UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 14, 2019**

Hepion Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36856**	**46-2783806**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

399 Thornall Street, First Floor
Edison, NJ 08837
(Address of principal executive offices)

Registrant's telephone number, including area code: **(732) 902-4000**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	HEPA	Nasdaq Capital Market

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 communication 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 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 14, 2019, Hepion Pharmaceuticals, Inc. issued a press release announcing that that it has dosed the first patient in a 28-day multiple ascending dose clinical trial of CRV431. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Hepion Pharmaceuticals, Inc. Press Release dated August 14, 2019

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.

Dated: August 14, 2019

HEPION PHARMACEUTICALS, INC.

By: /s/ Robert Foster
Robert Foster
Chief Executive Officer

Exhibit 99.1

Hepion Pharmaceuticals Announces Dosing of First HBV Patient in 28-Day Study of CRV431

- Study Represents the Third and Final Stage of CRV431's Streamlined Early Clinical Program -

EDISON, N.J., **August 14, 2019** - Hepion Pharmaceuticals, Inc. (NASDAQ:HEPA), a biopharmaceutical company focused on the development of therapeutic drugs for the treatment of liver disease arising from non-alcoholic steatohepatitis ("NASH") and chronic viral infection, today announced that it has dosed the first patient in a 28-day multiple ascending dose clinical trial of CRV431.

Designed to assess safety, tolerability and pharmacokinetics of CRV431, this study is the third and final stage of CRV431's streamlined early clinical program, which was agreed upon with the U.S. Food and Drug Administration ("FDA").

Patients in four cohorts will be administered CRV431 in doses ranging from 75 mg to 375 mg in combination with 300 mg tenofovir disoproxil fumarate (TDF) antiviral therapy, over a 28-day period. Each cohort is comprised of four patients, equally divided between hepatitis B e-antigen ("HBeAg") positive and negative.

"Having established safety and tolerability of CRV431 alone, as well as when co-dosed with TDF, this trial will monitor safety, tolerability and pharmacokinetics of CRV431 when administered repeatedly for 28 days in virally-suppressed HBV patients," stated Dr. Foster, Hepion's CEO. "Although the study's focus will be on markers of safety, we will also look for any anti-viral and anti-fibrotic activity."

The study will include a fifth dosing cohort of HBV patients with Metavir scores, a measure of inflammation and fibrosis, of F2/F3. These patients will be administered 225 mg CRV431 to analyze exploratory markers of HBV infection and liver fibrosis.

"CRV431 is a promising candidate for HBV patients who still need therapies in the absence of a cure," said Dr. Stephen Harrison of Pinnacle Clinical Research and a Visiting Professor of Hepatology at Radcliffe Department of Medicine, University of Oxford. "As a new class of drug for liver disease with a novel mechanism of action, CRV431 has the potential to decrease viral markers and fibrosis."

In the first stage of CRV431's streamlined clinical program, CRV431 met the primary endpoints of safety and tolerability in a single ascending dose study of healthy volunteers. In the second stage, Hepion confirmed the safety of co-dosing CRV431 and TDF in a single-dose, drug-drug interaction study in healthy subjects.

About CRV431

CRV431 is a clinical stage cyclophilin inhibitor. Its primary biochemical action is inhibition of cyclophilin isomerase activity, which is known to play a key role in protein folding. In non-clinical, experimental models of NASH, CRV431 reduced fibrosis scores and hepatocellular carcinoma (HCC) tumor burden. In addition, CRV431 has also shown activity against certain viruses including HBV, HCV, and HIV-1. CRV431 has demonstrated an ability to reduce multiple markers of HBV infection including reductions in DNA, HBsAg, HBeAg, and HBV uptake by liver cells. These multiple modes of action may play an important role

in the overall treatment of liver disease, from triggering events through to end-stage liver disease. CRV431 has completed phase 1 human clinical trials.

About Hepion Pharmaceuticals

Hepion Pharmaceuticals is a clinical stage biopharmaceutical company focused on the development of targeted therapies for liver disease arising from non-alcoholic steatohepatitis (NASH) and chronic hepatitis virus infection (HBV, HCV, HDV). The Company's lead drug candidate, CRV431, reduces liver fibrosis and hepatocellular carcinoma tumor burden in experimental models of NASH. Preclinical studies also have demonstrated antiviral activities towards HBV, HCV, and HDV through several mechanisms. These diverse therapeutic activities result from CRV431's potent inhibition of cyclophilin enzymes, which are involved in many disease processes. Currently in clinical phase development, CRV431 shows potential to play an important role in the overall treatment of liver disease - from triggering events through to end-stage disease.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated," and "intend," among others. These forward-looking statements are based on Hepion Pharmaceuticals' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties with respect to lengthy and expensive clinical trials, that results of earlier studies and trials may not be predictive of future trial results; uncertainties of government or third party payer reimbursement; limited sales and marketing efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any drug candidates under development, there are significant risks in the development, regulatory approval, and commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful, or that any product will receive regulatory approval for any indication or prove to be commercially successful. Hepion Pharmaceuticals does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Hepion Pharmaceuticals' Form 10-K for the year ended December 31, 2018 and other periodic reports filed with the Securities and Exchange Commission.

For further information, please contact:

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