
**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) September 22, 2015

Heron Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33221
(Commission
File Number)

94-2875566
(I.R.S. Employer
Identification No.)

123 Saginaw Drive
Redwood City CA
(Address of principal executive offices)

94063
(Zip Code)

Registrant's telephone number, including area code (650) 366-2626

N/A
(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 (see General Instruction A.2. below):

- 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))
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ITEM 8.01 Other Events.

On September 22, 2015, Heron Therapeutics, Inc. (the “Company”) issued a press release announcing top-line results from the Company’s Phase 2 clinical study of HTX-011 in the management of post-operative pain in patients undergoing bunionectomy, as described in the press release furnished herewith as Exhibit 99.1.

A copy of presentation materials describing the results of the Phase 2 clinical study of HTX-011 in patients undergoing bunionectomy, all or a part of which may be used by the Company in investor or scientific presentations from time to time, is furnished as Exhibit 99.2 hereto. The attached materials have also been posted on the Company’s website at www.herontx.com. The Company does not undertake any obligation to update this presentation.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 22, 2015
99.2	HTX-011 Presentation, dated September 2015

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.

Date: September 22, 2015

Heron Therapeutics, Inc.

/s/ Esme C. Smith

Esme C. Smith

Vice President, General Counsel & Secretary



Heron Therapeutics Reports Positive Top-Line Results from Phase 2 Study of HTX-011 in the Management of Post-Operative Pain

- Pain intensity through 24 hours reduced by 69%*
- Pain intensity through 72 hours reduced by 40%*
- Time to first use of opiate rescue medication increased by 488%*
- 32% of patients received no opiate rescue through 72 hours compared to 5% for placebo*

Conference call and webcast at 8:30 am ET on September 23

REDWOOD CITY, Calif. – September 22, 2015 – Heron Therapeutics, Inc. (NASDAQ: HRTX), a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs, today announced positive, top-line results from its Phase 2 clinical study of HTX-011 in the management of post-operative pain in patients undergoing bunionectomy. HTX-011, which utilizes Heron's proprietary Biochronomer® drug delivery technology, is a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam. The primary and all key secondary endpoints in the study were met with a high degree of statistical significance.

This randomized, placebo-controlled, double-blind, Phase 2 clinical study in 64 patients undergoing bunionectomy evaluated the efficacy and safety of HTX-011, containing 200 mg or 400 mg of bupivacaine combined with meloxicam, compared to placebo. The primary endpoint was the difference as compared to placebo in pain intensity as measured by the Summed Pain Intensity (SPI) score in the first 24 hours post-surgery (SPI 0-24). Key secondary endpoints included: the difference in SPI in the first 48 hours post-surgery (SPI 0-48); the difference in SPI in the first 72 hours post-surgery (SPI 0-72); time to the first use of opiate rescue medication; and the percent of patients who received no opiate rescue medication in the first 72 hours post-surgery. The study's major efficacy findings for the more effective, 400 mg dose of HTX-011 as compared to placebo include:

- Pain intensity in the first 24 hours post-surgery was reduced by 69% (SPI of 38.5 versus 124.2, $p < 0.0001$).
- Pain intensity in the first 48 hours post-surgery was reduced by 52% (SPI of 106.9 versus 224.8, $p < 0.0001$).

- Pain intensity in the first 72 hours post-surgery was reduced by 40% (SPI of 170.2 versus 285.9, p=0.0064).
- Time to the first use of opiate rescue medication was increased by 488% (48.2 hours versus 8.2 hours, p<0.0001).
- 32% of patients received no opiate rescue medication during the entire 72-hour period post-surgery, compared to 5% for placebo (p<0.0001).

HTX-011 was generally well tolerated in the study. The most frequent adverse events reported were headache, nausea, vomiting, erythema, cellulitis, dizziness, and hypoxia, none of which were considered drug-related.

“Although opioid analgesics are standard of care for post-operative pain management, too often they are associated with unacceptable adverse effects often prolonging hospitalization and recovery,” stated Jeffrey A. Gudin, MD, Director, Pain Management and Palliative Care, Englewood Hospital and Medical Center, Englewood, NJ. “Thus, there is a major unmet need for a pain management treatment that can substantially reduce our dependence on post-operative opioids. The ability of HTX-011, administered once during surgery, to significantly reduce pain and the need for pain medications for three days following surgery (as compared to a control group) is truly promising.”

“At Heron, we are dedicated to the development of best-in-class medicines that can have a major impact on patients’ lives,” commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. “We are very pleased with these results, and we now will turn our attention to executing on a broad-based development program designed to enable us to bring HTX-011 to the many patients undergoing a wide range of surgeries who experience significant post-operative pain.”

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Wednesday, September 23 at 8:30 a.m. ET (5:30 a.m. PT). The conference call can be accessed by dialing (877) 311-5906 for domestic callers and (281) 241-6150 for international callers. Please provide the operator with the passcode 46461973 to join the conference call. The conference call will also be available via webcast under the investor relations section of Heron’s website at www.herontx.com and will be archived there for 90 days following the call. Please connect to Heron’s website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About HTX-011 for Post-Operative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer® drug delivery technology, is a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. By delivering sustained levels of both a potent anesthetic and an anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while potentially reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. In September 2015, Heron reported positive top-line results from a Phase 2 study of HTX-011 in patients undergoing bunionectomy. In this study, HTX-011 significantly reduced pain intensity, significantly reduced the need for opioid rescue medications, and significantly increased the time to first use of rescue medications. HTX-011 is the subject of a broad-based development program designed to target the many patients undergoing a wide range of surgeries who experience significant post-operative pain.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents. Heron's goal is to build on therapeutics with well-known pharmacology by improving their tolerability and efficacy as well as broadening their potential field of use. Heron is currently developing four pharmaceutical products for patients suffering from cancer or pain. SUSTOL® (granisetron) Injection, extended release is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC). CINV is one of the most debilitating side effects of chemotherapy and is a leading cause of premature discontinuation of cancer treatment. Heron recently reported positive, top-line results from its Phase 3 MAGIC study. In July 2015, Heron resubmitted its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA), and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016. HTX-019, also being developed for the prevention of CINV, has the potential to become the first polysorbate 80-free, intravenous formulation of aprepitant, a neurokinin-1 (NK₁) receptor antagonist. Heron intends to file an NDA for HTX-019 using the 505(b)(2) regulatory pathway in the second half of 2016. HTX-011 is Heron's long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam. In September 2015, Heron reported positive, top-line results from a Phase 2 study of HTX-011 in patients undergoing bunionectomy. In this study, HTX-011 significantly reduced pain intensity and the need for opioid rescue medications. HTX-011 is the subject of a broad-based development program designed to target the many patients undergoing a wide range of surgeries who experience

significant post-operative pain. HTX-003, a long-acting formulation of buprenorphine, is being developed for the potential management of chronic pain and opioid addiction. All of Heron's product candidates utilize Heron's innovative science and technology platforms, including its proprietary Biochronomer® drug delivery technology, which can deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period of days to weeks with a single injection.

