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): March 11, 2021

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 x

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. x

Item 8.01 Other Events

On March 11, 2021, Hepion Pharmaceuticals, Inc. issued a press release announcing that it will present at the NASH-TAG 2021 Conference, being held virtually on March 11-13. 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 March 11, 2021

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: March 11, 2021

HEPION PHARMACEUTICALS, INC.

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

Exhibit 99.1

Hepion Pharmaceuticals to Present on CRV431 and AI-POWR™ at NASH-TAG 2021

EDISON, N.J., March 11, 2021 - 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 it will present at the NASH-TAG 2021 Conference, being held virtually on March 11-13.

The NASH-TAG Conference is designed to bring together clinicians and researchers in academia and the pharmaceutical industry for a focused interactive educational update highlighting the most relevant advances and challenges in the diagnosis and therapy of NASH and liver fibrosis.

An oral presentation, to be delivered by Hepion's CEO, Dr. Robert Foster, will review the positive 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, as well as the planned use of its AI-POWR™ platform in conjunction with PK-PD (pharmacokinetics-pharmacodynamics) studies to enrich its Phase 2b study design and optimize it for outcomes.

Presentation Details

Title: CRV431 – Pancyclophilin Inhibitor
Session: New Pharmacological Targets
Date: Saturday, March 13, 2021
Time: 7:15 – 7:30 p.m. MT

"We are very pleased to have been selected to present at NASH-TAG, widely regarded as one of the most prestigious NASH meetings globally," said Dr. Foster. "In this, the first public oral presentation of the top line data from the low dose cohort in the 'AMBITION' Phase 2a study, we are excited to share both our findings and to highlight the clinical trial risk mitigation potential of AI-POWR™ as we plan for the initiation of our Phase 2b study."

A copy of the presentation materials will be accessible on the Company's website at www.hepionpharma.com under "Publications" in the Pipeline section.

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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