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): September 19, 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 September 19, 2017, Gemphire Therapeutics Inc. ("Gemphire") issued a press release regarding its clinical development plan for gemcabene and information from a new analysis of data from prior studies.

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 September 19, 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: September 19, 2017

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

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated September 19, 2017.

Exhibit 99.1

Gemphire Announces Plans to Advance Gemcabene into Phase 3 Clinical Development

New analysis of data show clinically meaningful reductions in LDL-C and hsCRP across multiple trials and confirms support to advance gemcabene into Phase 3

End of Phase 2 meetings planned for early 2018

ROYAL-1 study accepted for presentation at AHA Scientific Sessions in November 2017

COBALT-1 study to be presented at the FH Foundation's Summit meeting on Monday, September 25th

Conference call at 4:30 pm ET today

LIVONIA, Mich., Sep. 19, 2017 -- 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 plans to advance its product candidate gemcabene into Phase 3 development in 2018. Gemcabene successfully achieved the primary endpoint in two recently completed Phase 2b studies, COBALT-1 and ROYAL-1, and the Company is now preparing for end of Phase 2 meetings with both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), anticipated to take place in early 2018. The primary focus of these meetings is to reach agreement on the design of the Phase 3 development programs for its hypercholesterolemia indications. Twenty clinical studies have shown gemcabene to be safe and effective as monotherapy or in combination with all current treatments for hypercholesterolemia, including the highest intensity statins, PCSK9 inhibitors and ezetimibe, and thus appears to be beneficial for high-risk patients that have not achieved lipid goals.

Gemphire is developing gemcabene as an add-on therapy to diet and maximally-tolerated statins for the treatment of several hypercholesterolemic populations, including atherosclerotic cardiovascular disease (ASCVD), with an emphasis on the high risk cardiometabolic subset of ASCVD patients, heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH). The Company also plans to develop gemcabene as monotherapy or as add-on therapy to diet and other lipid lowering therapies for the treatment of severe hypertriglyceridemia (SHTG). Gemcabene has been shown to be safe and effective in combination with all current treatments for hypercholesterolemia, including the highest intensity statins, PCSK9 inhibitors and ezetimibe.

"I believe we have accumulated a compelling body of clinical data demonstrating the ability of gemcabene to reduce low density lipoprotein cholesterol (LDL-C) in both orphan and broad dyslipidemic conditions," said Dr. Steven Gullans, Interim CEO of Gemphire. "Gemcabene is a unique late stage clinical asset and the only compound in development across the full spectrum of dyslipidemia that targets the triple threat of LDL-C, inflammation and triglycerides (TG). We look forward to reviewing these data with the FDA and EMA to seek agreement on the design of our comprehensive Phase 3

clinical program to confirm the benefits observed in prior studies and to support regulatory approval for the various indications and commercialization in the major markets."

"Many high-risk patients are unable to achieve optimal LDL-C reductions and levels with the currently available therapies," said Evan Stein, MD Director Emeritus of the Metabolic & Atherosclerosis Research Center, in Cincinnati, Ohio. "As such, physicians and patients need additional options that can be combined safely with statin therapy, which is the first therapy utilized for most patients, and can provide additional efficacy across multiple parameters associated with cardiovascular risk. Given the recent data released by Novartis Inc. establishing reduction of inflammation and hsCRP as a novel mechanism to decrease cardiovascular disease (CVD), the combined effect of gemcabene on LDL-C, apolipoprotein B and hsCRP is very promising for patients at high risk for CVD events."

New Analysis Shows That 600 mg of Gemcabene Reduced LDL-C by 21% in Hypercholesterolemic Patients and by 25% in Mixed Dyslipidemic Patients across Multiple Clinical Trials

The Company has performed an extensive analysis of data on hypercholesterolemic patients across previously completed clinical trials for gemcabene, including the most recently completed COBALT-1 and ROYAL-1 studies. In addition to the LDL-C reduction in the overall cohorts, efficacy was assessed according to baseline LDL-C levels, and other baseline characteristics, such as the degree of obesity, magnitude of HbA1c, mixed dyslipidemia, level of inflammation, a responder analysis and combinations of these factors.

