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): February 05, 2019

Pain Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-29959**	**91-1911336**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

7801 N Capital of Texas Highway, Suite 260, Austin, TX 78731
(Address of Principal Executive Offices) (Zip Code)

512-501-2444
(Registrant's telephone number, including area code)

Not Applicable
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
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 5, 2019, Pain Therapeutics, Inc. (the "Company") issued a press release announcing feedback from a recent meeting with the U.S. Food and Drug Administration. A copy of Company's press release is attached hereto as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit No. Description.

99.1	Press Release issued by Pain Therapeutics, Inc. on February 5, 2019

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.

Pain Therapeutics, Inc.

Date: February 08, 2019

By: /s/ Eric J. Schoen
Eric Schoen
Chief Financial Officer

Exhibit 99.1

Pain Therapeutics, Inc.

Pain Therapeutics Announces Feedback from Recent Meeting with FDA on REMOXY

- Going Forward, We Will Be Silent Regarding Future Expectations for REMOXY -

AUSTIN, TX – February 5, 2019 – Pain Therapeutics, Inc. (Nasdaq: PTIE), a clinical-stage drug development company, today announced feedback from a meeting held January 31, 2019 with the U.S. Food and Drug Administration (FDA) regarding the drug candidate, REMOXY ER. REMOXY is the trade name for a new type of abuse-deterrent, extended-release gel formulation of oxycodone (CII) with physical/chemical properties intended to deter abuse. As previously disclosed, we requested this meeting to resolve disagreement around comments and conclusions made by FDA in 2018 during a regulatory review of a New Drug Application (NDA) for REMOXY.

During this meeting, we learned that i) FDA denies making math errors, material mistakes or misrepresentations during a June 2018 Advisory Committee Meeting for REMOXY, despite clear evidence to the contrary; ii) comparator data is irrelevant for the evaluation of abuse-deterrent properties, despite FDA written guidance which explicitly states the opposite; and (ii) that we would need to rely on the Freedom of Information Act to access additional data generated by FDA with REMOXY. As a result of our recent meeting with FDA, we believe we are no closer today to product approval than we were over a year ago.

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"REMOXY remains an odyssey without a homecoming," said Remi Barbier, President & CEO of Pain Therapeutics. "We had hoped for a fair, neutral and impartial review of the REMOXY data. Instead, we walked out of this meeting feeling a bit disoriented by FDA's lack of transparency, clarity or helpfulness. It's a rare occasion when two parties can't agree on simple math. We can't work with shambolic regulations. This is not how you win support for innovation."

Historically, the lead candidate in our pipeline has been REMOXY, an analgesic drug that we conceived, patented, developed and tested in collaboration with corporate and academic partners. Over the years, we have conducted a successful clinical development program for REMOXY, including a large, well-controlled pivotal Phase III efficacy study whose primary endpoints met statistical significance ($p<0.05$). The clinical safety or analgesic efficacy of REMOXY for its intended purpose is not in question. Its abuse-deterrent properties, however, are subject of a difference of opinion. Abuse deterrence refers to properties that are embedded into an opioid formulation to prevent certain common methods of abuse. During the long development history of REMOXY, we generated nearly 9,000 unique data points in over 50 studies at a cost in excess of $100 million. Studies were designed in consultation with FDA and conducted by independent labs. Collectively, we believe these studies adequately characterize REMOXY's abuse-deterrent properties. In particular, we demonstrated that the two currently marketed extended-release oxycodone products -- OxyContin® and Xtampza® -- which both benefit from abuse-deterrent label claims, can both be defeated for purposes of abuse in under a minute using common household items. In contrast, REMOXY requires a significant investment of time, effort and equipment to defeat, and even then, results in less release of oxycodone. During our recent meeting with FDA we were informed they believe REMOXY capsules lack abuse deterrence via the injection route of abuse because "oxycodone can be extracted from the product", regardless of how much time, effort, frustration or equipment is required to so do. We are unable to follow the logic by which a drug product should never release drug. More generally, as the regulatory requirements for REMOXY have changed frequently and suddenly over time, we have experienced significant delays and have incurred unanticipated expenses related to the overall REMOXY development program.

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We believe innovative products such as REMOXY can serve a meaningful social purpose and, potentially, may save lives during the worst drug crisis in American history. By necessity, however, we rely on reasonably predictive regulatory pathways to guide our product candidates through development in preparation for commercialization. We also rely on principles of good governance, in which similar drugs receive similar regulatory treatment under rules that are clear, publicized, and evenly applied. In our experience with REMOXY, the regulatory environment around abuse-deterrence lacks these essential qualities.

There are procedures in place at the FDA and other government agencies to help promote a fair resolution of disputes. Such procedures can be complex and may not be rapid, predictable or even viable. Going forward, we will generally be silent regarding our plans or future expectations for REMOXY, unless a significant material event occurs that compels us to update our public disclosures around this product candidate.

About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a clinical-stage biopharmaceutical company that develops novel drugs. Our focus is on neurodegeneration, including an on-going Phase II program with our drug candidate, PTI-125, in patients with Alzheimer's disease. We own worldwide development and commercial rights to PTI-125 and related technology, including diagnostic, without royalty or milestone obligations to any third-parties. The FDA has not yet established the safety or efficacy of any of our drug candidates. For more information, please visit www.paintrials.com.

For More Information Contact:
Eric Schoen
Chief Financial Officer
Pain Therapeutics, Inc.
(512) 501-2450

Note Regarding Forward-Looking Statements*: This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Pain Therapeutics disclaims any intent or obligation to update these forward-looking statements and claims the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, statements regarding the clinical status of PTI-125 and the Company's future plans, if any, for its abuse-deterrent product candidates, such as REMOXY. Such statements are based on management's current expectations, but actual results may differ materially due to various factors. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the ability to demonstrate the specificity, safety, efficacy or potential health benefits of a blood-based diagnostic. For further information regarding these and other risks related to our business, investors should consult our filings with the U.S. Securities and Exchange Commission.*

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