For more information, please visit www.herontx.com.

Forward Looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Heron cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, but are not limited to, those associated with: whether the U.S. Food and Drug Administration (FDA) approves the SUSTOL NDA as submitted or supports as broad of a labeled indication for SUSTOL as requested, the progress in the research and development of HTX-019, HTX-011, HTX-003 and our other programs, including the timing of preclinical, clinical, and manufacturing activities, safety and efficacy results from our studies that may not justify the pursuit of further development of our product candidates, the launch and acceptance of SUSTOL and new products generally, our financial position and our ability to raise additional capital to fund operations, if necessary, or to pursue additional business opportunities, strategic business alliances we may pursue or the potential acquisition of products or technologies, and our ability to grow our organization to sustain the commercial launch for SUSTOL, and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and Heron takes no obligation to update or revise these statements except as may be required by law.

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A Phase 2 Study of HTX-011 in the Management of Post-Operative Pain

Positive Top-Line Results

September 22, 2015



Forward-Looking Statements

This presentation contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with the development, regulatory approval, manufacture, launch and acceptance of new products, completion of clinical studies and the results thereof, the ability to establish strategic alliances and/or acquire desirable assets, progress in research and development programs and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. None of the Company's product candidates discussed in this presentation have been approved by the FDA or any other regulatory agency. Actual results may differ materially from the results anticipated in our forward-looking statements. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

Heron Post-Operative Pain Program



Objective:

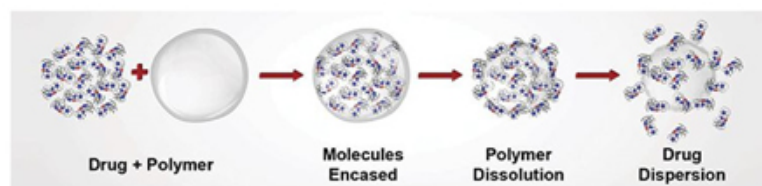
- Develop a best-in-class therapeutic for post-operative pain that can substantially reduce dependence on opiates

Target Product Profile:

- Maximal pain relief that lasts for 2-3 days
- Maximal reduction of opioid use
- Maximal reduction of length of hospital stay

Heron Post-Operative Pain Program

- Introducing HTX-011:
 - An injectable pain therapeutic that utilizes proprietary Biochronomer® polymer-based drug delivery platform technology
 - Contains bupivacaine and low concentration of meloxicam
 - Designed to deliver both drugs evenly over 2-3 days



HTX-011 builds on other innovations in the category and has best-in-class potential

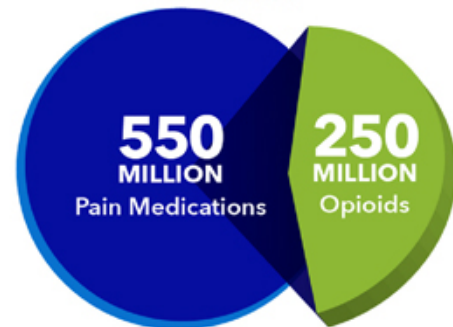
Post-Operative Pain Market

Surgeries Per Year

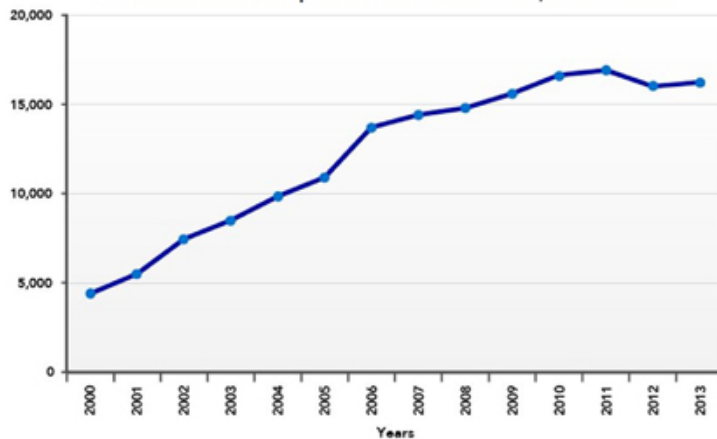
69 Million
in U.S.
234 Million
Worldwide

65%
Will Experience
Moderate-to-Severe
Post-Operative Pain

Annual Rx in U.S.



Deaths Due to Opioid Overdose: U.S., 2000-2013



Opiate analgesics, the cornerstone of post-operative pain management, are associated with:

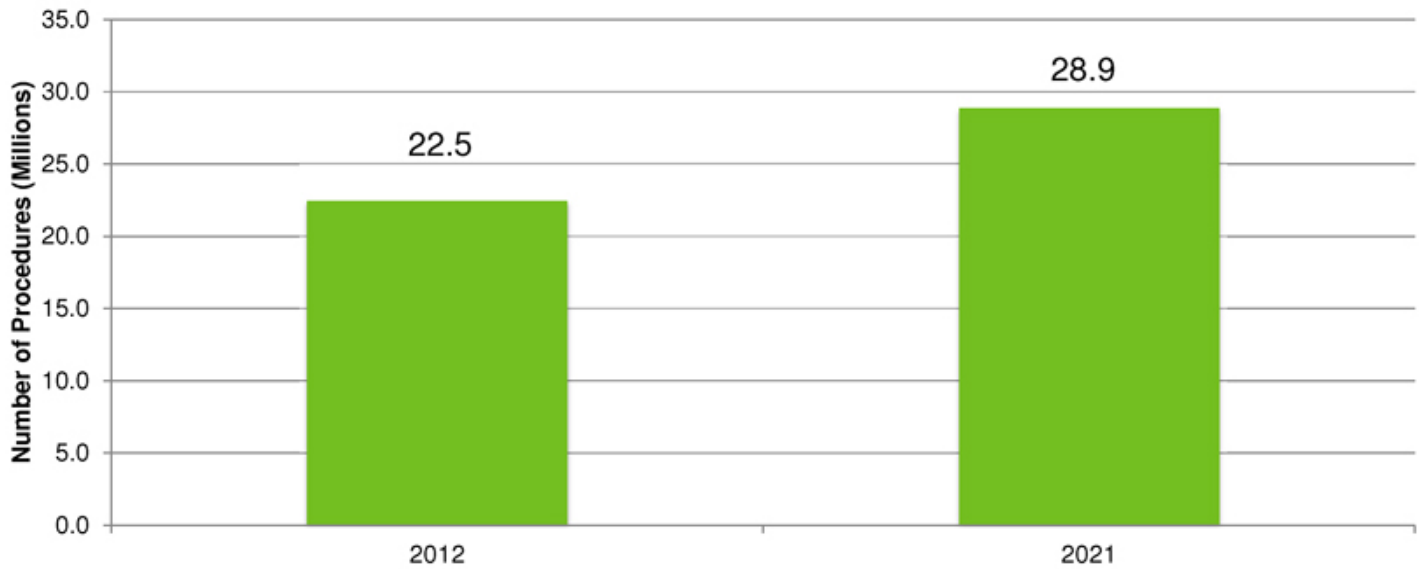
- Harmful side effects
- Longer hospital stays
- Abuse
- Addiction

