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): August 7, 2017 (August 7, 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 August 7, 2017, Gemphire Therapeutics Inc. ("Gemphire") issued a press release regarding its ROYAL-1 Phase 2b clinical trial of gemcabene in hypercholesterolemic 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 August 7, 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: August 7, 2017

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

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated August 7, 2017.

Gemphire Announces Top-Line Data from ROYAL-1 Phase 2b Clinical Trial in Hypercholesterolemic Patients

Gemcabene met the primary endpoint and demonstrated a statistically significant lowering in LDL-C

Company to host conference call at 8:00 am ET, Monday, August 7, 2017

LIVONIA, Michigan, August 07, 2017 -- Gemphire Therapeutics Inc. (NASDAQ:GEMP) today announced top-line data based upon the Company's preliminary review of the limited top-line data set from the completed double-blind, placebo-controlled, randomized Phase 2b ROYAL-1 trial. ROYAL-1 evaluated the efficacy, safety, and tolerability of oral gemcabene 600 mg dosed once daily.

ROYAL-1 enrolled patients who were not adequately controlled, with an existing LDL-C value ≥100 mg/dL (2.59 mmol/L) and a TG value < 500 mg/dL (5.65 mmol/L), on stable high- or moderate-intensity statin and/or ezetimibe therapy. Patients were stratified according to background statin intensity and diabetes status. One hundred and five subjects were enrolled at sites in the US and randomized to either gemcabene 600 mg or placebo for a total of 12 weeks. The primary endpoint was the percent change in LDL-C from baseline. Secondary endpoints included safety as well as the percent change from baseline in non-HDL-C, TC, TG, HDL-C, VLDL-C, Apo B, hsCRP and several other biomarkers.

Fifty-six (56) females and 49 males with a mean age of 61 years were enrolled. The mean baseline LDL-C was 130 mg/dL. Gemcabene 600 mg produced a mean percent change in LDL-C of -17.2% vs -5.5% for placebo (ANCOVA: $p=0.0057$). Gemcabene 600 mg produced a median percent change in hsCRP of -40.0% (ranked ANCOVA: $p<0.0001$) vs -6.1% for placebo. Additional secondary results and subpopulations assessments will be provided once the full dataset has been analyzed.

"In ROYAL-1, gemcabene met the primary endpoint and demonstrated a statistically significant lowering in LDL-C, although the magnitude of LDL-C lowering was less than observed in certain prior studies of gemcabene," stated Dr. Lee Golden, Chief Medical Officer. "The company will perform additional analyses to thoroughly evaluate the results of the trial. Once the additional analyses are complete, we will provide an update."

There were no serious adverse events in the study. Adverse events (AEs) were generally mild to moderate in intensity and consistent with previously reported AEs. Three subjects discontinued from the study, 1 from the gemcabene and 2 from the placebo groups. The subject randomized to gemcabene discontinued because of reported dizziness. No subjects in the study had a transaminase elevation > 3x ULN. One placebo subject had a creatine kinase elevation > 5x ULN on consecutive measurements. No gemcabene subjects had consecutive elevations in creatine kinase > 3 x ULN. The lack of liver or muscle toxicities in ROYAL-1, on top of the highest doses of statin therapy, is consistent with previous safety data from 19 prior completed studies.

“The ROYAL-1 study results support gemcabene’s safety profile as a potential add-on therapy to any statin intensity without signs of drug-drug interactions,” added Dr. Steven Gullans, Interim CEO. “The data, in combination with previous clinical data of gemcabene, including the recently reported results of the COBALT-1 trial, will be used to plan gemcabene’s future development.”

Additional information on the ROYAL-1 trial, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov using the NCT Identifier NCT02634151.

Conference Call and Webcast
Gemphire will further review the top-line data from the ROYAL-1 Phase 2b clinical trial in hypercholesterolemic patients in a conference call today at 8:00 am ET. To participate, please dial (844) 494-0188 (domestic) or (425) 278-9114 (international) and reference conference ID 67117890. A webcast replay will be available on the News & Events section of the Gemphire website for all interested parties following the call and will be archived and available for 90 days.

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 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. 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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