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): June 28, 2017 (June 28, 2017)

GEMPHIRE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37809**	**47-2389984**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(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 8.01 Other Events.

On June 28, 2017, Gemphire Therapeutics Inc. issued a press release announcing top-line data on the LDL-C primary endpoint from its COBALT-1 Phase 2b clinical trial of gemcabene in homozygous familial hypercholesterolemia (HoFH) patients.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of such website addresses in this Current Report on Form 8-K by incorporation by reference of the press release is as inactive textual references only.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release dated June 28, 2017.

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: June 28, 2017

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated June 28, 2017.

Gemphire Announces Top-Line Data from COBALT-1 Phase 2b Clinical Trial in HoFH Patients

Gemcabene achieves primary endpoint for LDL cholesterol in phase 2b HoFH trial

Company to host conference call at 4:30 pm ET today

LIVONIA, Michigan, June 28, 2017 -- Gemphire Therapeutics Inc. (NASDAQ:GEMP) today announced top-line data on the LDL-C primary endpoint from the completed open label Phase 2b COBALT-1 trial. COBALT-1 evaluated gemcabene in homozygous familial hypercholesterolemia (HoFH) patients who are on stable maximally tolerated lipid-lowering therapies to assess the efficacy, safety, and tolerability of multiple rising doses of gemcabene.

COBALT-1 enrolled patients clinically or genetically diagnosed as HoFH, who were on a variety of background therapies including the highest doses of statins and/or ezetimibe and/or PCSK9 inhibitors. These therapeutic classes represent the current initial drug therapies for HoFH. Eight subjects (5 male and 3 female, all Caucasian, average age 53 years) on previously prescribed therapy (which included statins, ezetimibe, evolocumab, cholestyramine, and omega-3 fatty acids) were enrolled from sites in the US, Canada and Israel. Patients were sequentially administered oral gemcabene once daily (dosage escalating from 300 mg to 600 mg and then 900 mg every 4 weeks) for a total duration of 12 weeks.

The mean baseline LDL-C was 351 mg/dL (range from 138-623 mg/dL). Gemcabene 300 mg lowered LDL-C by a mean of 25% ($p=0.0063$; range -55% to +1%), gemcabene 600 mg lowered LDL-C by a mean of 30% ($p=0.0047$; range -51% to +2%), and gemcabene 900 mg lowered LDL-C by a mean of 29% ($p=0.0035$; range -54% to +6%). The complete data for COBALT-1 will be submitted to a cardiovascular conference for presentation, as well as for publication in a peer reviewed journal.

Adverse events (AEs) were mild to moderate in intensity across all doses of gemcabene and consistent with previously reported AEs. There were no serious AEs or withdrawals due to AEs in the COBALT-1 study.

"We are excited by these results from our COBALT-1 Phase 2b trial in HoFH patients," said Steven Gullans, Ph.D., Interim CEO of Gemphire Therapeutics. “Gemcabene’s mean LDL-C reductions compare favorably with the LDL-C reductions, generally 15-25%, observed for approved therapies to treat HoFH patients and are consistent with the LDL-C reductions seen in our prior hypercholesterolemia trials. These data continue to support gemcabene’s complementary mechanism of action, which is additive to existing lipid lowering therapies.”

COBALT-1 was designed to evaluate the LDL-C lowering efficacy of gemcabene in up to 8 patients with either genetic confirmation or a clinical presentation of HoFH on a stable low-fat, low cholesterol diet in combination with a pre-existing, regulatory-approved, lipid-lowering therapy for at least 4 weeks prior to treatment. Patients were excluded if they were undergoing

apheresis or taking mipomersen or lomitapide. All enrolled patients were further evaluated for known DNA mutations causing HoFH. The primary endpoint for each dose of gemcabene (300, 600 and 900 mg) was mean percent change in LDL-C from baseline at 4, 8, and 12 weeks respectively. Secondary endpoints include mean percent change from baseline in hsCRP, apoB, non-HDL-C, TG, VLDL-C and total cholesterol. Safety was being assessed by AE monitoring, clinical laboratory assessments, electrocardiograms, physical examinations and vital signs.

“These data announced today continue to demonstrate the additive lipid lowering efficacy of gemcabene that has been demonstrated in the extensive clinical program to date,” said Lee Golden, MD, CMO of Gemphire Therapeutics. “Gemcabene has a novel mechanism of action and demonstrates important additive lipid lowering to existing approved therapies for HoFH patients, who are the patient group with the most severe form of dyslipidemia. As shown from this and other studies, HoFH patients continue to have elevated LDL-C and additional therapies are needed to help these patients. We believe the lipid lowering observed in COBALT-1 should support discussions with the FDA to advance this program into Phase 3.”