Sources: Centers for Disease Control and Prevention, 2015; Weiser et al, *Lancet*, 12;372(9633):139-44, 2008; Coley et al, *J Clin Anesth*, 14(5):349-53, 2002; Symphony Health; United Nations Office on Drugs and Crime, 2015

Procedures Eligible for Long-Acting Local Anesthetic



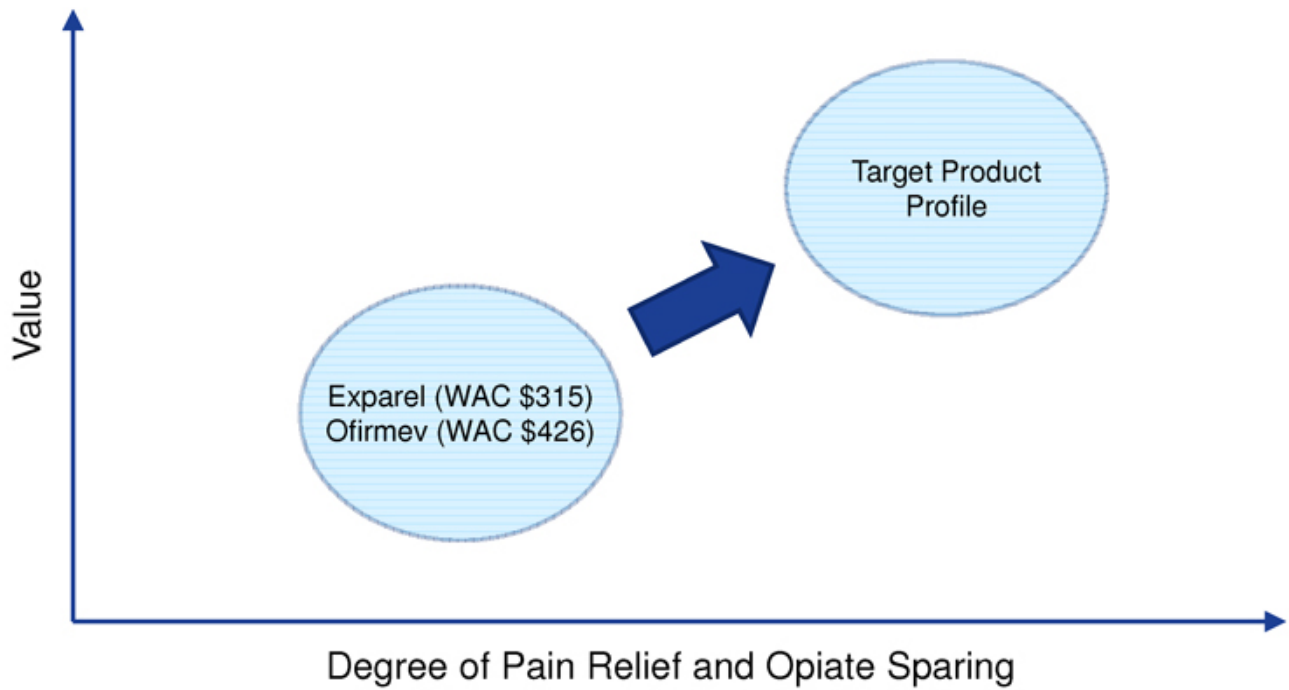
Estimated Number of Procedures in the U.S. Eligible for Long-Acting Local Anesthetic




Sources: Decision Resources, *Commercial Market Assessment: Post-Operative Pain, 2013*



Superior Efficacy Would Address Major Unmet Medical Need

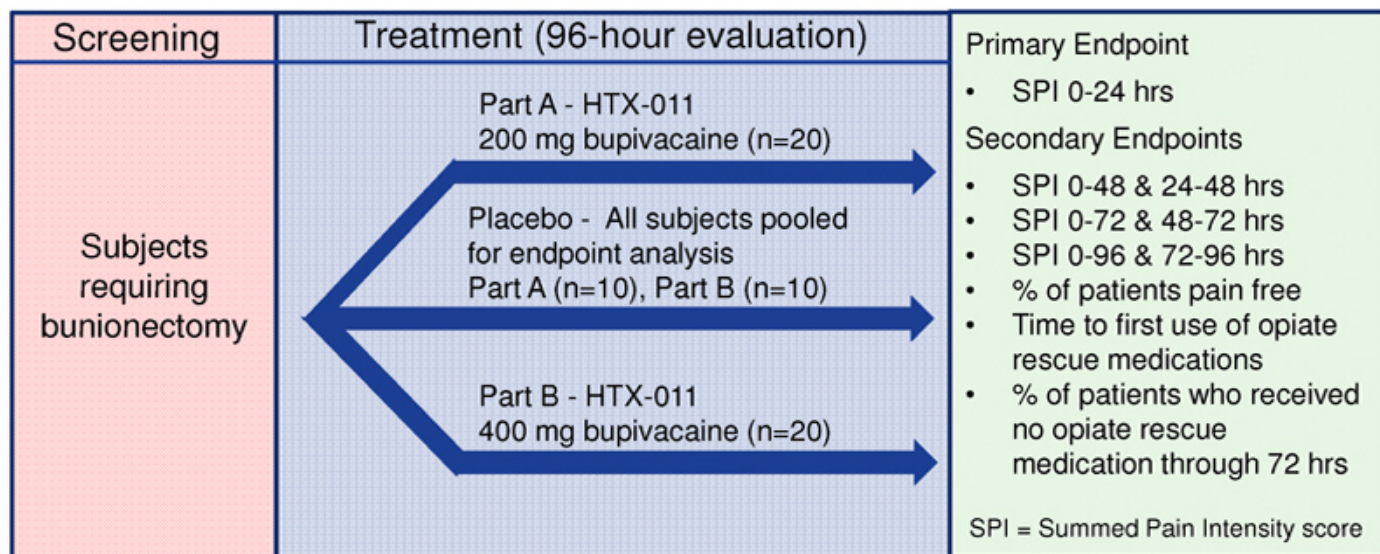


Source: PriceRx



**A Randomized, Placebo-
Controlled, Double-Blind, Phase 2
Study of HTX-011 in the
Management of Post-Operative
Pain in 64 Patients Undergoing
Bunionectomy**

