Pain Therapeutics, Inc.

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# Pain Therapeutics Reports Q3 2015 Financial Results and Update on REMOXY

**- Focus Remains on NDA Resubmission to FDA, Targeted for Q1 2016 -**

**AUSTIN, Texas – November 9, 2015** – Pain Therapeutics, Inc. (Nasdaq: PTIE) today reported financial results for the quarter ended September 30, 2015. Net loss in Q3 2015 was $3.7 million, or $0.08 per share, compared to a net loss in Q3 2014 of $3.5 million, or $0.08 per share.

We had $34.9 million of cash and investments at September 30, 2015 and no debt. We continue to expect that net cash usage for full-year 2015 will be approximately $12 million.

"We are excited by our progress and recent data with REMOXY", said Remi Barbier, President and CEO of Pain Therapeutics. "We think the data all point in a good direction for the future of REMOXY. We also continue to believe REMOXY is on-track for an NDA resubmission in Q1 2016."

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## Update on REMOXY®

Since last quarter, we have compiled and reviewed a sea of data necessary for the completion of the REMOXY NDA. This includes interim results from stability tests made on commercial drug lots. Test results demonstrate that REMOXY meets the regulatory guidance on drug dissolution specifications at 18 months, which we believe supports a resubmission of the REMOXY NDA. Importantly, we believe these data address prior concerns over the dissolution and stability of the REMOXY formulation.

We also continue to make good progress with commercial manufacturing for REMOXY. Working in conjunction with our commercial manufacturing partner, over a dozen batches of REMOXY have now been made at commercial scale.

In May, we announced positive top-line results of a human abuse potential study with REMOXY. That study was paid for, conducted and analyzed by our previous corporate partner for REMOXY. Since then, we have hired a third-party consultant to conduct an independent statistical analysis of that study. Independent analysis supports our previous disclosure that REMOXY met the study's primary endpoints with statistical significance in this FDA Category 3 Human Abuse Potential Study.

With regards to the NDA itself, we are making substantial progress towards its completion and eventual electronic submission to FDA. This is a 505(b)(2) submission for which we have completed -- and sent to our consultants for publishing to the NDA -- many elements of each module of the actual NDA since last quarter.

In addition, since last quarter we have also completed study reports for four clinical studies conducted by our previous corporate partner for REMOXY: dose-proportionality study, pivotal bioequivalence study, food-effect study and alcohol interaction study.

We also continue to review and discuss with third-parties potential commercialization strategies for REMOXY. We have previously disclosed that such potential strategies may include consummating a strategic transaction that monetizes our entire pipeline of drug candidates; forming a commercial collaboration around REMOXY; or building a small, highly focused in-house sales and marketing team.

## Other Highlights for Q3 2015

- In September 2015, we announced that the National Institutes of Health (NIH) had awarded us a $1.7 million innovation grant. This grant award provides a path forward for us to develop PTI-125, which is a novel small molecule drug that offers a promising new approach to treat Alzheimer's Disease. Using this NIH grant award, we have now started to conduct pre-clinical studies that are expected to enable an Investigational New Drug (IND) regulatory filing for PTI-125. We own all world-wide commercial rights to PTI-125.

- We also continue to develop FENROCK™, a proprietary abuse deterrent transdermal pain patch (fentanyl). We previously generated proof-of-concept studies. More recently, we have filed new intellectual property around FENROCK. As a next step, in 2016 we expect to develop a final formulation using FENROCK technology. We own all world-wide commercial rights to FENROCK.

## Financial Highlights for Q3 2015

- At September 30, 2015, cash and investments were $34.9 million, compared to $37.3 million at June 30, 2015. The Company has no debt.
- Net cash used in Q3 2015 was $2.4 million.
- Research and development expenses increased to $2.4 million in Q3 2015 from $2.1 million in Q3 2014, primarily due to increased activities related to REMOXY, and included non-cash stock-related compensation costs of $0.3 million in Q3 2015 and $0.5 million in Q3 2014.
- General and administrative expenses decreased to $1.3 million in Q2 2015 from $1.4 million in Q3 2014, primarily due to lower non-cash stock-related compensation costs, and included non-cash stock-related compensation costs of $0.5 million in Q3 2015 and $0.6 million in Q3 2014.

### About REMOXY®

We own world-wide commercial rights to our lead drug candidate, REMOXY Extended-Release Capsules CII, a unique, twice-a-day formulation of oral oxycodone. REMOXY's intended indication is for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time and for which alternative treatments are inadequate. REMOXY's sticky, high viscosity formulation is specifically intended to discourage certain common methods of drug tampering and misuse, such as injection and snorting. The REMOXY NDA is supported by multiple clinical trials, including a successful Phase III efficacy program that was conducted under a Special Protocol Assessment.

### About Pain Therapeutics, Inc.

Pain Therapeutics, Inc. is a biopharmaceutical company that develops novel drugs. The FDA has not approved our drug candidates for commercial sale. For more information, please visit www.paintrials.com.

***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, our projected net cash usage in 2015; information and specific contents of an acceptable resubmission of the REMOXY New Drug Application, the timing of such resubmission, plans to develop PTI-125, conducting pre-clinical studies that are expected to enable an IND and the potential benefits of PTI-125; and the timing of announcement of a final formulation for FENROCK. 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 difficulties or delays in the return of REMOXY to us in connection with the termination of the Collaboration Agreement with our former corporate partner; difficulties or delays in completion of non-clinical activities for REMOXY and development and testing of our other 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 potential for abuse-deterrent pain medications or other competing products to be developed by competitors and potential competitors or others; and difficulties or delays in developing PTI-125 and the results of our pre-clinical studies of PTI-125 not supporting further development, which could result in termination of NIH funding prior to receipt of the entire $1.7 million grant. 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.*

– Financial Tables Follow –

PAIN THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Operating expenses | | | | |
| Research and development | $ 2,356 | $ 2,116 | $ 5,480 | $ 6,198 |
| General and administrative | 1,330 | 1,429 | 4,188 | 4,068 |
| Total operating expenses | 3,686 | 3,545 | 9,668 | 10,266 |
| Operating loss | (3,686) | (3,545) | (9,668) | (10,266) |
| Interest income | 15 | 11 | 40 | 36 |
| Net loss | $ (3,671) | $ (3,534) | $ (9,628) | $ (10,230) |
| Net loss per share, basic and diluted | $ (0.08) | $ (0.08) | $ (0.21) | $ (0.23) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 45,356 | 45,345 | 45,356 | 45,240 |

CONDENSED BALANCE SHEETS
(in thousands)

| | September 30, 2015 (Unaudited) | December 31, 2014[1] |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash, cash equivalents and marketable securities | $ 34,893 | $ 40,590 |
| Other current assets | 520 | 239 |
| Total current assets | 35,413 | 40,829 |
| Other assets | 240 | 77 |
| Total assets | $ 35,653 | $ 40,906 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable and accrued development expenses | $ 1,540 | $ 198 |
| Other accrued liabilities | 1,046 | 652 |
| Total current liabilities | 2,586 | 850 |
| Non-current liabilities | — | — |
| Total liabilities | 2,586 | 850 |
| Stockholders' equity | | |
| Common stock and additional paid-in-capital | 159,187 | 156,548 |
| Accumulated other comprehensive income | 1 | 1 |
| Accumulated deficit | (126,121) | (116,493) |
| Total stockholders' equity | 33,067 | 40,056 |
| Total liabilities and stockholders' equity | $ 35,653 | $ 40,906 |

(1) Derived from the Company's annual financial statements as of December 31, 2014, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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