

PERNIX THERAPEUTICS HOLDINGS, INC.

Form 8-K

November 13, 2015

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): November 12, 2015

PERNIX THERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Maryland (State or other jurisdiction of incorporation)	001-14494 (Commission File Number)	33-0724736 (IRS Employer Identification No.)
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10 North Park Place, Suite 201 Morristown, NJ (Address of principal executive offices)	07960 (Zip Code)
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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:

- 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))

Item 8.01 Other Events

On November 12, 2015 Graybar Pharmaceuticals, LLC (Graybar) filed a petition with the United States Patent and Trademark Office (USPTO) to institute an Inter Partes Review of US Patent No. 7,332,183 (the '183 patent). The '183 patent is owned by POZEN Inc. and licensed by Pernix and is one of the several FDA Orange Book listed patents covering Treximet® (sumatriptan/naproxen sodium), a prescription medication for acute migraine attacks, with or without aura.

The validity of the '183 patent has previously been upheld on all counts by the United States Court of Appeals for the Federal Circuit. In 2012, the Federal Circuit upheld the District Court's decision on validity of the '183 patent against challenges by three generic companies. The '183 patent broadly claims a bi-layer pharmaceutical tablet having a triptan and an NSAID (nonsteroidal anti-inflammatory drug) in separate layers that release independently of each other. This patent expires April 2026, including six months pediatric exclusivity.

Inter Partes Review is a trial proceeding conducted with the USPTO Patent Trial and Appeal Board (PTAB) to review the patentability of one or more claims of a patent. Such review is limited to grounds of novelty and obviousness on the basis of prior art consisting of patents and printed publications. Although a petition for Inter Partes Review has been filed, grant of the petition by the PTAB is required for the proceeding to be instituted.

Graybar is a Delaware limited liability company formed less than 6 months ago and currently has no marketed products. Graybar's principal leading this initiative is Kevin Barnes, founder of Ferrum Ferro Capital, LLC, a New York-based hedge fund. At this time, it does not appear that Graybar has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for approval to market a generic version of Treximet. Graybar has not provided POZEN or Pernix with notification of an ANDA or a "paragraph IV certification" under 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act. Generally, such a certification states that the ANDA applicant believes that the claims of a patent to which a paragraph IV certification is made do not properly prevent that ANDA applicant from commercializing the product that is the subject of its ANDA. When an ANDA contains a paragraph IV certification, notice of that certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA.

Pernix will oppose the request to institute the IPR, and if it is allowed to proceed, we will oppose the full proceedings. Pernix is confident in the validity of the '183 patent and the other FDA Orange Book listed patents covering Treximet.

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, thereunto duly authorized.

PERNIX THERAPEUTICS HOLDINGS, INC.

Dated: November 13, 2015

By: /s/ Sanjay Patel
Sanjay Patel
Chief Financial Officer