



## **Pain Therapeutics, Inc.**

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### **Pain Therapeutics Reports First Quarter 2018 Financial Results and Provides Corporate Update on REMOXY<sup>®</sup> ER**

**– June 26<sup>th</sup> Advisory Committee Meeting for REMOXY ER –**

**– August 7<sup>th</sup> PDUFA Target Date for REMOXY ER –**

**AUSTIN, Texas – May 9, 2018** – Pain Therapeutics, Inc. (Nasdaq: PTIE), a drug development company, today reported financial results for the first quarter ended March 31, 2018. Net loss was \$2.2 million, or \$0.33 per share. This compared to a net loss of \$2.7 million, or \$0.42 per share, for the same period in the prior year. Cash and cash equivalents were \$10.7 million as of March 31, 2018.

“FDA’s acceptance of the NDA filing for REMOXY ER in Q1 2018 is a milestone”, said Remi Barbier, Chairman, President & CEO. “Our focus is now on REMOXY ER’s potential to receive marketing clearance later this year. As part of this focus, we are preparing a strategic and thorough presentation of our key data for an upcoming FDA Advisory Committee Meeting for REMOXY ER, scheduled for June 26<sup>th</sup> in Washington, DC. We also continue to maintain tight fiscal discipline, and to advance our early-stage programs with non-dilutive funding.”

*– more –*

### **Financial Highlights for First Quarter 2018**

- Net loss for the quarter was \$2.2 million, or a net loss per share of \$0.33. This compared to a net loss of \$2.7 million, or \$0.42 per share, for the same period in the prior year, representing a 19% decrease.
- Cash and cash equivalents were \$10.7 million. This compared to \$10.5 million in the prior quarter, representing a 2% increase. Cash and cash equivalents for the quarter includes \$1.9 million of net proceeds raised through issuance of shares of our common stock under a Capital on Demand™ program with JonesTrading Institutional Services LLC.
- We have no debt.
- We believe existing capital resources are sufficient to meet our projected operating requirements for at least the next 12 months.
- We received \$0.4 million in research grant funding from the National Institutes of Health, recorded as a reduction in research and development expenses (R&D).
- R&D expenses were \$1.1 million. This compared to \$1.4 million for the same period in the prior year, representing a 23% decrease. R&D expenses included non-cash stock related compensation costs of \$0.4 million, versus \$0.3 million for the same period in the prior year.
- General and administrative (G&A) expenses were \$1.1 million. This compared to \$1.4 million for the same period in the prior year, representing a 20% decrease. G&A expenses included non-cash stock-related compensation costs of \$0.5 million, versus \$0.5 million for the same period in the prior year.

## **About REMOXY ER (extended-release oxycodone capsules CII)**

REMOXY ER is in registration with the US Food and Drug Administration (FDA) as a new type of abuse-deterrent, twice-daily, capsule gel formulation of oral oxycodone, a strong opioid drug. REMOXY ER has physical/chemical properties intended to deter abuse and still provide 12 hours of steady pain relief when properly prescribed by physician and used appropriately by patients.

Studies were extensive. The clinical efficacy of REMOXY ER was established in a Phase III study conducted under a Special Protocol Assessment. In total, over 2,400 subjects were exposed to REMOXY ER in 30 clinical studies. 9,000 unique data points were generated from 11 lab studies. The assessment of REMOXY ER's abuse deterrence is supported by data from FDA Category 1 (lab), Category 2 (pharmacokinetic) and Category 3 (human abuse potential) studies. In addition, in November 2017 the Company and FDA held a pre-NDA meeting to confirm the sufficiency of data included in the REMOXY ER NDA resubmission.

REMOXY ER has a thick, sticky, high viscosity, hydrophobic, gel formulation that abusers cannot cut, grate or divide into smaller discrete particle sizes. The gel formulation resists syringe-ability, injection, and rapid extraction in ingestible solvents. REMOXY ER's high viscosity and adhesive properties also cause it to stick to tools and equipment used for abuse. When exposed to heat, REMOXY ER releases an irritant to the eyes and lungs. REMOXY ER resists dose-dumping when challenged by alcohol and common physical and chemical manipulations.

We are requesting marketing approval of REMOXY ER as an analgesic drug with properties that can be expected to deter against injection, snorting and inhalation/smoking routes of abuse.

