

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): August 27, 2018



PERNIX THERAPEUTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

<u>Maryland</u>	<u>001-14494</u>	<u>33-0724736</u>
(State or Other Jurisdiction)	(Commission File Number)	(IRS Employer Identification No.)
<u>10 North Park Place, Suite 201, Morristown, NJ</u>		<u>07960</u>
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: **(800) 793-2145**

(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 (*see* General Instruction A.2. below):

- ☐ Written communications 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 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 August 27, 2018, Pernix Therapeutics Holdings, Inc. (the "Company") issued a press release announcing a ruling in the patent litigation concerning Zohydro® ER with BeadTek®. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits**(d) Exhibits.****Exhibit****No. Document**

99.1 [Press release dated August 27, 2018.](#)

SIGNATURES

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.

PERNIX THERAPEUTICS HOLDINGS, INC.

Date: August 27, 2018

By: /s/ John A. Sedor

Name: John A. Sedor

Title: Chief Executive Officer



Pernix Therapeutics Announces Ruling in Patent Litigation Concerning Zohydro® ER with BeadTek®

MORRISTOWN, N.J. - August 27, 2018 - Pernix Therapeutics Holdings, Inc. (NASDAQ: PTX), a specialty pharmaceutical company, announced today that in the Company's litigation against Alvogen Malta Operations, Ltd. (Alvogen), the United States District Court for the District of Delaware found the asserted claims of U.S. Patent Nos. 9,265,760 and 9,339,499, which relate to methods of treating patients with mild and moderate hepatic impairment with hydrocodone bitartrate, to be infringed, but invalid. The litigation relates to Alvogen's submission of an Abbreviated New Drug Application (ANDA) to the U.S. Food & Drug Administration (FDA) seeking approval to market a generic version of Pernix's Zohydro® ER with BeadTek® (hydrocodone bitartrate).

While Pernix is pleased that the Court confirmed that Alvogen has infringed, it is disappointed with the Court's invalidity ruling and intends to appeal this aspect of the Court's decision.

Absent a reversal of the Court's decision, pursuant to a previous settlement agreement dated September 29, 2016, between Alvogen and Recro Gainesville LLC, Alvogen can launch a generic version of Zohydro® ER with BeadTek®, subject to final approval of an ANDA from the FDA, as early as October 1, 2019. All other terms of the settlement agreement are confidential.

Further, the Court's decision has no immediate impact on Pernix's settlement agreement with Actavis Laboratories FL that was announced on January 29, 2018, and also relates to a proposed generic version of Zohydro® ER with BeadTek®. Under the terms of the Actavis settlement agreement, Pernix granted Actavis a license to begin selling a generic version of Zohydro® ER with BeadTek® on March 1, 2029. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro® ER with BeadTek®.

About Pernix Therapeutics

Pernix Therapeutics is a specialty pharmaceutical business with a focus on acquiring, developing and commercializing prescription drugs primarily for the U.S. market. The Company is currently focused on the therapeutic areas of Pain and Neurology, and has an interest in expanding into additional specialty segments. The Company promotes its branded products to physicians through its internal sales force and markets its generic portfolio through its wholly owned subsidiaries, Macoven Pharmaceuticals, L.L.C and Cypress Pharmaceuticals, Inc.

To learn more about Pernix Therapeutics, visit www.pernixtx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements including words such as "estimate," "plan," "project," "forecast," "intend," "expect," "anticipate," "believe," "seek," "target" or similar expressions are forward-looking statements. These statements reflect the Company's current views, expectations and beliefs concerning future events. In addition, any statements related to Pemix's future strategy and plans with respect to its intellectual property portfolio and other statements related to the outcome of pending litigation, settlement discussions or other adverse proceedings or rulings contained herein are forward-looking statements. Such plans, expectations and statements are as to future events and are not to be viewed as facts, and reflect various assumptions of management of the Company and are subject to significant business, financial, economic, operating, competitive, litigation and other risks and uncertainties and contingencies (many of which are difficult to predict and beyond the control of the Company) that could cause actual results to differ materially from the statements included herein. The inclusion of forward-looking statements should not be regarded as a representation by Pemix that any of its plans will be achieved. Investors should note that many factors, including the risks and uncertainties inherent in the outcome of pending litigation and settlement proceedings, as more fully described in Pemix's filings with the Securities and Exchange Commission ("SEC") (including, but not limited to, its Annual Report on Form 10-K for the year ended December 31, 2017, its Quarterly Report on Form 10-Q for the Quarterly Period ended June 30, 2018 and subsequent filings with the SEC), could affect the Company's future financial results and could cause actual results to differ materially from those expressed in forward-looking statements, such as those contained in this press release. The forward-looking statements in this press release are qualified by risk factors identified by the Company. These risk factors, individually or in the aggregate, could cause our actual results to differ materially from expected and historical results. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

CONTACT

Investor Relations

Bob Yedid

LifeSci Advisors, LLC

Bob@LifeSciAdvisors.com
