

## **Gemphire Announces Second Quarter 2017 Financial Results and Provides Corporate Update**

August 14, 2017 6:00 AM ET

*Gemcabene Successful in Phase 2 COBALT-1 HoFH Trial*

*Gemcabene Hits Primary Endpoint in Phase 2 ROYAL-1 Hypercholesterolemia Trial*

LIVONIA, Mich., Aug. 14, 2017 (GLOBE NEWSWIRE) -- Gemphire Therapeutics Inc. (NASDAQ:GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and NASH, today announced financial results for the three and six month periods ended June 30, 2017, and provided a corporate update.

“Gemphire successfully met its two major Phase 2 clinical milestones in the last six months demonstrating safety and LDL-C lowering efficacy of gemcabene in patients with HoFH in the COBALT-1 trial and in patients with hypercholesterolemia in the ROYAL-1 trial,” said Steven Gullans, Ph.D., interim CEO of Gemphire. “These data continue to support gemcabene’s development for LDL-C reduction when used in combination with approved therapies, including atorvastatin, rosuvastatin and simvastatin at the highest intensity, as well as PCSK9 inhibitors and ezetimibe. We believe these and our historical data uniquely position gemcabene as the only oral add on therapy in late stage development with the potential to safely combine on top of any currently-approved therapy at any dose to further enhance LDL-C lowering.”

“Our strategy is to develop gemcabene in patients who are at high risk for life threatening conditions due to their dyslipidemias despite current therapies. We believe the results of the COBALT-1 and ROYAL-1 trials, combined with the 18 Phase 1 and 2 trials previously completed will provide us with sufficient data to support an end of Phase 2 meeting in 2018 to discuss the company’s gemcabene Phase 3 programs in patients with hypercholesterolemia (ASCVD and HeFH), and HoFH. We are also pursuing the utility of gemcabene in NASH and plan to initiate a Phase 2 clinical trial later in 2017,” concluded Dr. Gullans.

### **Second Quarter & Recent Corporate and Financial Highlights**

- In June, we announced that gemcabene achieved the primary endpoint for LDL cholesterol in our Phase 2b COBALT-1 trial. COBALT-1 evaluated gemcabene in homozygous familial hypercholesterolemia (HoFH) patients who are on stable maximally tolerated lipid-lowering therapies.
- In May, we presented a poster on gemcabene’s mechanism of action based on preclinical findings at the Arteriosclerosis, Thrombosis and Vascular Biology | Peripheral Vascular Disease (ATVB|PVD) 2017 Scientific Sessions. Across the various animal models, gemcabene was shown to lower hepatic gene biomarkers for lipid regulation (ACC1, APOC-III, Sulfatase 2, ADH4, and HMG-CoA Synthase 2) and inflammation (CRP, TNF- $\alpha$ , MCP-1, CCR2, CCR5, NF- $\kappa$ B, MIP-1 $\beta$ ) as well as plasma biomarkers (LDL-C, TG, hsCRP).
- In May, we hosted a key opinion leader meeting for investors in New York featuring David E. Cohen, M.D., Ph.D., of Weill Cornell Medical Institute who discussed the clinical landscape for the treatment of nonalcoholic steatohepatitis (NASH).
- In May, Steven Gullans was appointed as interim president and chief executive officer, following the departure of our former CEO, Mina Sooch.
- Cash and cash equivalents at June 30, 2017, totaled \$22.5 million compared to \$24.0 million at Dec. 31, 2016.
- Second quarter and six month 2017 results include a \$2.6 million non-recurring compensation expense consisting of \$0.5 million of cash compensation and \$2.1 million of non-cash compensation resulting from the separation of our former CEO.
- In July, we entered into a term loan agreement for up to \$15 million with Silicon Valley Bank, subject to funding in several tranches, and immediately drew \$10 million to extend Gemphire’s cash runway for the ongoing development program for gemcabene. The remaining \$5 million under the term loan may be drawn, at our option, subject to the

achievement of certain pre-clinical and clinical milestones, prior to July 31, 2018.

- In August, we announced that gemcabene achieved the primary endpoint for LDL cholesterol in our Phase 2b ROYAL-1 trial. ROYAL-1 evaluated gemcabene in hypercholesterolemic patients on stable high- or moderate-intensity statin and/or ezetimibe therapy.

### **Upcoming 2017 and 2018 Clinical Milestones**

- Additional data from our COBALT-1 and ROYAL-1 trials and communication of continued development plans of gemcabene in HoFH, HeFH and ASCVD are targeted for release in the second half of 2017.
- Top-line results from our INDIGO-1 Phase 2b trial in severe hypertriglyceridemia (SHTG) are targeted for the first quarter of 2018 based on the current pace of enrollment.
- Plan to initiate Phase 2 clinical development program in NASH in the second half of 2017 with top-line results targeted for second half of 2018.