Study Design

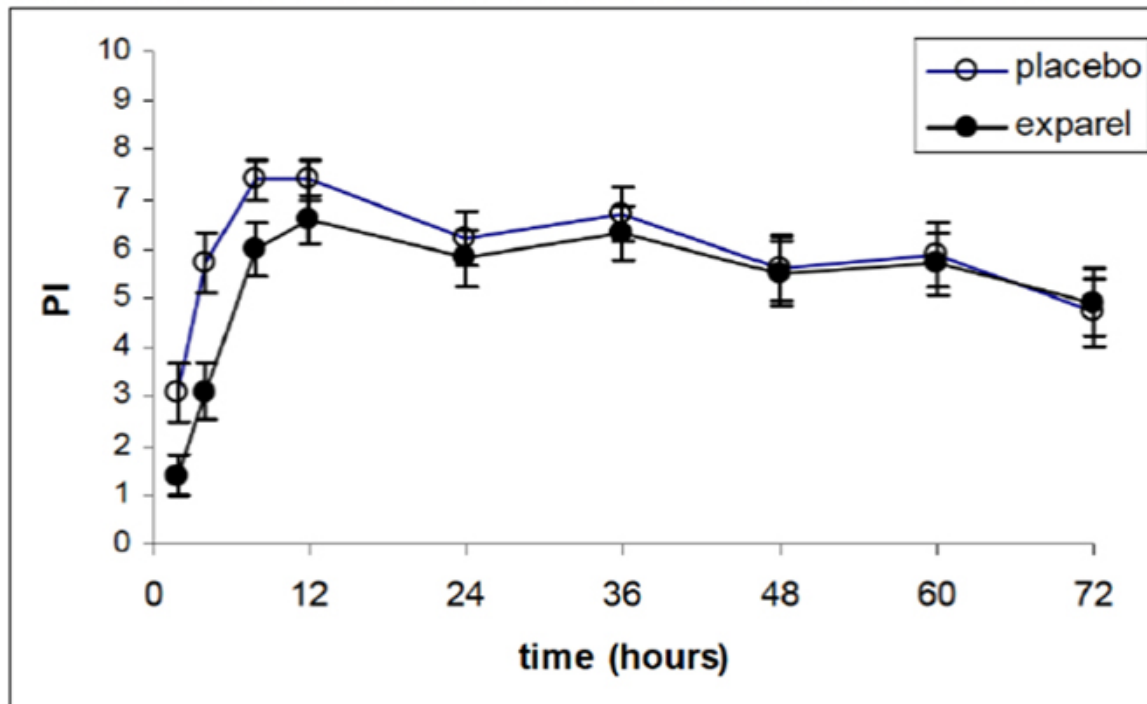


Efficacy assessments:

- Pain intensity scores (NPRS) using 0-10 point scale at 1, 2, 4, 6, 8, 10, 12, 14, 18, 24, 30, 36, 42, 48, 54, 60, 72, 78, 84, and 96 hours after administration of study medication
- Patient's global assessment of pain control at 24, 48, 72, and 96 hours after administration of study medication
- Percent of patients who are pain free, use of rescue medication, and nausea assessments (NNRS) at 6, 24, 48 and 72 hours after administration of study medication

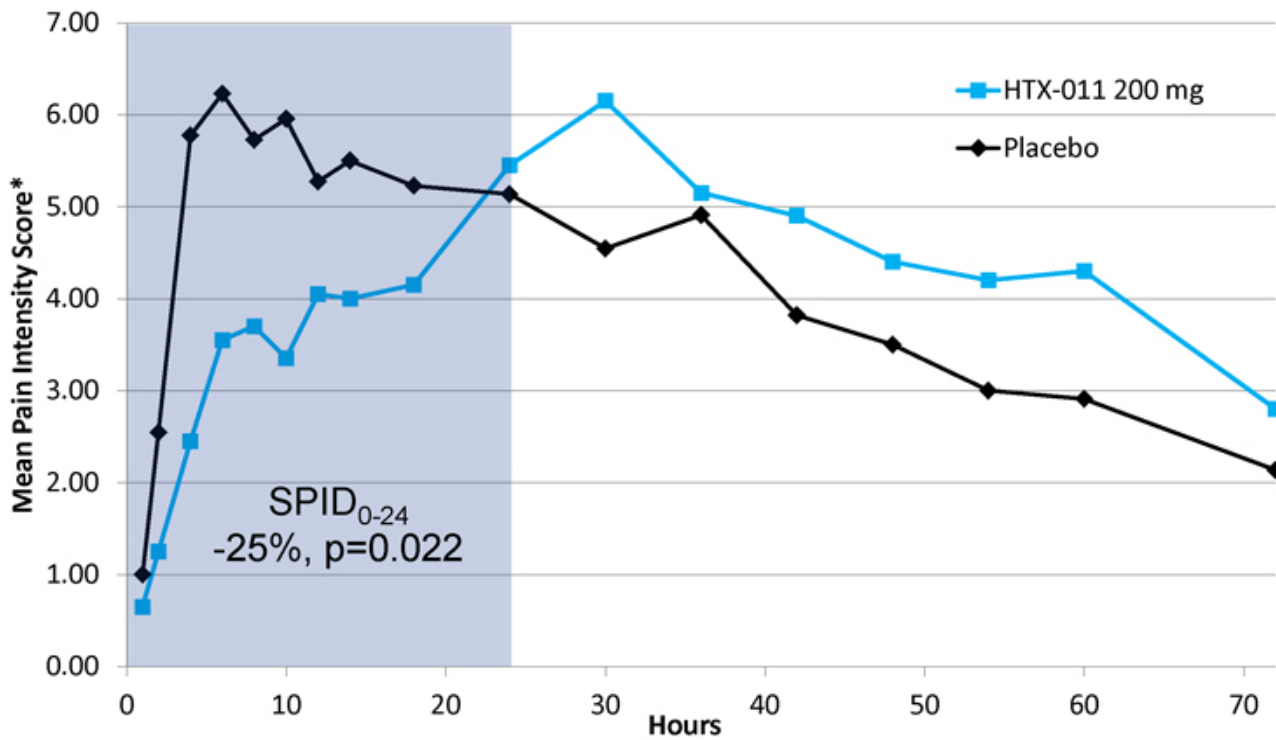
Historical Context: Exparel Pivotal Bunionectomy Study

Figure 2. Mean Pain Intensity versus Time plot for bunionectomy study (C-317)



