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) August 1, 2016

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))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01 Other Events.

On August 1, 2016, Heron Therapeutics, Inc. (the "Company") issued a press release announcing positive top-line results from the Company's Phase 2 studies of HTX-011 for management of post-operative pain, as described in the press release furnished herewith as Exhibit 99.1.

A copy of presentation materials describing the results of the Company's Phase 2 studies of HTX-011, 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 <u>www.herontx.com</u>. The Company does not undertake any obligation to update this presentation.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 1, 2016

99.2 Corporate Presentation, dated August 1, 2016

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: August 1, 2016

Heron Therapeutics, Inc.

/s/ Brian Drazba

Brian Drazba Vice President, Finance and Chief Financial Officer



Heron Therapeutics Reports Positive Top-Line Results from Phase 2 Studies of HTX-011 for Management of Post-Operative Pain

-Statistically and clinically significant reductions in pain intensity through 96 hours after bunion surgery and through 48 hours after hernia surgery

-Increase in time to first opioid rescue and decrease in overall opioid use in both studies

-HTX-011 statistically superior to standard-of-care bupivacaine solution on both pain intensity and opioid use

-HTX-011 shown effective when administered by infiltration or by Mayo Block (nerve block)

-Instillation, an easier, less invasive and potentially safer route of administration into the wound, was equally as effective as injection

-Conference call and webcast at 8:30 a.m. ET on August 1

REDWOOD CITY, Calif. – August 1, 2016 – 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, announced preliminary, positive, top-line efficacy results from two Phase 2 clinical studies of HTX-011, its lead product candidate for the management of post-operative pain in patients undergoing bunionectomy (Study 208) and inguinal hernia repair (Study 202) and safety data from our ongoing Phase 2 program. HTX-011, which utilizes Heron's proprietary Biochronomer® drug delivery technology, is the first long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam and is designed to target both post-operative pain and its associated inflammation.

Study 208 – Bunionectomy

Study 208 was a randomized, placebo- and active-controlled, double-blind Phase 2 clinical study in patients undergoing bunionectomy. This study evaluated the

efficacy and safety of two formulations of HTX-011 at 200 mg compared to the standard dose of bupivacaine solution and placebo. Bupivacaine solution is the standard-of-care agent for the management of post-operative pain. In addition, HTX-011 was evaluated when administered via Mayo Block (nerve block via closed wound injection) or infiltration (open wound injection).

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 postsurgery (SPI 0-24). Key secondary endpoints included comparison to bupivacaine solution, the time to first use of opioid rescue medication, total opioid consumption and difference in pain intensity compared to placebo or bupivacaine solution when administered as a Mayo Block or infiltration. The major findings for our Phase 3 formulation of HTX-011 are as follows:

- There was a 66% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by infiltration to placebo (p<0.0001). There was a 64% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by infiltration to bupivacaine solution (p<0.0001).
- There was a 69% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by nerve block to placebo (p<0.0001). There was a 71% reduction in pain as measured by SPI 0-24 when comparing HTX-011 administered by nerve block to bupivacaine solution (p<0.0001).
- Significant reductions in pain were maintained through 96 hours post-surgery (SPI 0-96) for all groups: HTX-011 by infiltration versus placebo (p=0.005), HTX-011 by infiltration versus bupivacaine solution (p=0.019), HTX-011 by nerve block versus placebo (p=0.004), and HTX-011 by nerve block versus bupivacaine solution (p=0.007).
- Mean time to first opioid rescue medication was 716% longer than for placebo (p<0.0001) and 167% longer than for bupivacaine solution (p<0.036).
- Over the first 24 hours post-surgery, patients receiving HTX-011 consumed 74% less opioids than placebo patients (p<0.0001) and 67% less than bupivacaine solution patients. Over the first 96 hours post-surgery, patients receiving HTX-011 consumed 53% less opioids than placebo patients (p=0.003) and 50% less than bupivacaine solution patients (p=0.008).

<u>Study 202 – Inguinal Hernia Repair</u>

Study 202 was a randomized, placebo-controlled, double-blind Phase 2 clinical study in patients undergoing inguinal hernia repair. The study evaluated the efficacy and safety of two formulations of HTX-011 at two doses (200 mg and 400 mg), compared to placebo.

In addition, two routes of administration into the wound (injection and instillation) were evaluated. Instillation into the incision site is an easier and potentially safer route of administration as it avoids multiple injections around the wound (as many as 10 or more in large operations) that carry the risk of venous puncture.

