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): **September 11, 2017**

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 September 11, 2017, ContraVir Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved an Investigational New Drug (IND) Application in the U.S. for its lead HBV compound, 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 September 11, 2017

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: September 11, 2017

CONTRAVIR PHARMACEUTICALS, INC.

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

Exhibit 99.1

ContraVir Pharmaceuticals Receives HBV
IND Approval for Tenofovir Exalidex (TXL™) in the United States

EDISON, N.J., **September 11, 2017** - 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 approved an Investigational New Drug (IND) Application in the U.S. for its lead HBV compound, TXL™ for the treatment of chronic hepatitis B.

Earlier this year, ContraVir announced that it had completed a Phase 1, multiple dose study in healthy subjects and a Phase 2a, 28 day study in HBV-infected patients. These studies were conducted in Thailand, a country with a high prevalence of chronic HBV infection. Having successfully achieved proof-of-concept, ContraVir intends to expand the TXL™ clinical program and initiate its first US-based clinical trial for TXL™ in the fourth quarter of 2017, pending approval by the Institutional Review Board. The study will enroll patients with severe renal impairment, and thus will generate data which we believe will further support the favorable safety profile of TXL™.

“While we already have an existing open IND for TXL™ in HIV, the approval of the IND for TXL™ in HBV, is a significant step to further drive the expansion of our development program,” said James Sapirstein, Chief Executive Officer of ContraVir. “We are particularly excited about this news, as it broadens the reach of our clinical program and allows us to conduct co-development programs in the U.S. for patients with both HIV and HBV infection.”

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™ currently in Phase 2, is designed to deliver high intrahepatic concentrations of TFV, while minimizing off-target effects caused by high levels of circulating TFV. 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. ContraVir is also developing Valnivudine™, an orally available nucleoside analogue prodrug; Valnivudine™ is currently in Phase 3 for the treatment of herpes zoster. In addition to direct antiviral activity, Phase 2 data suggest that Valnivudine™ has the potential to reduce the incidence of debilitating shingles-associated pain known as post-herpetic neuralgia (PHN). 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, 2016 and other periodic reports filed with the Securities and Exchange Commission.

For further information, please contact:
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