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 22, 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 22, 2020, Hepion Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has accepted its investigational new drug ("IND") application for CRV431, a novel cyclophilin inhibitor for the treatment of COVID-19. 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 22, 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 22, 2020

HEPION PHARMACEUTICALS, INC.

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

Exhibit 99.1

Hepion Pharmaceuticals Announces FDA Clearance of IND Application for CRV431 for COVID-19

- IND Expands Potential Indications for CRV431 Beyond NASH to Include COVID-19 -

- CRV431 Poised to Move Directly into Phase 2 Clinical Study for COVID-19 -

- Company May Seek Partnership(s) for COVID-19 Drug Development -

EDISON, N.J., **December 22, 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 the U.S. Food and Drug Administration ("FDA") has accepted its investigational new drug ("IND") application for CRV431, a novel cyclophilin inhibitor for the treatment of COVID-19.

On July 7, 2020, Hepion announced a potential two-pronged strategy to treat COVID-19. First, preclinical cell culture experiments demonstrated CRV431 decreased SARS-CoV-1 production of infectious virus. Second, in a non-viral, acute lung injury model, CRV431 demonstrated attenuated lung inflammation and damage similar to or better than dexamethasone, including reductions in neutrophils and IL-6. This property may be beneficial to patients suffering longer term consequences of COVID-19 infection, including acute respiratory distress syndrome ("ARDS"). Importantly, COVID-19 patients developing ARDS have a higher mortality rate.[1] Taken together, this dual mode of action suggested that CRV431 may offer an opportunity to treat both the viral infection as well as lung injury in COVID-19.

"The recent identification of a mutational variant of SARS-CoV-2 that is potentially more infectious than previous strains is a reminder that we must continue to battle this virus on all fronts. Host cyclophilins play a key role in the propagation of viruses. CRV431, a cyclophilin inhibitor, interrupts the ability of the virus to use these human cyclophilins and thereby reduces viral propagation. As such, CRV431 is likely less prone to treatment resistance that may be seen when viral mutations occur," stated Dr. Daren Ure, Hepion's Chief Scientific Officer. "There is a great deal of well-deserved optimism now that vaccines have been approved. However, for the foreseeable future, we anticipate there will continue to be the need for active antiviral treatments as well as treatment for ARDS. CRV431 potentially offers both."

"Clearance of the COVID-19 IND by the FDA speaks to the versatility of CRV431, a novel orally active cyclophilin inhibitor," commented Dr. Robert Foster, Hepion's CEO. "Even with the decades of experience our core team has with the research and development of this specialized drug class, we continue to be amazed at the number of diseases that could potentially benefit from inhibiting cyclophilins. The diverse roles that cyclophilins play in disease processes such as cell injury, inflammation, fibrosis, viral infections, and cancer are due to the actions of many different isoforms of cyclophilins. CRV431 inhibits several of these isoforms with similar potencies, which gives rise to its broad therapeutic potential."

Dr. Foster continued, "As part of the IND filing, Hepion provided data to the FDA from its previously completed Phase 1 studies of CRV431. Although Hepion's focus and lead indication remain squarely on the treatment of NASH, this IND may allow us opportunities to seek collaboration partnerships to support the initiation of Phase 2 studies of CRV431 for COVID-19, and to explore sources of non-dilutive external funding for our COVID-19 program."

Reference

[1]*The Lancet*, Volume 8, Issue 12, 1201-1208, December 2020

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:

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