The primary endpoint was the difference as compared to placebo in pain intensity as measured by SPI 0-24. Key secondary endpoints included the time to first use of opioid rescue medication and total opioid consumption. The major findings for the 400 mg dose of our Phase 3 formulation of HTX-011 as compared to placebo are as follows:

- There was a 29% reduction in pain as measured by SPI 0-24 (p=0.008).
- HTX-011 by instillation (28.4% reduction in SPI 0-24) was equally as effective as HTX-011 by injection (29.2% reduction in SPI 0-24).
- The pain reduction was long-lasting, with a statistically significant, 25% reduction through 48 hours (SPI 0-48; p=0.038).
- Mean time to first opioid rescue medication was 110% longer (13.3 hours versus 27.9 hours).
- Mean total opioid consumption was 36% less through 96 hours post-surgery.
- The number of patients that did not take any opioid rescue medication at all through 96 hours post-surgery was approximately double (21% versus 11%).

HTX-011 has been generally well tolerated in the ongoing Phase 2 program, which has involved more than 250 administrations of HTX-011. The most frequent treatment-related adverse events reported have been nausea and vomiting, which occurred at similar rates in active and control patients.

"With today's results in hand, we could not be more excited about the potential of HTX-011 to represent a best-in-class therapeutic for post-operative pain," commented Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. "HTX-011 is the first extended-release local anesthetic to demonstrate significant benefit over bupivacaine solution, the standard of care

for the management of post-operative pain, following bunionectomy, one of the most painful surgeries. As we move toward our broad-based Phase 3 registration program, we remain focused on our goal of delivering a therapeutic tool that can not only greatly reduce pain levels following surgery, but also help address the nationwide burden of opioid abuse and dependence."

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Monday, August 1, 2016 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 58069081 to join the conference call. A slide presentation accompanying today's press release and conference call may also be found on Heron's website at <u>www.herontx.com</u> under the investor relations section. The conference call will also be available via webcast under the investor relations section of Heron's website. 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. An archive of today's teleconference and webcast will be available on Heron's website for 60 days following the call.

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 fixeddose 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. HTX-011 is the subject of a broadbased 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 for patients suffering from cancer or pain. For more information, visit <u>www.herontx.com</u>.

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 involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, those associated with: whether the Phase 2 study results are indicative of the results in future studies related to HTX-011, the sufficiency of the Phase 2 data to allow the commencement of Phase 3 registration studies for HTX-011, the potential market opportunity for HTX-011, 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.

Investor Relations and Media Contact:

Jennifer Capuzelo Associate Director, Investor Relations 858-703-6063 jcapuzelo@herontx.com

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Exhibit 99.2



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

Positive Top-Line Results across Bunion and Hernia Studies

August 1, 2016



Forward-Looking Statements

This presentation contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. We caution investors that forward-looking statements are based on management's expectations and assumptions as of the date of this presentation, and involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, those associated with: whether the Phase 2 study results are indicative of the results in future studies related to HTX-011, the sufficiency of the Phase 2 data to allow the commencement of Phase 3 registration studies for HTX-011, the potential market opportunity for HTX-011, 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 we take no obligation to update or revise these statements except as may be required by law.

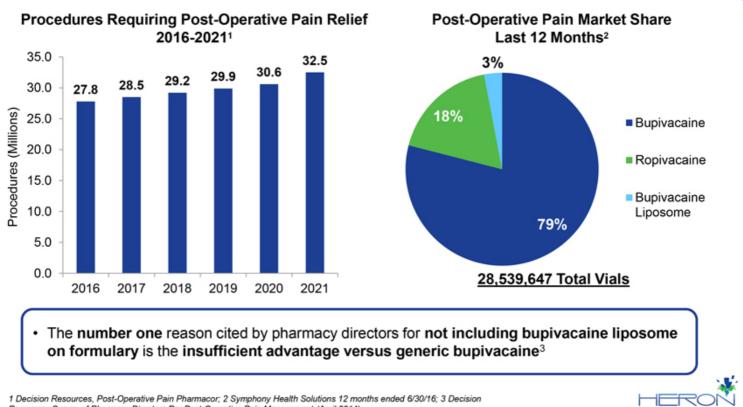


The Ideal Therapeutic for Post-Operative Pain

- The ideal therapeutic for post-operative pain would:
 - Significantly reduce pain for several days after surgery
 - Significantly reduce opioid use:
 - Reduce total amount of opioids consumed
 - Increase number of patients who NEVER need an opioid
 - Demonstrate these benefits versus bupivacaine solution, the current standard of care
 - Cover a wide range of surgeries, including where nerve block is preferred
 - Require no/minimal injections with local administration, making it easy to administer and reducing the risk of inadvertent venous puncture
 - Not be amenable to mixing with bupivacaine solution, reducing the chance of dosing errors and systemic toxicity



