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 10, 2018**

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 Number)	(IRS Employer Identification No.)

17199 N. Laurel Park Drive, Suite 401, Livonia, MI 48152
(Address of principal executive offices) (Zip Code)

(734) 245-1700
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

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 7.01 Regulation FD Disclosure.

On August 10, 2018, Gemphire Therapeutics Inc. (the "Company") issued a press release regarding the proof-of-concept clinical trial studying gemcabene in pediatric NAFLD (nonalcoholic fatty liver disease). A copy of the press release is furnished herewith as Exhibit 99.1 hereto.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On August 10, 2018, the Company announced that the Data and Safety Monitoring Board ("DSMB") at Emory University School of Medicine overseeing the investigator-led open label Phase 2a proof-of-concept trial evaluating gemcabene in pediatric patients with non-alcoholic fatty liver disease ("NAFLD") has recommended that the trial be terminated due to unanticipated problems. Data on the first three patients who underwent 12 weeks of treatment showed that all three experienced an increase in liver fat content, as measured by non-invasive magnetic resonance (MRI) imaging — proton density fat fraction (MRI-PDFF), and demonstrated increases in serum alanine transaminase (ALT), an enzyme that serves as a biomarker of liver function. The increase in liver fat was deemed an unexpected problem by the trial investigator because it was an unexpected consistent pattern of worsening of the disease, rather than improvement, creating risk to the patients, which the investigator believed was likely due to the drug. Other patients currently enrolled in the trial have now been taken off gemcabene and early termination visits are being scheduled.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 10, 2018.

SIGNATURES

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.

Dated: August 10, 2018

GEMPHIRE THERAPEUTICS INC.

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

Exhibit 99.1

Gemphire Announces Termination of Phase 2a Clinical Trial of Gemcabene in Pediatric NAFLD

LIVONIA, Mich., Aug. 10, 2018 — Gemphire Therapeutics Inc. (NASDAQ: GEMP), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for cardiometabolic disorders, including dyslipidemia and nonalcoholic steatohepatitis (NASH), announces today that the Data and Safety Monitoring Board (DSMB) at Emory University School of Medicine overseeing the investigator-led open label Phase 2a proof-of-concept trial evaluating gemcabene in pediatric patients with non-alcoholic fatty liver disease (NAFLD) has recommended that the trial be terminated due to unanticipated problems.

This pediatric NAFLD trial was initiated in early 2018. Patients were treated with gemcabene at a dose of 300 mg once daily. The primary endpoint is a measure of the change in serum alanine transaminase (ALT), an enzyme that serves as a biomarker of liver function, from baseline to 12 weeks, and secondary endpoints include, among others, change in hepatic steatosis (liver fat) as measured by non-invasive magnetic resonance (MRI) imaging — proton density fat fraction (MRI-PDFF).

Data on the first three patients who underwent 12 weeks of treatment showed that all three experienced an increase in liver fat content, as measured by MRI-PDFF, and demonstrated increases in ALT. The increase in liver fat was deemed an unexpected problem by the trial investigator because it was an unexpected consistent pattern of worsening of the disease, rather than improvement, creating risk to the patients, which the investigator believed was likely due to the drug. Other patients currently enrolled in the trial have now been taken off gemcabene and early termination visits are being scheduled. The DSMB has recommended additional follow-up of the study subjects to gather additional safety data. The DSMB will provide Gemphire with a written report of their findings in the future once all the patient results have been collated and analyzed.

“Patient safety has always been our primary concern and we will work closely with the DSMB, the physicians at the clinical trial site, and other KOLs to analyze all the results and identify potential reasons for these unexpected events,” said Dr. Steven Gullans, CEO of Gemphire. “Previously, Gemcabene had been administered to nearly 1,200 adult subjects across 25 Phase 1 and Phase 2 trials for up to 12 weeks with no drug-related serious adverse events (SAEs) reported. Gemcabene-related adverse events (AEs) in these adult subject trials were observed to be comparable to those seen with placebo treatment. We remain confident that gemcabene has the potential to be an effective therapy for a host of cardiometabolic patients and we intend to continue to develop gemcabene to address multiple indications.”

As part of Gemphire’s NAFLD/NASH program, gemcabene is also being studied in a Phase 2a study being conducted at the University of Michigan to assess the efficacy and safety of two dosing regimens of the drug in patients with familial partial

lipodystrophy (FPL) who have elevated triglycerides and NASH. FPL is a rare genetic disorder and orphan disease characterized by an abnormal distribution of fatty (adipose) tissue, which can lead to a variety of metabolic abnormalities including NASH. An initial safety review of the first three patients in this study on a dose of 300 mg/day has not uncovered any safety or tolerability concerns nor was there a change in biomarkers that would indicate concerns about liver function. The principal investigator in the trial, Dr. Elif Oral, intends to closely monitor these patients while waiting for MRI-PDFF scans to be reviewed at an interim time point in the near future before dosing additional patients.

As previously reported, the Company's cash balance at June 30, 2018 was $28 million and management believes that, based on current projections and taking into account the delay of significant cash expenditures for clinical trials and manufacturing, it will be sufficient to fund the Company's operations into the 4th quarter of 2019.

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's Phase 2 clinical program is evaluating the efficacy and safety of gemcabene in hypercholesterolemia, including FH and ASCVD, SHTG and NASH/NAFLD. Two trials supporting hypercholesterolemia and one trial in SHTG have been completed under NCT02722408, NCT02634151 and NCT02944383, respectively. Please visit **www.gemphire.com** for more information.

Forward Looking Statements

Any statements in this press release that are not statements of historical fact, including statements about Gemphire's future expectations, milestones, goals, plans and prospects, and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "promising," "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: Gemphire's ability to analyze the results and understand the reasons for the unexpected events reported in this press release; the impact of the unexpected events on the Phase 2a study in FPL or the enrollment of patients; that MRI-PDFF scans or other follow-up tests of patients in the pediatric NAFLD, FPL or other trials may show similar increases in liver fat content or ALT or other undesirable side effects; uncertainties inherent in the clinical drug development process and the regulatory approval process, including the risk that gemcabene may cause undesirable side effects or have other properties that could delay or prevent regulatory approval; Gemphire's substantial dependence on its product candidate, gemcabene; developments in the

capital markets; 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; the actions of Gemphire's competitors; 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 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.

Contact:

Ashley Robinson
LifeSci Advisors, LLC
(617) 535-7742

Jeff Mathiesen, CFO
Gemphire Therapeutics Inc.
(734) 245-1700