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 29, 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 29, 2020, Hepion Pharmaceuticals, Inc. (the "Company") issued a press release announcing that an independent Data Safety Monitoring Board ("DSMB") has approved the continuation of the Company's Phase 2a 'AMBITION' clinical trial. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

In addition, on December 29, 2020, the Company issued a press release announcing top line data from the low dose cohort in the Company's Phase 2a 'AMBITION' clinical trial of CRV431. A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Hepion Pharmaceuticals, Inc. Press Release dated December 29, 2020
99.2	Hepion Pharmaceuticals, Inc. Press Release dated December 29, 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 29, 2020

HEPION PHARMACEUTICALS, INC.

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

Exhibit 99.1

Hepion Pharmaceuticals Data Safety Monitoring Board Recommends Continuation with Final Dose Cohort in Phase 2a 'AMBITION' Clinical Trial for Treatment of Advanced NASH

- DSMB Review After Completion of the First Dose Cohort Affirmed No Safety or Tolerability Concerns with CRV431 in NASH Patients -

- DSMB Recommended the AMBITION Study Continue with Final Dosing Cohort -

- Final Cohort Expected to be Completed in Early 2021 -

EDISON, N.J., December 29, 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 an independent Data Safety Monitoring Board ("DSMB") has approved the continuation of the Company's Phase 2a 'AMBITION' clinical trial.

Two interim analyses were performed by a DSMB to evaluate the safety and tolerability of the 75 mg CRV431 dose cohort in NASH patients. The first analysis occurred half-way through the first dosing cohort and this, the second analysis, occurred at the completion of the first dosing cohort.

Hepion's lead novel drug candidate, CRV431, is a pan-cyclophilin inhibitor that inhibits multiple forms of cyclophilins. Cyclophilins, of which there are 17 known isoforms in humans, play a central role in protein folding and contribute to numerous biological effects including inflammation and fibrosis, to name a few. NASH, which is a severe form of non-alcoholic fatty liver disease affects approximately 17 million people in the U.S. and is a leading cause of liver transplantation. NASH may also lead to cirrhosis, liver cancer and death. Formation of liver fibrosis has been linked to mortality in NASH. To date, there are no approved drugs to treat NASH.

The AMBITION trial is the first placebo-controlled study of CRV431 in NASH patients with evidence of moderate-to-severe fibrosis. In this study, which is being conducted at 10 U.S. sites, CRV431 is administered orally, once-daily for 28 days. The primary objectives of the AMBITION trial are to assess safety and tolerability of CRV431, as well as to delineate pharmacokinetics. The secondary outcome measure of this Phase 2a trial is to evaluate decreases in non-invasive antifibrotic markers from baseline to the end of the study. Data from the AMBITION trial will be used alongside Hepion's proprietary AI-POWR^{TM} to guide and enrich future study design.

"This is the second successful review by the DSMB of our AMBITION trial in NASH patients with moderate-to-severe fibrosis," commented Dr. Robert Foster, Hepion's CEO. "Now that we have completed dosing in our 75 mg cohort, we are enrolling our final dosing cohort of 225 mg. Dosing of all patients is expected to be completed in Q1-2021 with final data read-out for both dosing cohorts expected thereafter. The release of our top line preliminary data from our 75 mg dosing group is imminent. Despite the challenges of conducting a clinical trial during the COVID-19 pandemic, we continue to make good progress."

About Hepion Pharmaceuticals

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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Hepion Pharmaceuticals Investor Relations
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Exhibit 99.2

Hepion Pharmaceuticals Announces Positive Top Line Data for Low Dose CRV431 in Phase 2a 'AMBITION' Clinical Trial for Treatment of Advanced NASH

- CRV431 Demonstrated to be Generally Safe and Well Tolerated –

- Clinically Significant Reductions in Important Biomarkers, ALT and AST, Observed in 28 Days –

- Study Continuing with Higher Dose -

EDISON, N.J., December 29, 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 top line data from the low dose cohort in the Company's Phase 2a 'AMBITION' clinical trial of CRV431, an oral, once daily novel cyclophilin inhibitor. This Phase 2a study is continuing with the higher dose of 225 mg CRV431, with NASH patient dosing expected to be completed in Q1-2021.

The AMBITION trial is a placebo-controlled study of CRV431 in NASH patients with evidence of moderate-to-severe fibrosis. In this study, which is being conducted at 10 U.S. sites, 75 mg CRV431 (low dose) was administered orally, once-daily for 28 days. A second dosing cohort of 225 mg CRV431 (high dose) is ongoing. Final results from both dosing cohorts are expected after the high dose group has completed active dosing, followed by a 14-day observation period.

The primary objectives of the AMBITION trial are to assess safety and tolerability of CRV431, as well as to delineate pharmacokinetics ("PK"). The secondary outcome measure of this Phase 2a trial is to evaluate decreases in antifibrotic markers from baseline to the end of study.

The results of the low dose group indicated that CRV431 was generally safe and well tolerated. The pharmacokinetics further indicated that blood concentrations of CRV431 were similar to those observed in earlier Phase 1 studies in healthy volunteers, suggesting that the PK profile in moderate-to-severe NASH patients did not appear to be altered by disease. Biomarkers of efficacy, including declines in alanine aminotransferase ("ALT") and aspartate aminotransferase ("AST") from baseline to day 28 were observed, with mean declines of 18.4% and 12.1%, respectively. At day 28 in the placebo group, the changes observed for ALT and AST from baseline were a 0.65% reduction and a 2.52% increase, respectively. Improvements in mean transaminase values were not powered to be statistically significant, as only 12 subjects received drug.

Dr. Stephen Harrison, Hepion's Consultant Medical Director, commented, "The reductions in the liver chemistry tests, ALT and AST, occurred rapidly and were sustained throughout the 28 days of dosing. These reductions began to return to baseline once the patients stopped taking CRV431 at the end of the study, indicative of a drug effect. As such, these early signals are supportive of positive actions on liver health in a short period of time with the low dose of CRV431, and we eagerly look forward to evaluating the fibrosis biomarkers, as well as the higher dose of CRV431, in the second cohort."

“We are pleased to see this positive movement in liver chemistry tests,” commented Dr. Robert Foster, Hepion’s CEO. “Although the primary focus of this Phase 2a study was to examine the safety and tolerability of CRV431 in NASH patients, we were hoping to see early signs of potential efficacy and are pleased with the results thus far. We will continue to monitor liver safety lab tests in our higher dose group and will also look at a panel of serum fibrosis biomarkers. Once completed, we will analyze all the data from the Phase 1 and 2a trials, as well as our non-clinical studies to conduct an *a priori* analysis with our artificial intelligence, AI-POWR™ to enrich our Phase 2b study design and optimize it for outcomes. Our Phase 2b trial is anticipated to start midway through 2021.”

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.

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