REMOXY ER intends to address the public health epidemic related to prescription opioids by advancing the science of abuse deterrence, providing an additional treatment option for physicians and patients, and increasing the range of available abuse deterrent technologies.

## **About Opioid Abuse**

Opioid drugs such as oxycodone are an important treatment option for patients with severe chronic pain. However, oxycodone abuse and diversion remain serious, persistent problems. Opioid overdose deaths exceeded 64,000 in 2016, according to the Center for Disease Control (CDC). For over a decade, Pain Therapeutics has pioneered Abuse-Deterrent Formulations (ADFs) to help in the fight against prescription drug abuse. ADFs attempt to raise the bar on prescription drug abuse by making it more difficult, longer or aversive to tamper with long-acting opioid formulations, recognizing that no drug can be made abuse-proof.

## **Our Pipeline of Drug Assets also Includes:**

**FENROCK™** (transdermal fentanyl patch system) – This is a proprietary, abuse-deterrent skin patch for severe pain. FENROCK is an early-stage program, substantially funded by a research grant award from National Institute on Drug Abuse (NIDA).

**PTI-125** – This proprietary, small molecule drug candidate is aimed at the treatment of Alzheimer’s disease. PTI-125 is a Phase I clinical-stage program, substantially funded by a research grant award from the National Institutes of Health (NIH).

**PTI-125DX** – This is a proprietary blood-based test to detect Alzheimer’s disease. PTI-125DX is an early-stage program, substantially funded by a research grant award from the NIH.

## **About Pain Therapeutics, Inc.**

We develop proprietary drugs that offer significant improvements to patients and physicians. Our expertise consists of developing new drugs and guiding these through various regulatory and development pathways in preparation for their eventual commercialization. We generally focus our drug development efforts around disorders of the nervous system. The FDA has not yet established the safety or efficacy of our drug candidates.

*NOTE: REMOXY® ER and FENROCK™ are trademarks of Pain Therapeutics, Inc.*

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*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 Company's financial future; the abuse deterrent properties of REMOXY ER; the timing of the regulatory review by the FDA of the REMOXY NDA; the potential approval by the FDA of REMOXY ER; or the therapeutic and commercial value, if any, of our pipeline of drug assets. The Company cautions that forward-looking statements are inherently uncertain. 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 development and testing of our drug candidates; unexpected adverse side effects or inadequate therapeutic efficacy of our drug candidates; the uncertainty of patent protection for our intellectual property or trade secrets; unanticipated additional research and development, litigation and other costs; the need to raise additional funding from time-to-time, and the potential for abuse-deterrent pain medications or other competing products to be developed by competitors and potential competitors or others. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release. 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 (SEC), which are available on the SEC's website at [www.sec.gov](http://www.sec.gov).*

– Financial Tables Follow –

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PAIN THERAPEUTICS, INC.		
CONDENSED STATEMENTS OF OPERATIONS		
(in thousands, except per share amounts)		
(Unaudited)		
	Three months ended March 31,	
	2018	2017
Operating expenses		
Research and development	\$ 1,068	\$ 1,388
General and administrative	1,099	1,376
Total operating expenses	2,167	2,764
Operating loss	(2,167)	(2,764)
Interest income	7	21
Net loss	\$ (2,160)	\$ (2,743)
Net loss per share, basic and diluted	\$ (0.33)	\$ (0.42)
Weighted-average shares used in computing net loss per share, basic and diluted	6,638	6,535
CONDENSED BALANCE SHEETS		
(in thousands)		
	March 31, 2018	December 31, 2017
	(Unaudited)	
<b>Assets</b>		
Current assets		
Cash, cash equivalents and marketable securities	\$ 10,734	\$ 10,479
Other current assets	155	184
Total current assets	10,889	10,663
Other assets	169	168
Total assets	\$ 11,058	\$ 10,831
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable and accrued development expenses	\$ 439	\$ 823
Other accrued liabilities	319	309
Total current liabilities	758	1,132
Non-current liabilities	—	—
Total liabilities	758	1,132
Stockholders' equity		
Common Stock and additional paid-in-capital	169,859	167,098
Accumulated other comprehensive income	—	—
Accumulated deficit	(159,559)	(157,399)
Total stockholders' equity	10,300	9,699
Total liabilities and stockholders' equity	\$ 11,058	\$ 10,831

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