Data for the ROYAL-1 study have been accepted for presentation at the American Heart Association's (AHA) Scientific Sessions in November 2017. Details of the ROYAL-1 data are embargoed until presentation at AHA; however, the additional analyses of ROYAL-1 showed similar trends as we will outline from the combined analysis below. As such, the announcement today is focusing on the combined analysis of the hypercholesterolemic patients involved in previously completed clinical studies.

Patients were included in the combined analysis if they were hypercholesterolemic and were on stable statin and/or other lipid lowering therapy, which represents the intended use for gemcabene in clinical practice for its hypercholesterolemic indications. The prior clinical trials included 352 hypercholesterolemic patients, composed of placebo (n=110) and gemcabene 150 mg (n=23), 300 mg (n=61), 600 mg (n=94) and 900 mg (n=64) dose groups. Data from the gemcabene 600 mg dose group are presented in the table below since this is the intended target dose for the Phase 3 trials for the reduction of LDL-C across the hypercholesterolemic patient population.

Gemphire believes gemcabene offers a unique value proposition for those patients with a high-risk cardiometabolic profile, specifically those with obesity, pre-diabetes /diabetes, inflammation and/or mixed dyslipidemia. Mixed dyslipidemia refers to a group of patients at high risk for cardiovascular disease that have elevated LDL-C, apolipoprotein B, and TGs. Cardiovascular demographics from the National Health and Nutritional Health Examination Survey (NHANES) data estimate that of the approximately 40 million patients on statins, approximately 6.1 million represent cardiometabolic patients who are not at goal and have LDL levels above 70 mg/dL with approximately 3 million of these patients being above 100 mg/dL. Cardiometabolic patients usually have several lipid abnormalities that can benefit from gemcabene's ability to lower LDL-C, hsCRP and TGs. The LDL-C reductions for mixed dyslipidemic patients who received 600 mg of gemcabene or placebo are presented separately in the table below.

Combined results from hypercholesterolemic patients across completed clinical studies			
All Hypercholesterolemic Subjects	**Gemcabene 600 mg n= 94**	**Placebo n=110**	**p value**
LDL-C reduction	-21%	-5%	p<0.0001
Mixed Dyslipidemia Subset (Baseline LDL-C ≥100 and TGs ≥200 and <500 mg/dL)	**Gemcabene 600 mg (high risk patients) n= 24**	**Placebo (high risk patients) n= 30**	**p value**
LDL-C reduction	-25%	-4%	p=0.0002

Ability of Gemcabene to Reduce hsCRP and Inflammation is Potentially a Key Differentiator

Elevated serum C-Reactive Protein (hsCRP) is a known biomarker for patients at increased risk of a cardiovascular event. As reported previously in the ROYAL-1 study, 600 mg of gemcabene lowered serum hsCRP by 40% (n=51) compared to 6% for placebo (n=51) (p<0.0001). Note that this effect was additive to the reduction of hsCRP provided by statins, as the ROYAL-1 patients were already taking maximally tolerated doses of statins. From the combined analysis in hypercholesterolemic patients the median hsCRP reduction for patients on gemcabene 600 mg was 40% (n=90) compared with 5% in the placebo group (n=108) (p<0.0001).

CRP is a plasma protein biomarker secreted into the blood from the liver in response to inflammation. Reducing this biomarker is associated with a reduction in cardiovascular risk, as confirmed by Novartis Inc.'s Canakinumab Anti-inflammatory Thrombosis Outcomes Study (CANTOS) recently presented at the European Society of Cardiology (ESC) congress in Barcelona, Spain, in August of this year. As reported by Novartis Inc. in August 2017, in the CANTOS study, patients with a history of myocardial infarction and elevated hsCRP received treatment with an injectable anti-inflammatory monoclonal antibody to the cytokine IL-1β to determine the direct potential impact of reducing inflammation on cardiovascular events. The results demonstrated that reducing inflammation as measured by hsCRP (with a median hsCRP reduction of 37%) led to a 15% reduction in cardiovascular related MACE (combination of non-fatal myocardial infarction, non-fatal stroke and cardiovascular death). The impact of orally administered gemcabene on hsCRP and inflammation remains a potentially key differentiator from other compounds that are approved or in development as add-on therapy to maximally tolerated statins.

