

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Hepion Pharmaceuticals, Inc.

Form: 8-K

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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): February 12, 2020

Hepion Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-36856
(Commission
File Number)

46-2783806
(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:

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
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 February 12, 2020, Hepion Pharmaceuticals, Inc. issued a press release announcing the advancement to the third dose level in its ongoing clinical trial of CRV431, a Phase 1 multiple ascending dose ("MAD") 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 February 12, 2020](#)

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: February 12, 2020

HEPION PHARMACEUTICALS, INC.

By: /s/ Robert Foster

Robert Foster
Chief Executive Officer

Hepion Pharmaceuticals Announces Advancement to Third Dose Level in Ongoing Multiple Ascending Dose Clinical Study of CRV431

EDISON, N.J., February 12, 2020 - 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"), today announced the advancement to the third dose level in its ongoing clinical trial of CRV431, a Phase 1 multiple ascending dose ("MAD") study.

The open-label MAD study is designed to assess safety, tolerability and pharmacokinetics of CRV431, administered orally to healthy volunteers, once daily for 28 days. The study is examining doses of 75 mg, 150 mg, 225 mg and 300 mg, or higher in anticipation of progressing to a Phase 2 program.

The Clinical Trial Management team has reviewed the 150 mg cohort data and determined this dosing level to be safe and well tolerated, authorizing advancement to the next dosing level of 225 mg daily for 28 days.

Dr. Stephen Harrison, Hepion's Consultant Medical Director, commented, "We are pleased that CRV431 continues to demonstrate safety and tolerability at increasing doses, and look forward to additional data that will inform the design of our Phase 2 NASH clinical trial, which we plan to initiate in the second half of 2020."

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 other types of hepatitis. 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 cyclophilins, 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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