Market Opportunity for HTX-011 in Post-Operative Pain Management

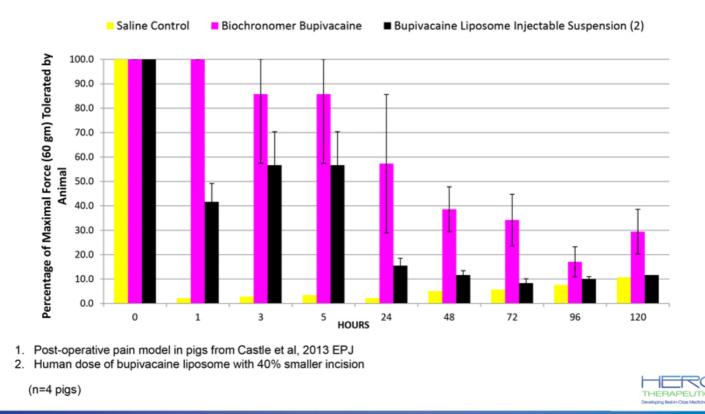


THERAPEUTIC

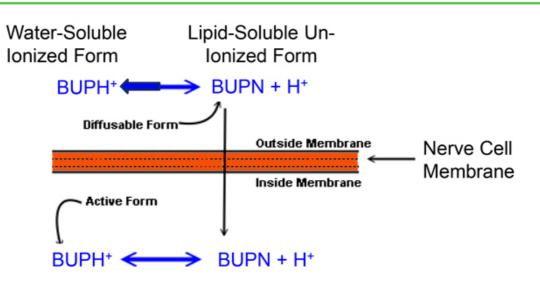
1 Decision Resources, Post-Operative Pain Pharmacor; 2 Symphony Health Solutions 12 months ended 6/30/16; 3 Decision Resources Survey of Pharmacy Directors Re: Post-Operative Pain Management (April 2014)

Biochronomer® Bupivacaine Produced Significant Reductions in Pain in Preclinical Models¹

Pig Post-Operative Pain Model



Local Anesthetics Exist in a Balance Between Water-Soluble and Lipid-Soluble Forms



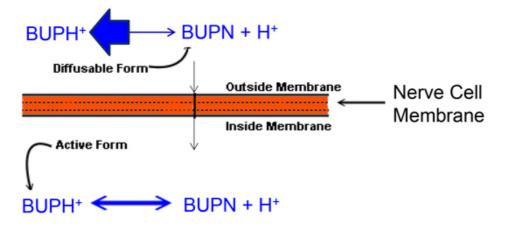
 Local anesthetics have pKa values > 7.4, so at normal physiologic pH of 7.4, the majority of molecules exist as the water-soluble quaternary salt not able to penetrate nerve cell membrane

Local anesthetic nerve penetration model adapted from Becker and Reed, Anesth Prog 53:98–109 2006



When Tissue Is Inflamed, Local Anesthetics Cannot Effectively Enter the Nerve Membrane

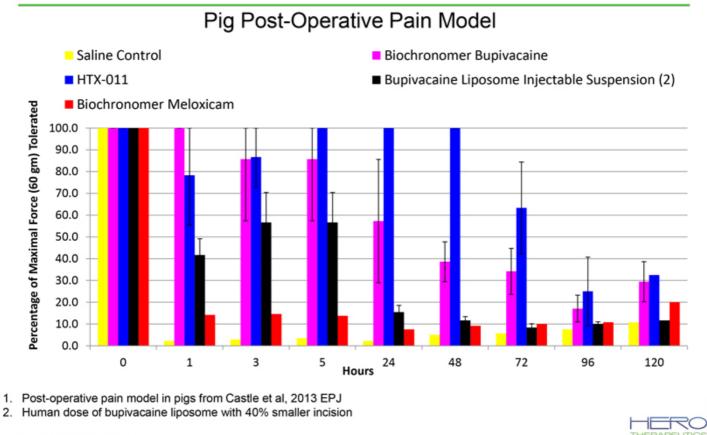
Inflammation Produces an Acidic Environment Which Shifts the Balance to Ionized Form Unable to Penetrate Nerve Cell Membrane



- The acidic environment associated with inflammation results in far less drug penetrating the nerve membrane and reduced anesthetic effects^{1,2}
- With a pKa of 8.1, bupivacaine is very sensitive to reduced pH



HTX-011's Unique Combination of Bupivacaine and Meloxicam Produced Marked Anesthesia through 72 Hours¹



8 (n=4 pigs in each arm)



HTX-011 IS THE FIRST AND ONLY LONG-ACTING ANESTHETIC THAT ADDRESSES BOTH POST-OPERATIVE PAIN AND ACCOMPANYING INFLAMMATION