### **Second Quarter 2017 Financial Update and Guidance**

General and administrative expense for the three and six months ended June 30, 2017 were \$4.7 million and \$6.9 million, respectively, compared to \$1.1 million and \$2.1 million for the three months and six months ended June 30, 2016, respectively. The current year second quarter and six month period expenses included \$2.6 million of non-recurring expenses associated with the separation of our former CEO. The remainder of the increase over the prior year periods reflects the added infrastructure and personnel costs to support our ongoing clinical trials as well as costs associated with operating as a public company.

Research and development expense for the three and six months ended June 30, 2017 were \$5.8 million and \$11.1 million, respectively, compared to \$0.8 million and \$2.0 million for the three and six months ended June 30, 2016, respectively. The increase reflects costs of three separate Phase 2b trials ongoing in the current year periods compared to minimal clinical trial activity in the respective prior year periods.

Net loss attributable to common stockholders for the three and six months ended June 30, 2017 was \$10.5 million and \$18.0 million, respectively, compared to \$1.5 million and \$3.8 million for the three and six months ended June 30, 2016.

Cash used in operations in the six months ended June 30, 2017 was \$12.8 million compared to \$3.8 million in the six months ended June 30, 2016.

Management expects operating expenses and cash used in operating activities to continue to trend above 2016 levels, primarily in research and development, as we fund our ongoing clinical trials and initiate our NASH clinical program. Based on the Company's current operating plans, management believes existing cash, including proceeds from the July 2017 term loan agreement, is sufficient to fund operations through completion of our remaining dyslipidemia trial as well as completion of the planned NASH clinical trial anticipated to be completed in the second half of 2018 and will support our work to develop our Phase 3 study plans.

### **About Gemcabene**

Gemphire's product candidate, gemcabene (CI-1027), is a first-in-class, once-daily, oral therapy that may be suitable for patients who are unable to achieve normal levels of LDL-C or triglycerides with currently approved therapies, primarily statins. Gemcabene's mechanism of action is designed to enhance the clearance of very low-density lipoproteins (VLDLs) in the plasma and inhibition of the production of cholesterol and triglycerides in the liver. The combined effect for these mechanisms has been clinically observed to result in a reduction of plasma VLDL-C, LDL-C, and triglycerides. In addition, gemcabene has been shown to markedly lower C-reactive protein and improve insulin sensitization. Gemcabene is liver-directed and reduces apoC-III mRNA and plasma levels. Gemcabene also reduces acetyl-CoA carboxylase (ACC1) and CCR2/CCR5 receptor mRNA levels, which may have applications in non-alcoholic steatohepatitis (NASH)/non-alcoholic fatty liver disease (NAFLD). Gemcabene has demonstrated proof of concept efficacy for NASH in the STAM™ model developed at SMC Laboratories in Tokyo, Japan. Gemcabene has been tested as monotherapy and in combination with statins and other drugs in 956 subjects across 20 Phase 1 and Phase 2 clinical trials and has

demonstrated promising evidence of efficacy, safety and tolerability.

### **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 has initiated 3 clinical trials for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH)/atherosclerotic cardiovascular disease (ASCVD), and severe hypertriglyceridemia (SHTG) under NCT02722408, NCT02634151, and NCT02944383, respectively with a fourth planned trial in NASH to initiate in second half of 2017. 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, expectations regarding operating expenses and cash used in operations, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "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: 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; 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 on Form 10-K for the year ended December 31, 2016, Gemphire's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 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)**

	June 30, 2017 (unaudited)	December 31, 2016
Cash and cash equivalents	\$ 22,491	\$ 24,033
Total assets	23,004	24,754
Accounts payable and accrued liabilities	5,272	4,121
Total liabilities	5,274	4,122

Common stock	18	17
Additional paid-in capital	62,769	47,674
Accumulated deficit	(45,057 )	(27,059 )
Total stockholders' equity	17,730	20,632

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

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2017	2016	June 30, 2017	2016
	(unaudited)		(unaudited)	
Operating expenses:				
General and administrative	\$ 4,678	\$ 1,051	\$ 6,901	\$ 2,101
Research and development	5,837	789	11,117	1,965
Total operating expenses	10,515	1,840	18,018	4,066
Loss from operations	(10,515 )	(1,840 )	(18,018 )	(4,066 )
Interest and other income (expense), net	13	449	20	572
Net loss	\$ (10,502 )	\$ (1,391 )	\$ (17,998 )	\$ (3,494 )
Adjustment to redemption value on Series A convertible preferred stock	—	(150 )	—	(299 )
Net loss attributable to common stockholders	\$ (10,502 )	\$ (1,541 )	\$ (17,998 )	\$ (3,793 )
Net loss per share:				
Basic and diluted	\$ (0.99 )	\$ (0.42 )	\$ (1.79 )	\$ (1.07 )
Number of shares used in per share calculations:				
Basic and diluted	10,603	3,627	10,065	3,548

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