

PERNIX THERAPEUTICS HOLDINGS, INC.

Form 8-K

November 21, 2018

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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FORM 8-K  
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CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):

**November 15, 2018**

PERNIX THERAPEUTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Maryland

001-14494

33-0724736

(State or Other Jurisdiction)

(Commission File Number)

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(IRS Employer Identification No.)

10 North Park Place, Suite 201, Morristown, NJ

07960

(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.

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Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 19, 2018, the Board of Directors of the Company (the "Board"), upon the recommendation of the Compensation Committee of the Board, approved an amendment to that certain employment agreement, dated November 3, 2016, by and between the Company and John A. Sedor, the Company's Chief Executive Officer (the "Employment Agreement Amendment"). Pursuant to the Employment Agreement Amendment, the Company will pay Mr. Sedor a housing allowance of \$6,300 per month through November 30, 2018 and \$6,612 per month from that time until the earlier of (i) June 30, 2019 or (ii) the expiration of Mr. Sedor's employment term, for a residence located within fifty (50) miles of the Company's offices in Morristown, NJ.

The foregoing description of the Employment Agreement Amendment does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the full text of the document which is attached as Exhibit 10.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

Item 8.01 Other Events.

On November 15, 2018, the Company received feedback from the U.S. Food and Drug Administration ("FDA") that following a review of the Company's supplemental application relative to a proposed formulation change to the 20 mg. strength capsule of Zohydro® ER with BeadTek

™ ("Zohydro"), the FDA has determined that it will consider this submission to be a "prior approval supplement" ("PAS"), rather than as a "changes being effective" ("CBE") supplement. Changes to a new drug application are statutorily categorized as either PAS, CBE, or annual reportable ("AR") and are distinguished by the relative risk or relative potential to have an adverse effect on the drug product. The change proposed by the Company is intended to address its supplier's previously disclosed manufacturing issue and relates to the quantitative formulation of an inactive ingredient, the polyethylene oxide beads.

The Company believes that as a result of the anticipated review cycle for this PAS, the 20 mg. strength capsule of Zohydro will be on back order until at least the second quarter of 2019. Importantly, the Company continues to market and distribute the other strengths of Zohydro, which consist of 10 mg., 15 mg., 30 mg., 40 mg., and 50 mg. strength capsules.

The Company is working closely with wholesalers and prescribers to minimize any disruption caused by the stockout, and with its supplier to ensure the return of 20 mg. strength capsules to the marketplace as soon as possible.

While utilization of 10 mg., 15 mg. and 30 mg. strength capsules of Zohydro are expected to increase in order to fulfill patient needs, the Company anticipates that the stockout of 20 mg. strength capsules will impact overall Zohydro prescription volume. However, after evaluating the scope of potential financial impact, the Company does not believe that this stockout will have a material financial impact on the Company.

Cautionary Note Regarding Forward-Looking Statements

This report 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. These forward-looking statements include statements regarding: our belief about the timing of the FDA's review cycle for this PAS; our expectation that the 20 mg. strength capsule of Zohydro will be on back order until at least the second quarter of 2019; our ability to minimize any disruptions caused by the stockout; our expectations regarding the impact the stockout will have on the 10 mg., 15mg. and 30mg strength capsules of Zohydro; the impact the stockout will have on the overall Zohydro prescription volume; and the financial impact the stockout will have on the Company. 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, including without limitation, the timing and results of the FDA review process and uncertainties regarding prescription volumes of other strengths of

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Zohydro and the financial impact on the Company arising from the stockout. The inclusion of forward-looking statements should not be regarded as a representation by Pernix that any of its plans will be achieved. Investors should note that many factors, including those more fully described in Pernix'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 and its Quarterly Report on Form 10-Q for the Quarterly Period ended September 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 report. The forward-looking statements in this report are qualified by risk factors previously 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit  
No.

Document

10.1

Amendment to Employment Agreement, dated November 20, 2018, by and between John A. Sedor and Pernix Therapeutics Holdings, Inc.

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: November 21, 2018

By:

/s/ Kenneth R. Piña

Kenneth R. Piña

Senior Vice President, Chief Legal & Compliance Officer and Corporate Secretary

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