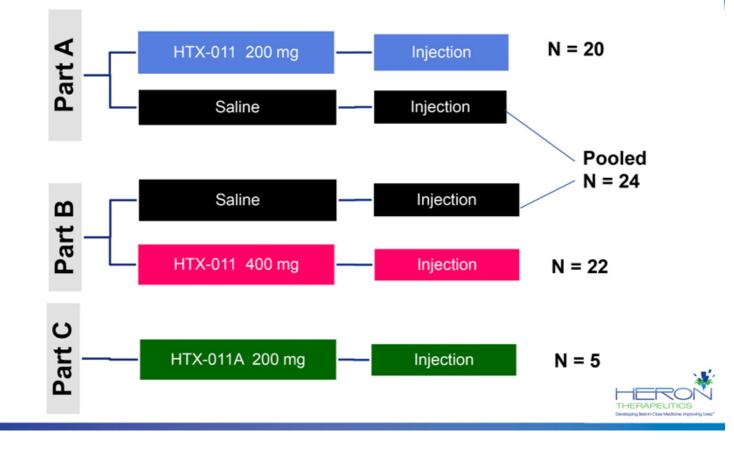




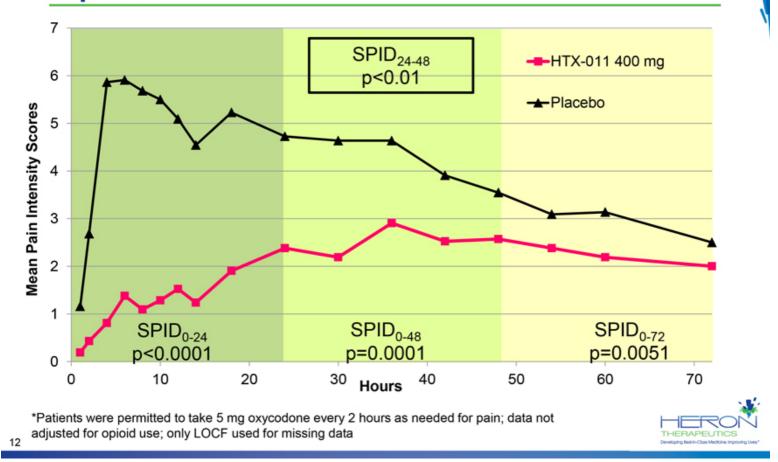
PREVIOUSLY PRESENTED PRELIMINARY RESULTS HTX-011-201 PHASE 2 BUNIONECTOMY

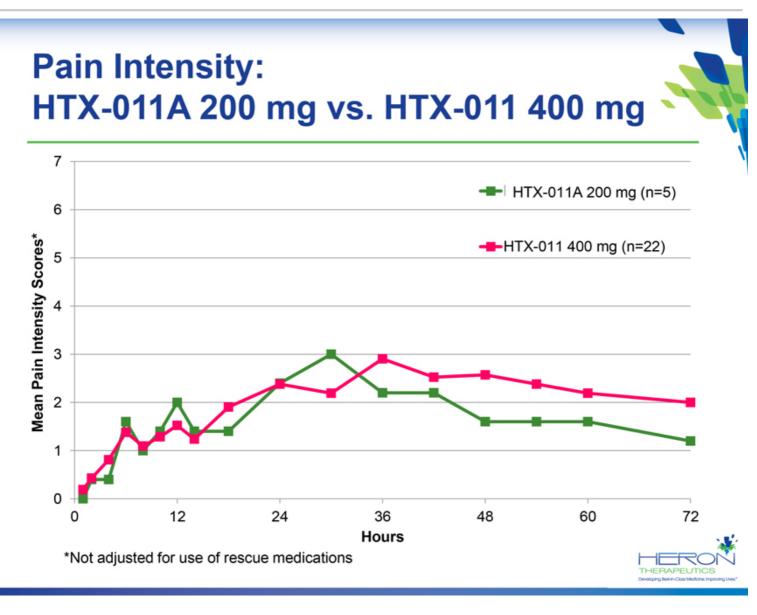


HTX-011 Study 201: Bunionectomy Study Design



Pain Intensity NOT Adjusted for opioid Use: HTX-011 Significantly Better Than Unlimited Opioids*





