test gemcabene in additional distinct high cholesterol and severe triglyceride patient populations not at goal on current therapies such as statins and ezetimibe. We also strengthened our management team with the appointment of Lee Golden, M.D. to the position of Chief Medical Officer. We look forward to reporting data on our three Phase 2b clinical trials throughout 2017."

### **THIRD QUARTER AND RECENT CORPORATE HIGHLIGHTS:**

- Enrolled the first patient in the open-label COBALT-1 trial designed to determine the efficacy, safety and tolerability of gemcabene in patients with homozygous familial hypercholesterolemia (HoFH).
- Published Phase 2 data for gemcabene in the Journal of Clinical Lipidology. The trial demonstrated that gemcabene, when added to stable statin therapy, resulted in a clinically meaningful reduction in LDL-C, hsCRP, and other key lipid parameters after eight weeks.
- Appointed Lee Golden, M.D. as Chief Medical Officer. Dr. Golden is an Interventional Cardiologist with extensive biotech and large cap pharma experience.
- Sponsored the FH Foundation to support research, advocacy, and education of all forms of familial hypercholesterolemia including HoFH and HeFH.
- Announced that the European Patent Office granted European Patent No. 2658536, covering the use of gemcabene for decreasing the risk of developing pancreatitis in patients having a blood triglyceride level of 500 mg/dl or higher (SHTG), which adds to Gemphire's corresponding patents in the United States, Australia, and Mexico.
- Furthered exploration of the utility of gemcabene in Nonalcoholic Steatohepatitis (NASH) and/or Nonalcoholic Fatty Liver Disease (NAFLD) given its mechanism of action of triglyceride lowering and reduction of inflammation which represent key hallmarks of NASH/NAFLD.
- Successfully completed an initial public offering of approximately 3 million shares of common stock, including the partial exercise of the underwriters' over-allotment option, at \$10.00 per share, for proceeds of \$26.2 million, net of underwriting discounts, commissions and offering-related transaction costs.

### **UPCOMING 2017 CLINICAL MILESTONES**

- Interim data on COBALT-1 (HoFH) is planned for early 2017
- Topline data readout from COBALT-1 is currently anticipated in June 2017
- Topline data readout from ROYAL-1 (HeFH/ASCVD) is currently anticipated in second half 2017
- Topline data readout from INDIGO-1 (SHTG) is currently anticipated in second half 2017

### **THIRD QUARTER FINANCIAL UPDATE**

Cash and cash equivalents at September 30, 2016 totaled \$28.4 million compared to \$3.6 million at December 31, 2015.

General and administrative expenses totaled \$1.5 million in the three months and \$3.6 million in the nine months ended September 30, 2016 compared to \$1.0 million and \$2.1 million, respectively, in comparable periods of 2015. The increases primarily resulted from increased non-cash share-based compensation expense, as well as increased staffing and professional fees to support our clinical trials.

Research and development expenses were \$1.9 million and \$3.9 million, respectively, for the three and nine months ended September 30, 2016 versus \$1.4 million and \$2.5 million in comparable periods of 2015. The increases reflect the Company's activities in preparation for three Phase 2b clinical trials for gemcabene, and include increased personnel, consulting and non-cash share-based compensation expense.

Net loss attributable to common stockholders in the three and nine months ended September 30, 2016 was \$3.9 million, or \$0.56 per share and \$7.7 million, or \$1.65 per share, respectively. This compares to losses of \$2.7 million, or \$0.87 per share and \$9.3 million, or \$3.39 per share, in the comparable periods of 2015.

The Company expects to see increased operating expenses over the next several quarters, as compared to the respective prior year periods, resulting from increased personnel, consulting and professional costs in support of the clinical development of gemcabene. The Company believes that cash on hand at September 30, 2016 will be sufficient to fund the three Phase 2b clinical trials and planned end of phase 2 meeting(s) with the FDA in the first half of 2018.

