

PAIN THERAPEUTICS INC  
Form 8-K  
March 22, 2019  
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): March 20, 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. ☐

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Item 1.02. Termination of a Material Definitive Agreement.

In November 2018, Pain Therapeutics, Inc. (the “Company”) announced that it had petitioned the U.S. Food and Drug Administration (the “FDA”) in connection with a Complete Response Letter it had received in August 2018, which commented on REMOXY’s New Drug Application, the product’s abuse deterrent properties and overall risk/benefit profile. The Company requested that the FDA re-examine our data on REMOXY. The FDA agreed to discuss the matter in January 2019. In February 2019, the Company announced the results from the January 2019 meeting with the FDA, and as a result, concluded that no further progress was made with respect to REMOXY product approval.

On March 20, 2019, the Company sent a letter to Durect Corporation pursuant to the Development and License Agreement, dated as of December 19, 2002, as amended (the “DLA”), that provided Durect Corporation with written notice of termination without cause of the DLA. The termination becomes effective no later than 90 days from March 20, 2019.

This and other actions effectively ends the Company’s development of REMOXY ER and the Company’s contractual relationship with Durect Corporation.

The written notice of termination without cause of the DLA is filed herewith as Exhibit 10.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit No. Description.

<u>10.1</u>	<u>Pain Therapeutics, Inc. termination notice to Durect Corporation dated March 20, 2019</u>
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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: March 22, 2019    By: /s/ Eric J. Schoen  
Eric J. Schoen  
Chief Financial Officer

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