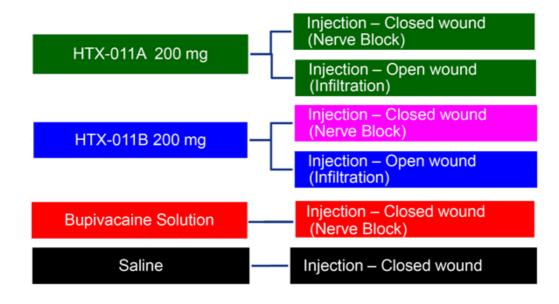


PRELIMINARY RESULTS HTX-011-208 PHASE 2 BUNIONECTOMY



HTX-011 Study 208: Bunionectomy Study Design





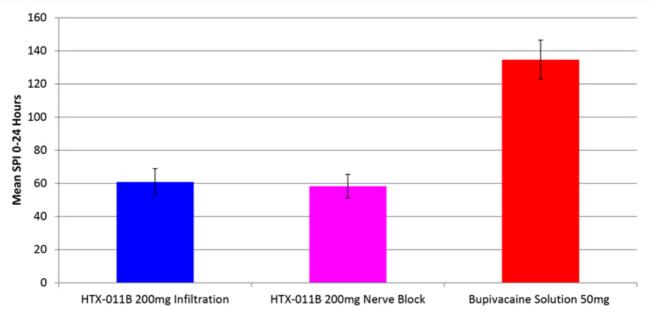


HTX-011-208: Demographics

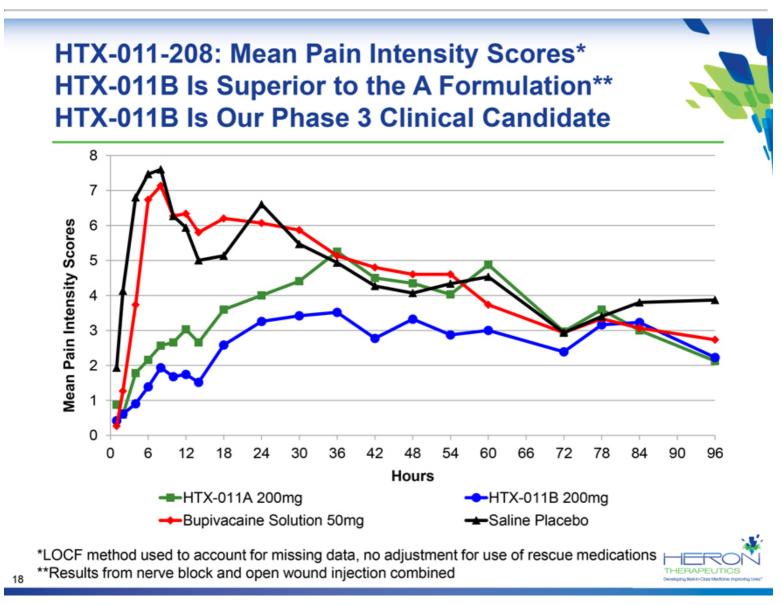
Characteristic	Parameter	HTX-011A 200mg	HTX-011B 200mg	Bupivacaine Solution	Saline
Age (Years)	n	32	31	15	15
	Mean	49.5	52.2	52.7	48
	Minimum	20.0	20.0	36.0	24.0
	Maximum	72.0	71.0	84.0	69.0
Gender n (%)	Male	5 (15.6)	5 (16.1)	2 (13.3)	3 (20.0)
	Female	26 (81.3)	26 (83.9)	13 (86.7)	12 (80.0)
Race n (%)	Caucasian	19 (59.4)	25 (80.6)	8 (53.3)	6 (40.0)
	African American	12 (37.5)	4 (12.9)	6 (40.0)	8 (53.3)
	Other	1 (3.1)	2 (6.5)	1 (6.7)	1 (6.7)
Ethnicity n (%)	Hispanic	9 (28.1)	5 (16.1)	2 (13.3)	2 (13.3)
	Not Hispanic	23 (71.9)	26 (83.9)	13 (86.7)	13 (86.7)



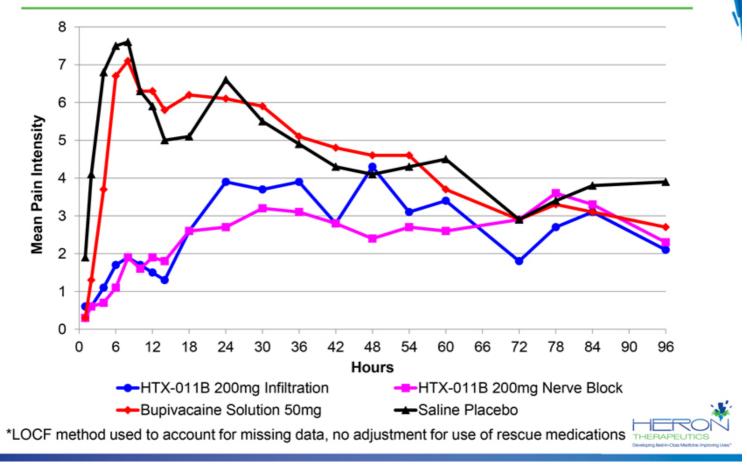
HTX-011-208: Route of Administration Did Not Impact Efficacy



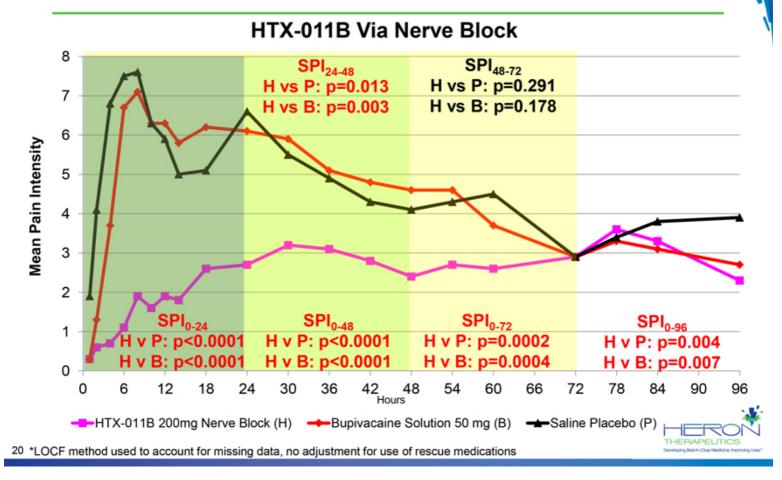
- No significant difference between routes, with both routes of HTX-011B administration significantly better than placebo and bupivacaine solution
- Study confirms the significant benefit of HTX-011 given as a local infiltration (open wound injection) or Mayo Block (i.e., nerve block or closed wound infiltration)



