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): December 10, 2020

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 December 10, 2020, Hepion Pharmaceuticals, Inc. (the "Company") issued a press release announcing that, in addition to completing patient dosing in the 75 mg CRV431 cohort of its Phase 2a 'AMBITION' clinical trial, it has dosed the first NASH patient in the 225 mg CRV431 dosing cohort. 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 December 10, 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: December 10, 2020

HEPION PHARMACEUTICALS, INC.

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

Exhibit 99.1

Hepion Pharmaceuticals Completes 75 mg CRV431 Dosing, Initiates 225 mg Dosing in Phase 2a 'AMBITION' Clinical Trial for NASH

EDISON, N.J., December 10, 2020 - Hepion Pharmaceuticals, Inc. (NASDAQ:HEPA, "Hepion"), a clinical stage biopharmaceutical company focused on Artificial Intelligence ("AI")-driven therapeutic drug development for the treatment of non-alcoholic steatohepatitis ("NASH") and liver disease, today announced that, in addition to completing patient dosing in the 75 mg CRV431 cohort of its Phase 2a 'AMBITION' clinical trial, it has dosed the first NASH patient in the 225 mg CRV431 dosing cohort.

The open-label Phase 2a 'AMBITION' study is designed to assess safety, tolerability, pharmacokinetics and biomarker analyses for early assessments of efficacy of 75 mg and 225 mg CRV431, administered orally to F2 and F3 NASH patients (n=18/dosing group), once daily for 28 days. Hepion will also conduct Fibroscans and examine a multitude of candidate biomarkers of NASH resolution and CRV431 efficacy including Pro-C3, Enhanced Liver Fibrosis (ELF) markers, collagens, matrix metalloproteinases, transcriptomics, liver transaminases, and full-scale lipidomic and genomic signatures. Identification of biomarkers will be facilitated by Hepion's proprietary, machine-learning platform, AI-POWR™.

"We are pleased to complete dosing of all NASH patients in our 75 mg CRV431 cohort," stated Dr. Robert Foster, Hepion's CEO. "All patients will now be observed for a 14-day follow-up period, which is scheduled to be completed by December 16, 2020. In parallel with the completion of this dosing cohort, we have now dosed the first NASH patient in the 225 mg cohort. We are delighted with our progress and anticipate that data from this trial will yield important insights that will be applied to our planned Phase 2b clinical trial, which is scheduled to begin in 2021."

"I continue to look forward to seeing the read-out from the 75 mg dosing cohort," commented Dr. Stephen Harrison, Hepion's Consultant Medical Director. "Thus far, CRV431 appears well-tolerated in patients. Importantly, we will also be examining fibrosis using multiple non-invasive measures and looking for a dose-response relationship between the 75 mg and 225 mg dosing groups."

About Hepion Pharmaceuticals

Hepion Pharmaceuticals is a clinical stage biopharmaceutical company focused on the development of targeted therapies for the treatment of non-alcoholic steatohepatitis (NASH) and other liver diseases.

The Company's lead drug candidate, CRV431, is a potent inhibitor of cyclophilins, which are involved in many disease processes. CRV431 is currently in clinical-phase development for the treatment of NASH, with the potential to play an important role in the overall treatment of liver disease - from triggering events through to end-stage disease. CRV431 has been shown to reduce liver fibrosis and hepatocellular carcinoma tumor burden in experimental models of NASH; and has demonstrated antiviral activities towards HBV, HCV, and HDV through several mechanisms, in preclinical studies.

Hepion has created a proprietary AI platform, called AI-POWR™, which stands for **A**rtificial Intelligence - **P**recision Medicine; **O**mics (including genomics, proteomics, metabolomics, transcriptomics, and lipidomics); **W**orld database access; and **R**esponse and clinical outcomes. Hepion intends to use AI-POWR™ to help identify which NASH patients will best respond to CRV431, potentially shortening development timelines and increasing the delta between placebo and treatment groups. In addition to using AI-POWR™ to drive its ongoing Phase 2a NASH program, Hepion will use the platform to identify additional potential indications for CRV431 to expand the company's footprint in the cyclophilin inhibition therapeutic space.

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; risks associated with delays, increased costs and funding shortages caused by the COVID-19 pandemic; 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, 2019 and other periodic reports filed with the Securities and Exchange Commission.

For further information, please contact:

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