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 12, 2018**

ContraVir 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)

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 February 12, 2018, ContraVir Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has agreed to allow the company to utilize the 505(b)(2) Regulatory Pathway to streamline the development and registration of TXL™ for the treatment of Chronic Hepatitis B.

The press release is attached as Exhibit 99.1 to this report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 ContraVir Pharmaceuticals, Inc. Press Release dated February 12, 2018

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 12, 2018

CONTRAVIR PHARMACEUTICALS, INC.

By: /s/ James Sapirstein
James Sapirstein
Chief Executive Officer

Exhibit 99.1

ContraVir Pharmaceuticals Reaches Agreement with the FDA on the NDA Package for TXL™ Leveraging the 505(b)(2) Regulatory Pathway

EDISON, N.J., **February 12, 2018** - ContraVir Pharmaceuticals, Inc. (NASDAQ:CTRV), a biopharmaceutical company focused on the development and commercialization of targeted antiviral therapies, announced today that the U.S. Food and Drug Administration (FDA) has agreed to allow the company to utilize the 505(b)(2) Regulatory Pathway to streamline the development and registration of TXL™ for the treatment of Chronic Hepatitis B.

The 505(b)(2) Regulatory Pathway allows a company to rely upon FDA's previous findings of safety and efficacy of an approved and marketed product to supplement its own safety and efficacy data, and may be considered in the review by the FDA of a future New Drug Application (NDA).

On January 8, 2018, the ContraVir Executive Team met with the FDA's Division of Antiviral Products at the Center for Drug Evaluation and Research, to review and discuss the data generated for TXL™ to date, as well as the data package that would be required for the filing of an NDA and successful registration of TXL ™ in the US leveraging the 505(b)2 Regulatory Pathway. On February 7, 2018, ContraVir received final written minutes from the FDA summarizing the outcome of the meeting and feedback received.

Key highlights from the meeting outcome include:

- Agreement on an abbreviated non-clinical Development Program
- Agreement on a Clinical Pharmacology Package
- Agreement on the major elements of Phase 3 trial design in treatment-naïve patients with chronic hepatitis B (both HBeAg and HeAg), including duration of treatment, clinical endpoints, comparator and;
- Agreement on number of patients for the safety database needed for NDA submission

The outcome of the meeting with FDA is a positive step towards the further execution of the streamlined development and registration of TXL™ in the US, which is expected to allow a faster and more cost-effective path to approval and commercialization in the US.

"We are very grateful the FDA supports our pursuit of the 505(b)(2) Regulatory Pathway," said James Sapirstein, Chief Executive Officer of ContraVir. "This critical feedback will allow us to significantly shorten our non-clinical development program by at least 12-18 months, and will accelerate our clinical program towards registration."

"The outcome of the meeting with FDA allows TXL™ to leverage the 505(b)2 Regulatory Pathway as one of the lead compounds in development for HBV," stated Carol L.Brosgart, MD, Clinical Professor of Medicine, Epidemiology and Biostatistics, University of California, San Francisco, an infectious diseases, hepatology, and biotechnology expert, and the Chair of ContraVir's Scientific Advisory Board. "TXL™'s liver-targeting design advances the development of the compound as a direct acting antiviral, which we anticipate to be the backbone to potential functional curative regimens."

About ContraVir Pharmaceuticals
ContraVir is a biopharmaceutical company focused on the development and commercialization of targeted antiviral therapies with a specific focus on developing a potentially curative therapy for hepatitis B virus (HBV). The company is developing two novel anti-HBV compounds with complementary mechanisms of action. TXL™, designed to deliver high intrahepatic concentrations of TFV while minimizing off-target effects caused by high levels of circulating TFV (bone and kidney), recently completed a Phase 2a trial. CRV431, the other anti-HBV compound, is a next-generation cyclophilin inhibitor with a unique structure that increases its potency and selective index against HBV. *In vitro* and *in vivo* studies have thus far demonstrated that CRV431 reduces HBV DNA and other viral proteins, including surface antigen (HBsAg). For more information visit www.contravir.com.

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 ContraVir’s 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. ContraVir does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in ContraVir’s Form 10-K for the year ended June 30, 2017 and other periodic reports filed with the Securities and Exchange Commission.

For further information, please contact:
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