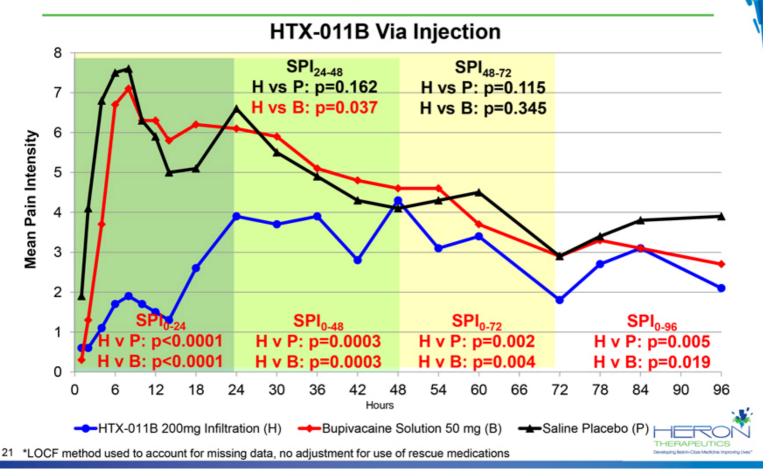
While Both Routes Were Significantly Better than Placebo or Bupivacaine Solution, the Best Reduction in Pain Was Observed with Nerve Block*



HTX-011-208: Mean Pain Intensity Scores* HTX-011B Via Nerve Block Is Significantly Better than Placebo or Bupivacaine Solution



HTX-011-208: Mean Pain Intensity Scores* HTX-011B Via Open Wound Injection Is Significantly Better than Placebo or Bupivacaine Solution



HTX-011-208: Secondary Endpoint Mean Use of Opioid Rescue Medication

Mean opioid Rescue Over Time	Placebo (P)	Bupivacaine Solution (B)	HTX-011B 200 mg	Percent Reduction
0 – 24 hours	20.3mg	15.9mg	5.2mg p<0.0001 v P P<0.0001 v B	74%↓ v P 67%↓ v B
0 – 48 hours	31.1mg	28.5mg	13.3mg p=0.0001 v P p=0.001 v B	57%↓ v P 53%↓ v B
0 – 72 hours	37.7mg	35.8mg	17.7mg p=0.003 v P p=0.007 v B	53%↓ v P 51%↓ v B
0 – 96 hours	38.1mg	35.8mg	17.9mg p=0.003 v P p=0.008 v B	53%↓ v P 50%↓ v B

HTX-011-208: Secondary Endpoints -Mean Time to First Opioid Increased by 716% -Significant Increase in Opioid-Free Patients

	Placebo (P)	Bupivacaine Solution (B)	HTX-011B 200 mg
Mean Time to First Opioid Rescue Medication	3.8hr	11.6hr	31.0hr p<0.0001 vs P p<0.037 vs B
Percent of Patients Opioid Free for First 24 Hours	0%	7%	32% p=0.019 vs P
Percent of Patients Opioid Free for First 96 Hours	0%	7%	16%