Gemcabene Appears Safe for High Risk Patients in Combination with Maximally Tolerated Statins and Other Approved Treatments

The COBALT-1 and ROYAL-1 trials were designed to determine the safety, tolerability and efficacy of gemcabene as an add-on to the highest doses of statins (e.g., rosuvastatin 20 and 40 mg and atorvastatin 40 and 80 mg doses; moderate intensity therapies were also included), as well as PCSK9 inhibitors, and ezetimibe.

We believe the results from all 20 clinical studies in which 956 patients were exposed to gemcabene have demonstrated that gemcabene is well tolerated and safe. Although in practice, most patients are on low and moderate intensity statins, in our clinical trials gemcabene demonstrated a clean safety profile even when combined with the highest doses of the high intensity statins, simvastatin,

atorvastatin and rosuvastatin. To date, there has been no evidence for hepatic or muscle related toxicities and no serious adverse events related to gemcabene treatment. Overall treatment emergent adverse events for gemcabene have been similar to placebo. Most adverse events have been mild to moderate in intensity and the most commonly reported adverse events have been infection and headache (based on occurrence in > 5% of subjects on gemcabene, although the rate for infection was less than placebo).

Gemphire's Commitment to Cardiometabolic Patients, Physicians and Payors

Cardiovascular disease remains the leading cause of death globally despite the availability of statins and other therapeutics. In addition, the large recent increases in the prevalence of obesity and diabetes will result in a much greater number of individuals at risk for cardiovascular and liver diseases, including NASH. The highest risk patients would benefit from a new therapy that can be added safely to all commonly prescribed statins at any dose. Gemcabene has been given to over 950 patients to date and it appears to be a safe and effective therapeutic option for millions of cardiometabolic patients who are already on maximally-tolerated statins to reduce LDL-C, hsCRP and other potentially atherogenic lipid particles. As a once daily oral therapy at an affordable price point, gemcabene has the potential to be a valuable new approach that will provide benefits to patients, physicians and payors.

"Gemcabene has demonstrated efficacy across a broad array of important lipid parameters, such as LDL-C, non-HDL-C, total cholesterol, apolipoprotein B and triglycerides, that have been associated with cardiovascular events, such as heart attacks, stroke and death. Gemcabene has also demonstrated significant effects on reducing hsCRP, a marker of inflammation, which may be an important new target of therapy in patients with cardiovascular disease, based on the CANTOS trial results. Importantly, gemcabene has demonstrated an excellent safety profile without evidence of hepatic or muscle toxicities, even when combined with the most potent statins," stated Dr. Lee Golden, Chief Medical Officer of Gemphire.

COBALT-1 study to be presented at the FH Foundation's Summit

Gemphire will also be announcing full results of the COBALT-1 (HoFH) study at the FH Foundation's Summit meeting in Miami, Florida on Monday, September 25th at 9:00 am ET. The results will be presented by Dr. Marina Cuchel, MD, PhD, Research Associate Professor at the Perelman School of Medicine at the University of Pennsylvania. The FH Summit is an invitation-only event that convenes global experts within various fields to tackle the most pressing issues facing FH populations today. The 2017 FH Global Summit will include topics on the challenges and opportunities of diverse FH subpopulations navigating diagnosis, care and access. For more information, refer to https://thefhfoundation.org/event/2017-fh-global-summit.

Gemphire to Soon Launch Proof of Concept Program in NASH

As previously announced, Gemphire will be initiating its proof of concept study in patients that suffer from fatty liver disease and nonalcoholic steatohepatitis (NASH) in the fourth quarter of 2017. Unmanaged cardiometabolic disease is the underlying cause of atherosclerosis and fatty liver disease. Gemcabene's unique mechanism of action has demonstrated positive attributes that may be protective to both the heart and liver. Approximately 6 million patients in the U.S. are affected by NASH for which there is currently no effective treatment available.

Conference Call and Webcast

Gemphire management will host a conference call for investors at 4:30 pm ET today. To participate, please dial (844) 494-0188 (domestic) or (425) 278-9114 (international) and reference conference ID 86185879. 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.

Gemcabene's Mechanism of Action and Safety Profile Are Highly Differentiated

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 non-HDL-C, VLDL-C, LDL-C, apolipoprotein B 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 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, regulatory submissions and meetings 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.

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