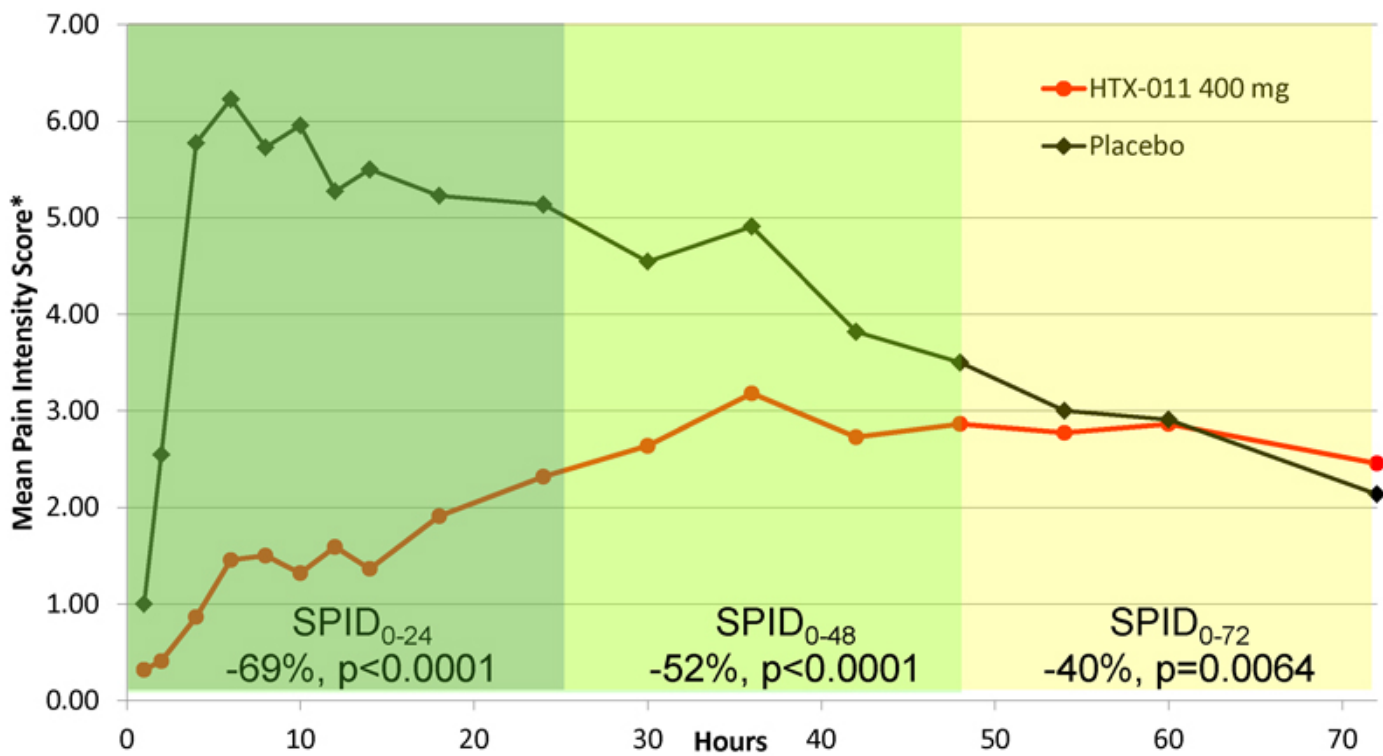
Source: FDA Clinical Review of NDA 022-496, page 48

Pain Intensity Difference at Low Dose



*Standard LOCF method used to account for use of rescue medications from *Golf et al, Adv Ther, 28(9):776-788, 2011*

Pain Intensity Difference at High Dose



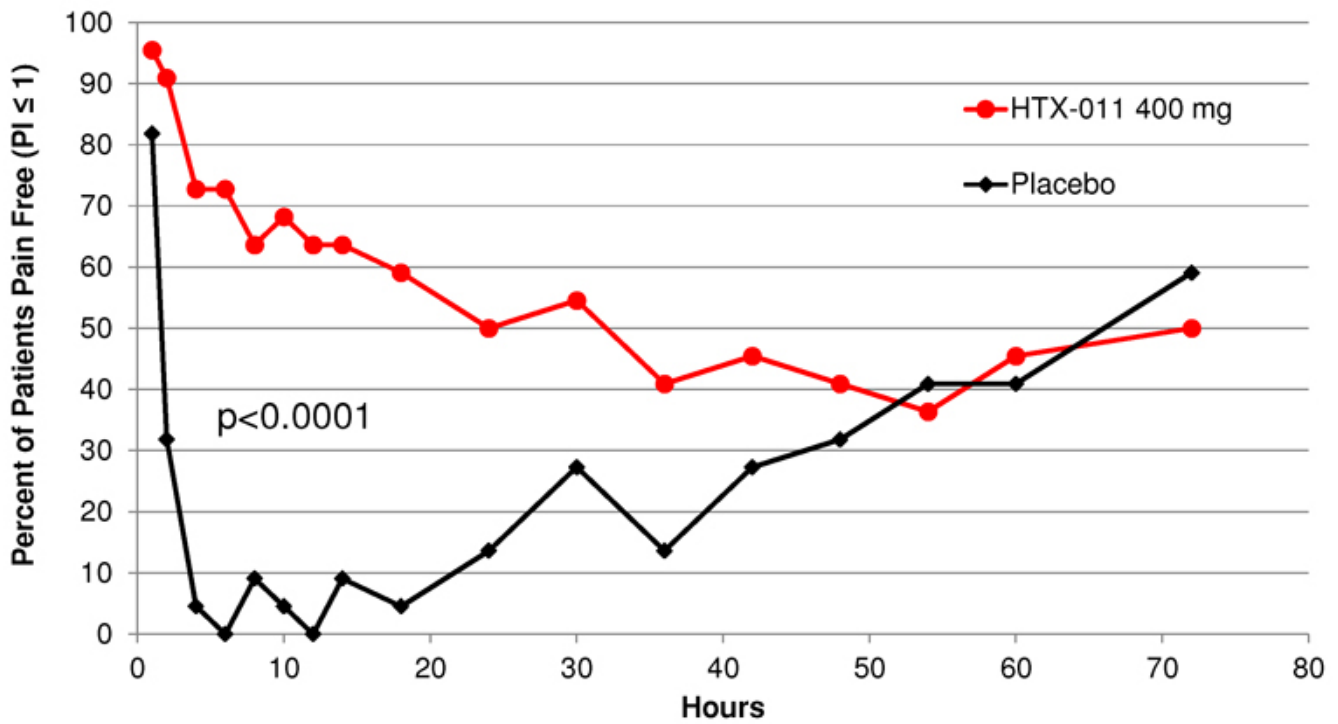
*Standard LOCF method used to account for use of rescue medications from *Golf et al, Adv Ther, 28(9):776-788, 2011*

Summed Pain Intensity (SPI) and Summed Pain Intensity Difference (SPID) over Time