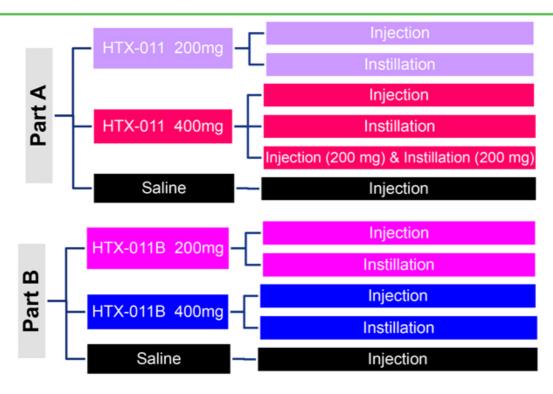


PRELIMINARY RESULTS HTX-011-202 PHASE 2 HERNIORRHAPHY



HTX-011 Study 202: Herniorrhaphy Study Design

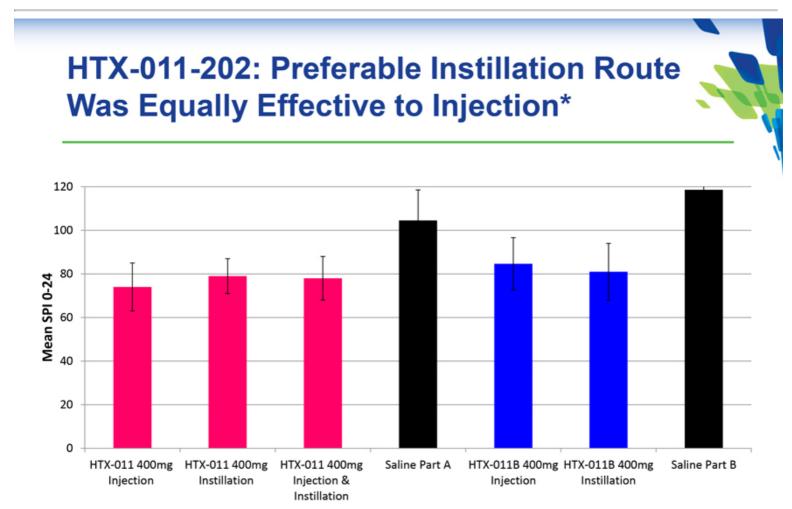






HTX-011-202: Demographics

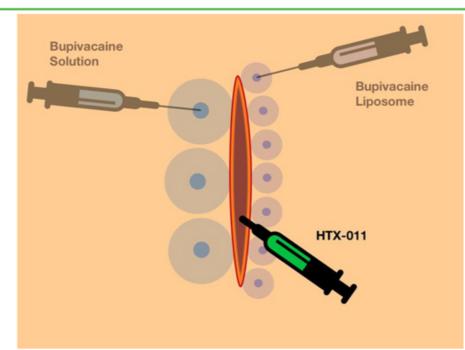
Characteristic	Parameter	HTX-011 400mg	Saline Part A	HTX-011B 400mg	Saline Part B
Age (Years)	n	54	18	24	31
	Mean	45.6	46.5	43.9	44.8
	Minimum	21	22	19	21
	Maximum	67	66	79	62
Gender n (%)	Male	52 (96)	18 (100)	23 (96)	30 (97)
. ,	Female	2 (4)	0 (0)	1 (4)	1 (3)
Race n (%)	Caucasian	47 (87)	18 (100)	18 (75)	24 (77)
	African American	7 (13)	0 (0)	2 (8)	7 (23)
	Asian	0 (0)	0 (0)	1 (4)	0 (0)
	Other	0 (0)	0 (0)	2 (8)	0 (0)
Ethnicity n (%)	Hispanic	25 (46)	7 (39)	9 (38)	12 (39)
	Not Hispanic	29 (54)	11 (61)	14 (58)	19 (61)



*Based on these results, the instillation and injection subgroups were pooled for efficacy comparisons



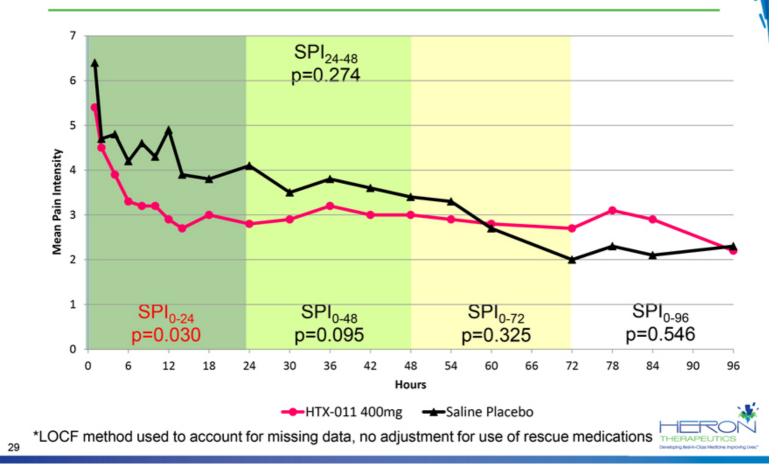
HTX-011: Instillation Is Easier and Potentially Safer



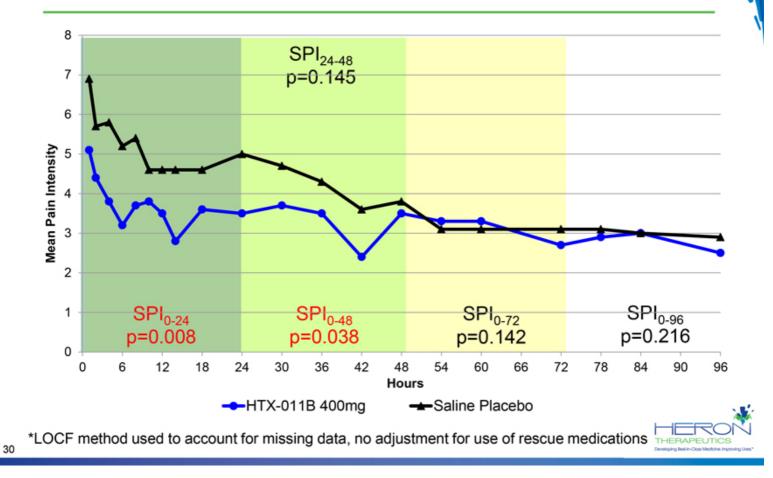
- · Compared to injection, instillation into the incision site is:
 - Easier to administer and less invasive, avoiding up to 10 or more injections into the skin with large operations
 - Safer, reducing the risk of venous puncture



