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): **July 29, 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**

ContraVir Pharmaceuticals, Inc.
(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 July 29, 2019, Hepion Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has reviewed its Investigational New Drug ("IND") application for CRV431 for the treatment of NASH and has authorized the Company proceed with its planned IND opening study. 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 July 29, 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: July 30, 2019

HEPION PHARMACEUTICALS, INC.

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

Exhibit 99.1

Hepion Pharmaceuticals Receives FDA Authorization to Proceed with IND Opening Study of CRV431 for NASH

EDISON, N.J., July 29, 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 the U.S. Food and Drug Administration ("FDA") has reviewed its Investigational New Drug ("IND") application for CRV431 for the treatment of NASH and has authorized that the Company proceed with its planned IND opening study. This IND for NASH is in addition to the Company's current open IND for hepatitis B virus ("HBV").

"We are delighted that the FDA has cleared our IND and we are excited to commence clinical trials of CRV431 for NASH, an increasingly prevalent disease for which there are currently no approved therapies," commented Dr. Robert Foster, the Company's CEO. "Based on the preclinical and clinical studies we've conducted, CRV431's anti-fibrotic and anti-inflammatory properties demonstrate its significant potential as a novel therapy for NASH, and more broadly, for liver disease."

"This is an important milestone that allows us to continue with CRV431's clinical development for NASH in addition to HBV. We look forward to commencing our IND opening study this year, which will assess CRV431 in patients with varying degrees of hepatic impairment."

Hepion's planned IND opening study, entitled "An Open-Label Single-Dose Study to Investigate the Effect of Hepatic Impairment on the Pharmacokinetics of CRV431," will enroll 24 patients consisting of eight with mild, eight with moderate, and eight with severe hepatic impairment, based on established Child-Pugh scores. Up to an additional 24 healthy subjects will serve as the control group. The objective of the IND opening study and proposed clinical development program is to characterize the safety, tolerability and pharmacokinetics of CRV431 monotherapy in patients with liver disease to establish dose ranges for patients with differing degrees of NASH.

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:

Stephen Kilmer
Hepion Pharmaceuticals Investor Relations
Direct: (646) 274-3580
skilmer@hepionpharma.com