# 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 22, 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 22, 2018, ContraVir Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to its lead investigational drug candidate, tenofovir exalidex (TXL™) for the treatment of chronic hepatitis B infection in a pediatric patient population (0 to 11 years old).

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 22, 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 22, 2018

CONTRAVIR PHARMACEUTICALS, INC.

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

**Exhibit 99.1**

**ContraVir Pharmaceuticals Announces TXL™ Has Been Granted Orphan Drug Designation**
**For the Treatment of HBV in a Pediatric Population**

**EDISON, N.J., February 22, 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 granted Orphan Drug Designation to its lead investigational drug candidate, tenofovir exalidex (TXL™) for the treatment of chronic hepatitis B infection in a pediatric patient population (0 to 11 years old).

Chronic hepatitis B virus (HBV) is a major public health burden affecting more than 350 million people worldwide, with high infection rates prevalent in children who are infected at birth or in early childhood. Current treatment options available for children [and adults] generally require lifelong treatment and have had limited success, creating a great need for improved therapies, ultimately leading to a functional cure.

"We are very pleased to report that TXL™ is currently the only investigational or approved HBV treatment granted orphan designation for the pediatric patient population," said James Sapirstein, Chief Executive Officer at ContraVir. "This designation underscores the significant unmet need in this highly vulnerable patient population and provides a critical development path for TXL™ to bring to market a new treatment option for this under-served patient population. As we previously reported the agreement with FDA on the 505(b)(2) registration pathway for TXL™, we have achieved yet another important regulatory milestone for TXL™, and we look forward to continued collaboration with the FDA addressing the urgency of successfully developing treatments for hepatitis B in the pediatric and adult populations."

Orphan designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing. Orphan drug designation qualifies TXL™ for seven years of market exclusivity in the U.S. upon approval, financial assistance in clinical research and development, and an accelerated evaluation of the registration package by the FDA Additionally, a marketing application for a prescription drug product that has received orphan designation is not subject to a prescription drug user fee for the rare disease or condition for which the drug is designated.

**About TXL™**

Tenofovir exalidex (TXL™) is a highly potent prodrug of the antiviral tenofovir. Tenofovir is the active component of both Vemlidy (tenofovir alafenamide) and Viread® (tenofovir disoproxil fumarate).TXL's novel liver-targeting prodrug structure results in decreased systemic circulating levels of tenofovir, thereby reducing the potential for renal and bone side effects. ContraVir has completed a Phase 2 trial of TXL™, in which HBV-infected subjects were administered doses up to 100 mg for 28 days and is now optimizing its formulation to further enhance drug delivery. To date, TXL™ has achieved clinical proof of concept for antiviral activity and displayed an excellent safety, tolerability, and pharmacokinetic profile. Based on the agent's best-in-class potential, ContraVir believes TXL™ can become the cornerstone of a curative combination therapy for hepatitis B.

**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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