HTX-011-202: Mean Pain Intensity Scores HTX-011 Significantly Better Than Placebo



HTX-011-202: Mean Pain Intensity Scores HTX-011B Significantly Better than Placebo through 48 Hours



HTX-011-202: Secondary Endpoints Mean Time to First Opioid Increased 110%

In addition to the significant reductions in pain observed with HTX-011B, opioid use was also reduced:

- Mean time to first opioid rescue medication increased by 110% (13.3 hours for placebo vs 27.9 hours for HTX-011B; p=0.09)
- Mean total opioid consumption decreased by 36% through 96 hours
- Percent of patients who required no opioid rescue medication approximately doubled from 11% to 21%

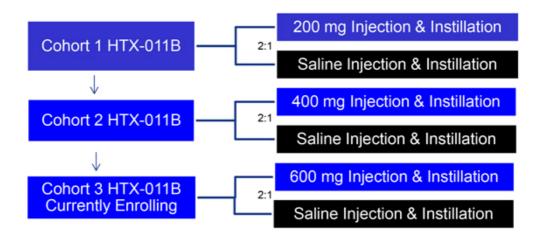




HTX-011-203 PHASE 2 ABDOMINOPLASTY UPDATE



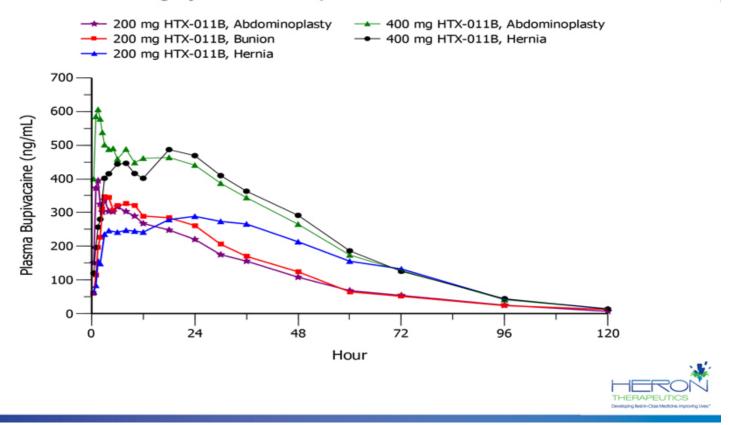
HTX-011 Study 203: Abdominoplasty Study Design





Comparative Bupivacaine PK: Hernia, Bunion, and Abdominoplasty

Location of Surgery Has Little Impact on HTX-011 Pharmacokinetics



Preliminary Safety from Ongoing Phase 2 Studies: HTX-011 Was Well Tolerated

Treatment-Emergent Related Adverse Events with at Least 2% in Either HTX-011 or Control (Saline or Bupivacaine Solution)

AE Preferred Term	HTX-011 (n=256)	Control (n=100)
Nausea	3.9%	5.0%
Vomiting	0.8%	5.0%
Bradycardia	4.3%	1.0%
Pruritus	0.4%	4.0%
Dizziness	2.7%	1.0%
Headache	2.3%	0.0%
Constipation	1.2%	2.0%

 Two SAEs were unblinded to assess causality: one was on HTX-011A (infection) and one was on placebo (infection)



Phase 3 Program Designed to Demonstrate HTX-011's Broad Utility and Clear Advantage over Standard of Care

- Heron's Phase 3 program for HTX-011 will:
 - Include multiple types of surgical procedures
 - Compare HTX-011 not only to placebo but also to bupivacaine solution, the current standard of care for postoperative pain
 - Include studies administering HTX-011 by infiltration and nerve block
 - Include studies administering HTX-011 by instillation
- Heron's target is to submit a New Drug Application based on this comprehensive program in 2018



HTX-011's Emerging Profile

- HTX-011 has been shown to:
 - Significantly reduce pain for several days after surgery
 - Significantly reduce opioid use:
 - Reduced total amount of opioids consumed
 - Increased number of patients who NEVER need an opioid
 - Demonstrate these benefits versus bupivacaine solution, the current standard of care
 - Cover a wide range of surgeries, including where nerve block is preferred
 - Require no/minimal injections, making it easy to administer and reducing the risk of inadvertent venous puncture
 - Not be amenable mixing with bupivacaine solution, reducing the chance of dosing errors and systemic toxicity