Additional analyses of 6 subjects that met the more stringent European Atherosclerosis Society (EAS) Consensus Panel diagnosis of HoFH had a mean baseline LDL-C of 374 mg/dL (range 138 to 623 mg/dL). Gemcabene 300, 600 and 900 mg lowered LDL-C by a mean of 18% (p=0.0059; range -32% to +1%), 23% (p=0.0010; range -44% to +2%), and 21% (p=0.0019; range -33% to +6%), respectively, in such subjects. Three subjects known at enrollment to have ‘negative’ (<2%) LDL-receptor activity had a mean baseline LDL-C of 551 mg/dL (range 430 to 623 mg/dL) but still responded to gemcabene: 300 mg lowered LDL-C by a mean of 10% (range -30% to +1%), 600 mg lowered LDL-C by a mean of 15% (range -44% to +2%), and 900 mg lowered LDL-C by a mean of 12% (range -24% to +6%).

“The overall reductions in LDL-C, and in particular more than 20% in the subgroup that met the EAS Consensus Panel criteria of HoFH, are very encouraging and clinically relevant,” said Evan Stein, MD Director Emeritus of the Metabolic & Atherosclerosis Research Center, in Cincinnati, Ohio, USA. “Despite recently approved therapies there remains a need for additional safe and effective therapies for HoFH patients. We believe these data suggest that gemcabene provides an effective, oral and complementary mechanism to reduce LDL-C for HoFH patients.”

“These data suggest that gemcabene can offer important additional add-on LDL-C reduction to approved therapies for HoFH patients,” said John Kastelein, MD, Professor of Medicine, Department of Vascular Medicine, Academic Medical Center/University of Amsterdam, The Netherlands. “I am encouraged by these data in the most severe patients, who are completely deficient of LDL-R activity. The data suggest that further evaluation of gemcabene is warranted in Familial Hypercholesterolemia per se.”

In 2014, gemcabene was granted Orphan Drug Designation for HoFH by the US FDA. Additional information on the COBALT-1 trial, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov using the NCT Identifier NCT02722408.

In addition to these phase 2 results from COBALT-1 (Trial 19) reported here today, gemcabene is currently being evaluated for LDL-C lowering on top of high and moderate intensity statins in

heterozygous familial hypercholesterolemic (HeFH)/atherosclerotic cardiovascular disease (ASCVD) patients in ROYAL-1 (Trial 20) and for the reduction in triglyceride levels in a severe hypertriglyceridemia (SHTG) patient population in INGIGO-1 (Trial 21).

Conference Call and Webcast
Gemphire will further review the top-line data from the COBALT-1 Phase 2b clinical trial in HoFH patients in a conference call today at 4:30 pm ET. To participate, please dial (844) 494-0188 (domestic) or (425) 278-9114 (international) and reference conference ID 45939668. A webcast will be available simultaneously on the News & Events section of the Gemphire website for all interested parties and will be archived and available for 90 days.

About HoFH
HoFH is a rare genetic disease that is most commonly caused by a mutation in both alleles of the LDL receptor gene responsible for removing LDL from the blood. As a result of having defective or deficient LDL receptor function, HoFH patients exhibit severely high LDL-C levels, are at very high risk of experiencing premature cardiovascular events, such as a heart attack or stroke, and develop premature and progressive atherosclerosis. LDL-C levels in untreated HoFH patients are typically in the range of 500 mg/dL to 1,000 mg/dL, compared to a normal target range of 70 mg/dL to 100 mg/dL. Unless treated, most patients with HoFH do not survive beyond 30 years of age. There are approximately 300 to 2,000 HoFH patients in the United States and approximately 6,000 to 45,000 patients in the rest of the world, with a prevalence rate of about one in 160,000 to one in one million. Gemphire is proud to be a supporter of the FH Foundation (https://thefhfoundation.org).

Currently approved widely available treatments for patients with HoFH include statins, ezetimibe, other approved LDL-C lowering therapies (such as bile acid sequestrants), injectable PCSK9 inhibitor Repatha®, and in some countries novel drugs mipomersen (KYNAMRO®) or lomitapide (Juxtapid®) which both include boxed warnings for liver toxicity. HoFH patients usually also require LDL apheresis when available. Despite the availability of various treatments which combined may lower LDL-C 40-45%, many patients are still unable to achieve recommended LDL-C levels.

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 enhances 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 903 subjects across 19 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 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 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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