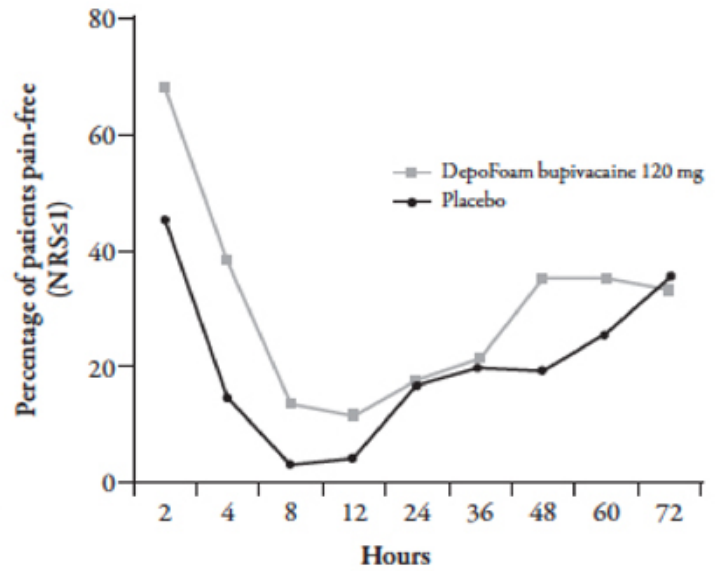
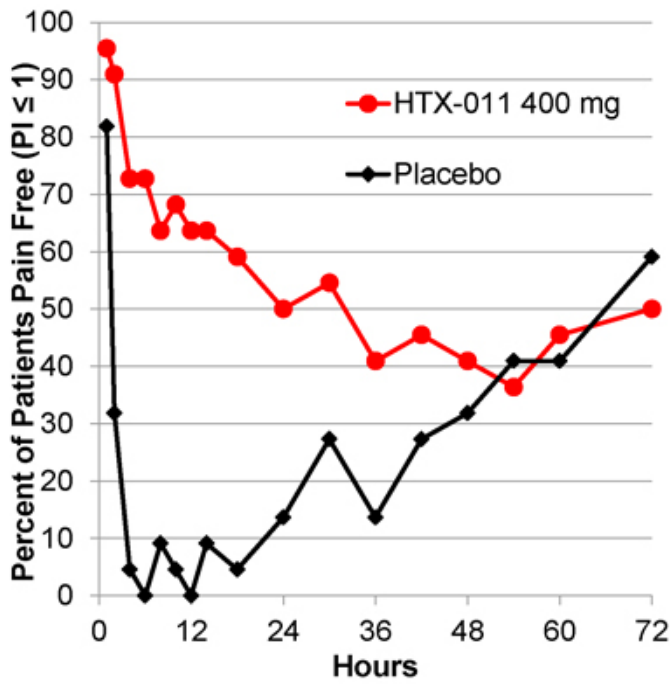
- Patients receiving HTX-011 had significantly lower pain scores for all three time periods of interest

	SPI Placebo	SPI HTX-011 400 mg	SPID
0–24 hours	124.2	38.5	-85.7 (-69%) p<0.0001
0–48 hours	224.8	106.9	-117.9 (-52%) p<0.0001
0–72 hours	285.9	170.2	-115.7 (-40%) p=0.0064

Percent of Patients Pain Free



Historical Context: Percent of Patients Pain Free, Cross-Study Comparison to Exparel



Source: Golf et al, *Adv Ther*, 28(9):776-788, 2011

Mean Time to First Use of Opiate Rescue Medication

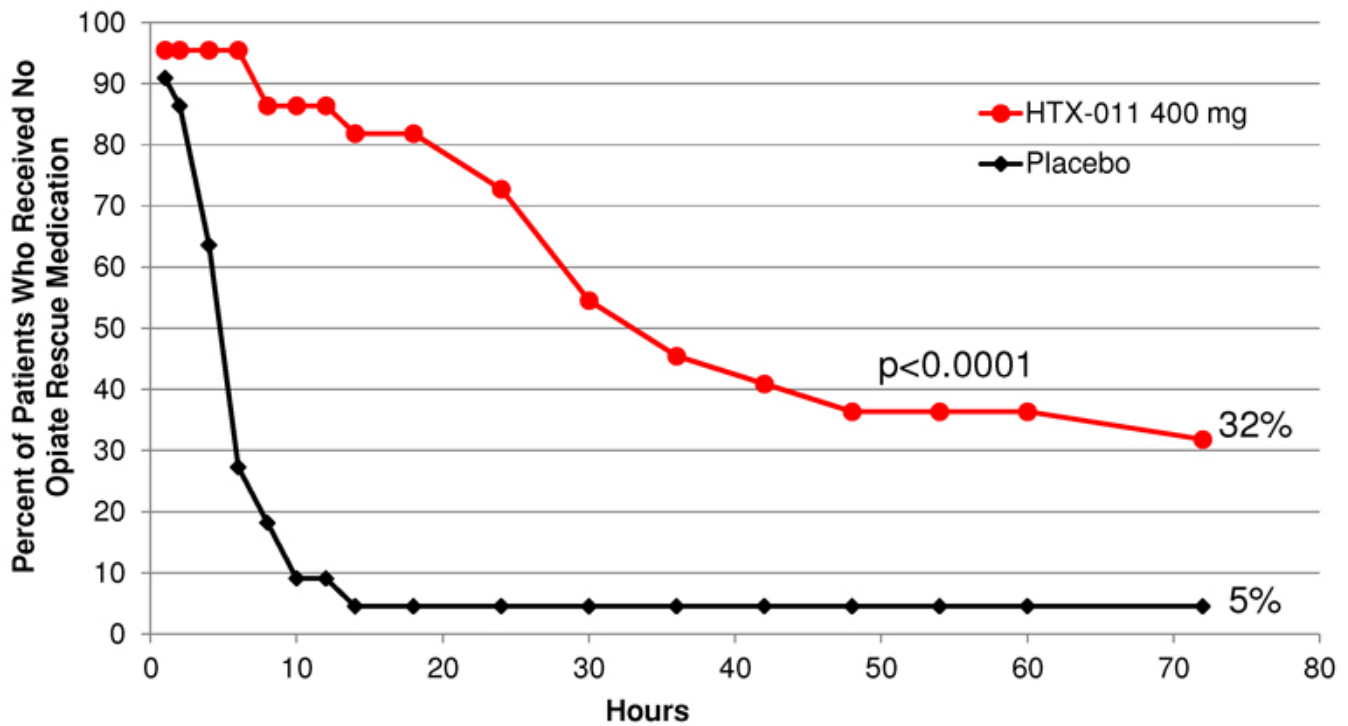
- 488% longer time to first use of rescue medications

Placebo	HTX-011 200 mg	HTX-011 400 mg
8.2 hours	20.8 hours p=0.15	48.2 hours p<0.0001