## **CORPORATE UPDATE**

In September, Gemphire announced publication of data from the previously completed Phase 2 clinical trial evaluating gemcabene in the *Journal of Clinical Lipidology*. The trial demonstrated clinically meaningful reduction in low-density lipoprotein cholesterol (LDL-C) and other key parameters after eight weeks of treatment with gemcabene. Two dose levels of gemcabene (300mg QD, 900mg QD) were compared with placebo, added on top of stable statin therapy, in 66 hypercholesterolemic patients whose LDL-C remained greater-than-or-equal-to 130 mg/dL. Patients in the 300 mg QD and 900mg QD cohorts on top of statins, achieved reductions in LDL-C of -23.4% and -27.7%, respectively, versus -6.2% for placebo and achieved additional reductions in CRP of -26.1% and -53.9%, respectively, versus a reduction of -11.1% for placebo. Gemcabene was well-tolerated with a safety profile on top of statins similar to statin therapy alone. These data provide strong support for the Company's Phase 2b clinical program. Shortly after announcing the Phase 2 data, Gemphire was pleased to announce enrollment of its first patient in the COBALT-1, Phase 2b clinical trial, to investigate gemcabene in the treatment of homozygous familial hypercholesterolemia (HoFH). The Phase 2b trial has been designed to assess the efficacy, safety, and tolerability of multiple rising doses of gemcabene in patients with HoFH who are on stable, lipid-lowering therapy, including statins, ezetimibe, and Repatha. The trial is expected to enroll up to eight adult patients at clinical sites in the United States, Canada, and Israel. The Company anticipates the 12-week trial will complete enrollment and all patient follow-up visits in the first half of 2017, with top line data expected in June 2017 with interim results early in 2017 from this open-label trial.

In October, Gemphire announced the appointment of Lee Golden, M.D. to the position of Chief Medical Officer. Dr. Golden brings more than 15 years of industry experience in the cardiovascular space, and will be an invaluable asset as the Company continues the clinical development program for gemcabene. Dr. Golden began his industry career at Pfizer as a Medical Director on the global Lipitor team, where his responsibilities included overseeing multinational cardiovascular trials.

Also in October, the Company announced that the European Patent Office had granted European Patent No. 2658536 "Gemcabene and Derivatives for Treating Pancreatitis" covering the use of gemcabene for decreasing a patient's risk of developing pancreatitis in patients having a blood triglyceride level of 500 mg/dl or higher. The patent is expected to provide coverage into 2031. Corresponding patents have also been granted in the United States, Australia, and Mexico with coverage into 2031 to 2032. These patents are wholly owned by Gemphire.

## **ABOUT GEMPHIRE**

Gemphire is 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, and NAFLD/NASH (nonalcoholic fatty liver disease). Please visit [www.gemphire.com](http://www.gemphire.com) for more information.

## FORWARD LOOKING STATEMENTS

Any statements in this press release about Gemphire's future expectations, 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 and future expectations and plans and prospects for Gemphire and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "targets," "may," "potential," "will," "would," "could," "should," "continue," 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 success and timing of Gemphire's regulatory submissions and pre-clinical and clinical trials; regulatory developments; changes to Gemphire's clinical trial designs and regulatory pathways; changes in Gemphire's capital resource requirements; 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 Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, 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.

## Gemphire Therapeutics Inc.

### Balance Sheet Data

(in thousands)

	September 30, 2016	December 31, 2015
	(unaudited)	
Cash and cash equivalents	\$ 28,369	\$ 3,620
Total assets	28,924	4,490
Accounts payable and accrued liabilities	1,936	2,148
Convertible notes	—	6,769
Total liabilities	1,936	8,917
Series A convertible preferred stock	—	7,953
Common stock	17	12
Additional paid-in capital	46,816	—
Accumulated deficit	(19,845 )	(12,392 )
Total stockholders' equity (deficit)	26,988	(12,380 )

**Condensed Statements of Comprehensive Loss**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	<b>For the Three Months Ended</b>		<b>For the Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Operating expenses:				
General and administrative	\$ 1,466	\$ 997	\$ 3,567	\$ 2,130
Research and development	1,936	1,369	3,901	2,527
Acquired in-process research and development	—	—	—	908
Total operating expenses	3,402	2,366	7,468	5,565
Loss from operations	(3,402 )	(2,366 )	(7,468 )	(5,565 )
Interest and other (expense) income	(476 )	(203 )	96	(894 )
Net loss	\$ (3,878 )	\$ (2,569 )	\$ (7,372 )	\$ (6,459 )
Adjustment to redemption value on Series A convertible preferred stock	(67 )	(152 )	(366 )	(2,818 )
Net loss attributable to common stockholders	\$ (3,945 )	\$ (2,721 )	\$ (7,738 )	\$ (9,277 )
Net loss per share:				
Basic and diluted	\$ (0.56 )	\$ (0.87 )	\$ (1.65 )	\$ (3.39 )
Number of shares used in per share calculations:				
Basic and diluted	6,983,667	3,124,804	4,703,774	2,732,876

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