SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Hepion Pharmaceuticals, Inc.

Form: 8-K

Date Filed: 2020-02-20

Corporate Issuer CIK: 1583771

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 19, 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 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 February 19, 2020, Hepion Pharmaceuticals, Inc. issued a press release announcing results from *in vitro* studies showing that CRV431 can decrease production of the extracellular matrix (ECM) molecules, collagen and fibronectin, from fibroblastic cells derived from five different organs. 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 19, 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 20, 2020

HEPION PHARMACEUTICALS, INC.

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

Exhibit 99.1

Anti-Fibrotic Activity of Hepion Pharmaceuticals' CRV431 Shows Potential to Extend to Multiple Organs and Fibrotic Diseases

- CRV431 Decreases Collagen and Fibronectin Production from Multiple Cell Types -

EDISON, N.J., **February 19, 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 results from *in vitro* studies showing that CRV431 can decrease production of the extracellular matrix (ECM) molecules, collagen and fibronectin, from fibroblastic cells derived from five different organs. Collagen and fibronectin over-production from these types of cells cause fibrotic scarring of injured organs, and therefore these results suggest that CRV431 could exert anti-fibrotic activity across a range of diseases.

The five cell types included in this study were lung fibroblasts from a patient with idiopathic pulmonary fibrosis ("IPF"), cardiac fibroblasts, dermal (skin) fibroblasts, renal mesangial cells, and the LX2 hepatic stellate cell line. CRV431 dose-dependently decreased procollagen and fibronectin secretion from all cell types with similar magnitude, as measured by enzyme-linked immunosorbent assay (ELISA). The extent of inhibition was similar whether or not the cells were stimulated with the profibrotic agent, transforming growth factor-beta (TGFβ), consistent with direct effects on ECM synthesis. CRV431 dose-dependently decreased ECM production by up to 55% at clinically relevant concentrations, without causing any reduction in cell viability. CRV431 is believed to reduce ECM production by inhibiting cyclophilin B, and consistent with this hypothesis, downregulation of cyclophilin B with small interfering RNA (siRNA) similarly decreased procollagen and fibronectin secretion.

"Fibrotic scarring is a major pathological feature and driver of organ dysfunction in many diseases, including liver cirrhosis, IPF, chronic kidney disease, and several heart conditions. Yet, there are very few treatments available that attenuate the scarring," said Dr. Daren Ure, Chief Scientific Officer of Hepion. "Most treatments attempt to reduce fibrosis by targeting the stimulation of fibroblastic cells, but these signaling events may vary by patient, type of fibrotic disease, or disease stage. The advantage of CRV431, based on our findings, is that its effects appear to be independent of the type of stimulatory signal. Therefore, CRV431 could be used to treat fibrosis without having to fully elucidate how the ECM-producing cells become over-activated."

According to Dr. Robert Foster, Hepion's Chief Executive Officer, "Liver fibrosis arising from NASH and other chronic insults continues to be Hepion's primary focus, but the results of these recent studies raise the intriguing possibility that CRV431 could be evaluated for a host of other disorders. IPF is one such example of an aggressive fibrotic disease in tremendous need of new treatments. In addition, our Phase 1 study in healthy volunteers continues to demonstrate a very good safety profile for CRV431, further supporting its possible use for other indications."

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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