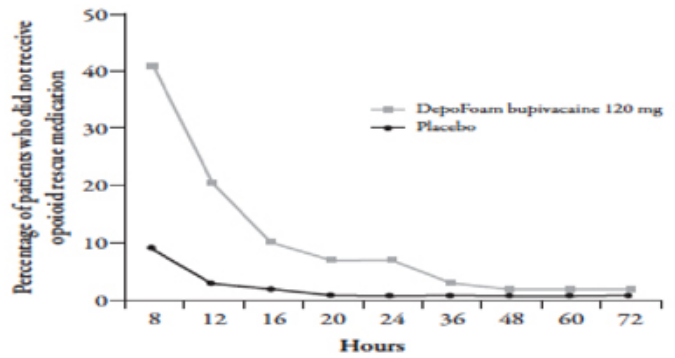
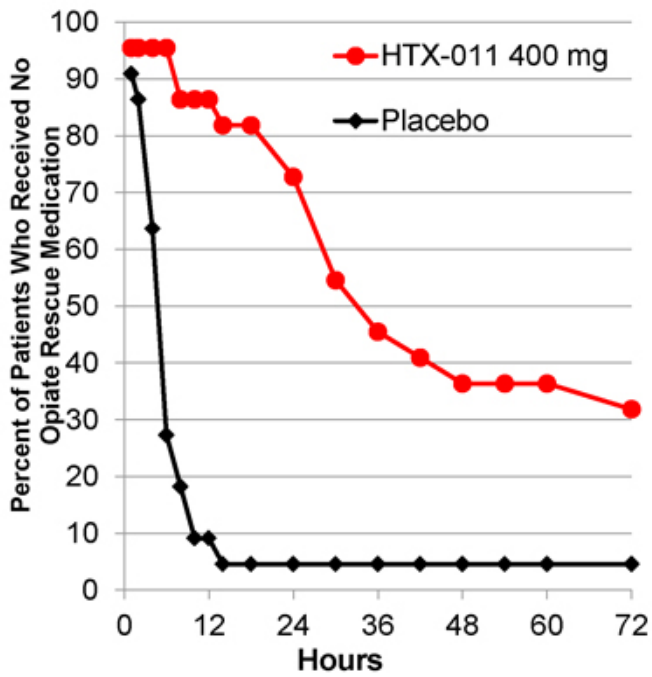
Cross-study comparison: Mean time with Exparel was 7.2 hours versus 4.3 hours on placebo

Source: Golf et al, *Adv Ther*, 28(9):776-788, 2011

Percent of Patients Who Received No Opiate Rescue Medication

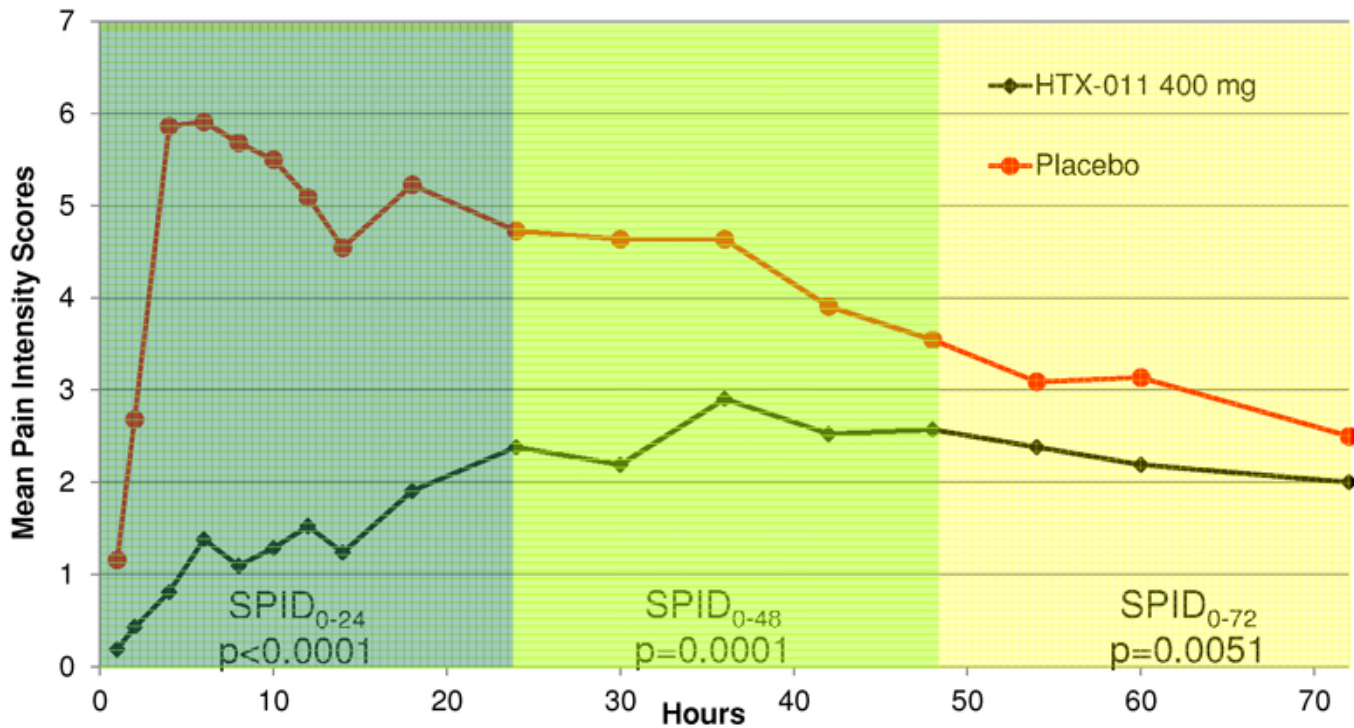


Historical Context: Percent of Patients Who Received No Opiate Rescue Medication, Cross-Study Comparison to Exparel



Source: *Golf et al, Adv Ther, 28(9):776-788, 2011*

Pain Intensity NOT Adjusted for Opiate Use: HTX-011 Significantly Better Than Unlimited Opiates*



*Patients were permitted to take 5 mg oxycodone every 2 hours as needed for pain; data not adjusted for opiate use

Preliminary Safety



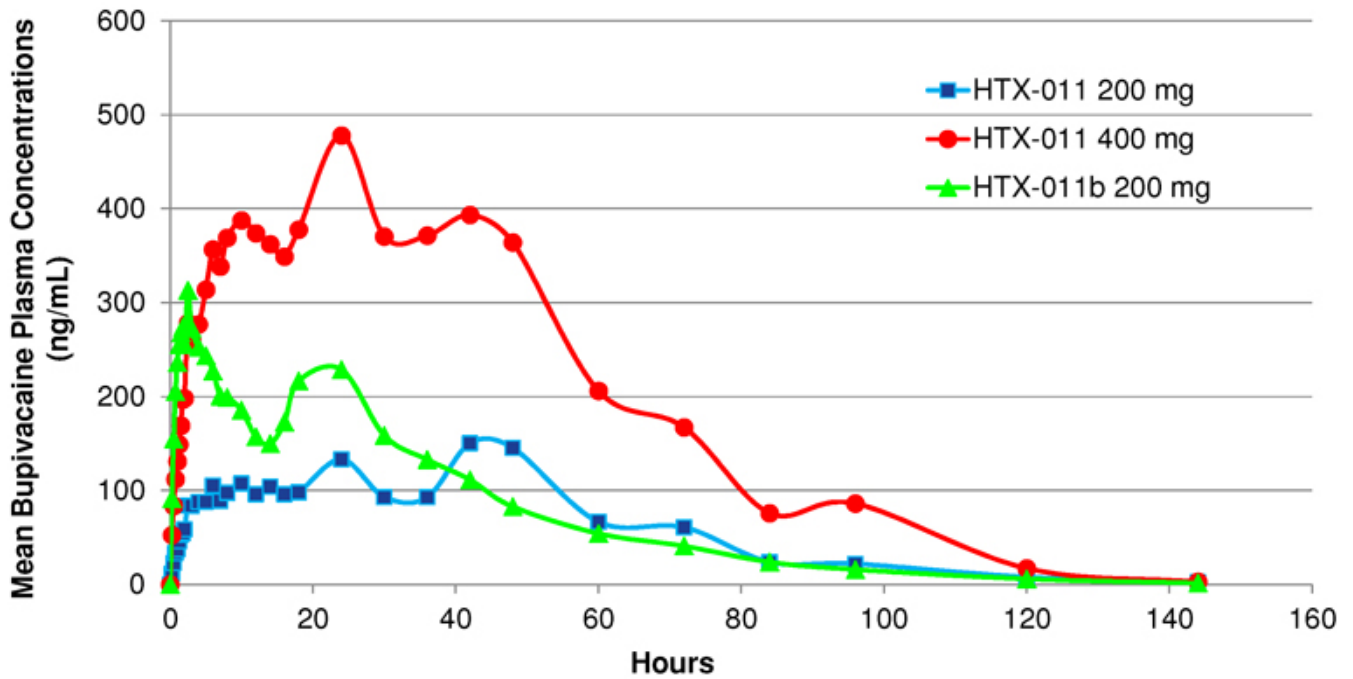
- HTX-011 was generally well tolerated
- The most common adverse events were: headache, nausea, vomiting, constipation, erythema, cellulitis, dizziness, and hypoxia, none of which were considered drug-related

HTX-011b: Second Formulation with Distinct Properties

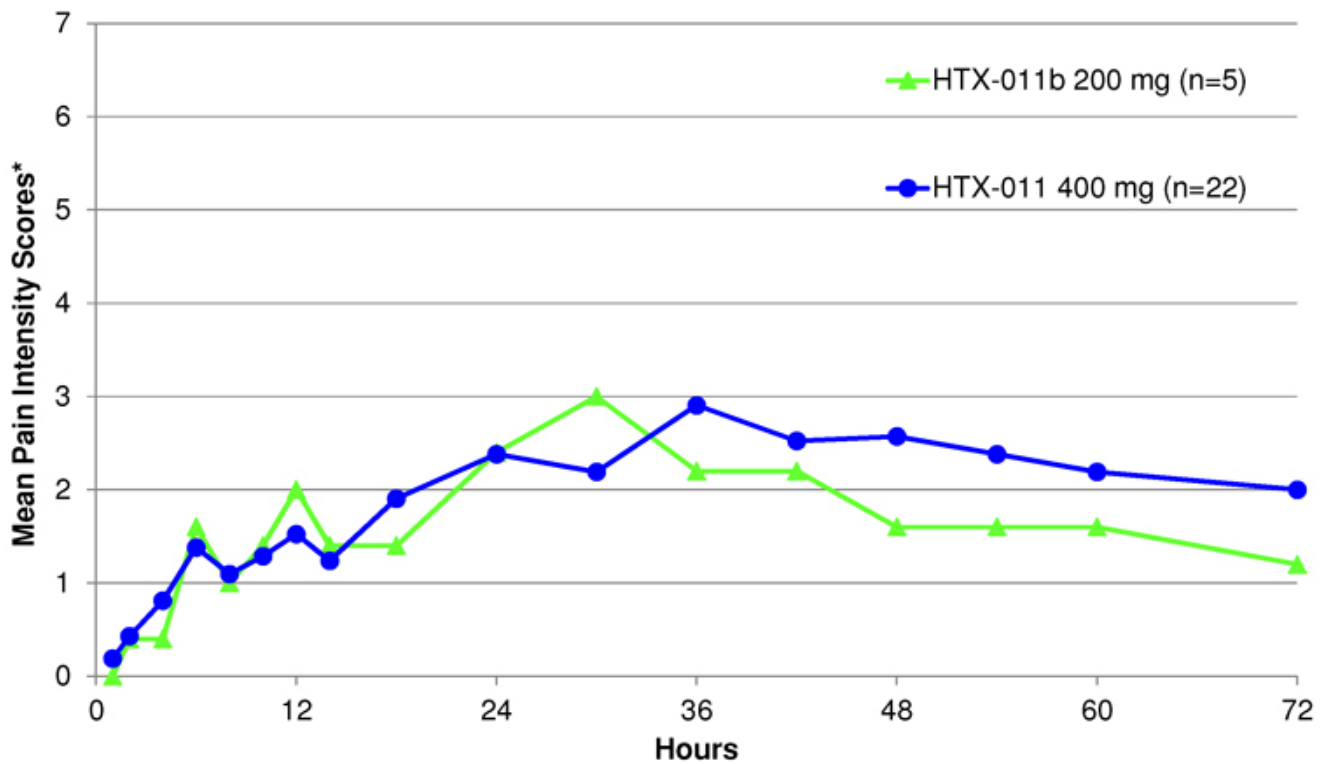


- HTX-011b is our second formulation
- Designed to possess distinct properties that may be ideal in certain surgical procedures:
 - Greater volume
 - Slightly faster onset
- Phase 1 study in healthy volunteers showed:
 - Therapeutic drug levels achieved faster
 - Higher drug levels achieved
- First cohort of Phase 2 study in 5 patients undergoing bunionectomy demonstrated 200 mg of HTX-011b comparable to 400 mg of HTX-011
- Dosing with 400 mg of HTX-011b to follow shortly
- Now that proof-of-concept has been established, Heron plans to develop a family of HTX-011 products to cover a wide range of surgical procedures

HTX-011b Provides Faster Onset and Substantially Greater Bupivacaine Levels



Pain Intensity: HTX-011b 200 mg vs. HTX-011 400 mg



*Not adjusted for use of rescue medications

Summary and Future Directions



- Phase 2 results demonstrate unprecedented level of efficacy for a local anesthetic in the management of post-operative pain
 - Major reduction in pain intensity
 - True opiate-sparing activity
 - One-third of patients required no opiates at all over first 72 hours
- Strong proof-of-concept combined with initial HTX-011b results create platform to develop a family of products with distinct properties
 - Onset of action, duration of action, volume
- Broad-based development program underway
 - Designed to target wide range of surgeries