#### 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) January 11, 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)

Dere-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.

A copy of presentation materials describing the business of Heron Therapeutics, Inc. (the "Company"), 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 99.1 hereto. These materials include updates to information previously furnished by the Company regarding the Company's research and development programs. The fact that these updated presentation materials are being furnished should not be deemed an admission as to the materiality of any information contained in the materials. 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.

Exhibit <u>Description</u>

99.1 Corporate Presentation, dated January 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: January 11, 2016

Heron Therapeutics, Inc.

/s/ Brian Drazba Brian Drazba

Vice President, Finance & Chief Financial Officer

Exhibit 99.1



## **Company Update**

January 11, 2016



# Legal Disclaimer



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 execute on business alliances or initiatives, progress in research and development programs, intellectual property, thirdparty relationships, regulatory oversight and developments, potential market acceptance of new products, financial results, adequacy and duration of capital resources 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.



Sta	Status of Product Portfolio						
	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Approved	X
SUSTOL®	Acute and	Delayed Nausea	a and Vomiting	Associated HEC	and MEC		
HTX-019	IV NK <sub>1</sub> fo Prever	r CINV ation	BE Study Unde Pathway – Pha NDA Submissic	rway – Developi se 2 & 3 should on Expected 2H1	ng with 505(b)(2 not be required; 6	)	
SUSTOL LCM		Improved form multiple CINV	ulation potential agents	ly delivering			
HTX-011	Long-Actir Meloxicam	ng Bupivacaine for Post-Op Pa	+ Phas in Surgi	e 2 Studies In M cal Models Unde	ultiple erway		
3	Because SUST or answer any	OL is under ac questions rega	tive review, we arding the NDA	e will not discus	s the NDA	THERAPEUTICS Developing Insch-Class Medicine Improv	Whig Uves*



# **CINV FRANCHISE**



# **SUSTOL**®



- SUSTOL<sup>®</sup> (granisetron) Injection, extended release, is a long-acting, injectable product for the prevention of chemotherapy-induced nausea and vomiting (CINV)
  - 1,341-patient, randomized, controlled, Phase 3 study demonstrated activity in acute and delayed CINV after moderately emetogenic chemotherapy (MEC), and acute CINV after highly emetogenic chemotherapy (HEC)
  - MAGIC: Complete Response in delayed nausea and vomiting in patients receiving HEC was significantly greater with the SUSTOL-based, three-drug regimen compared to standard-of-care. Significantly more patients had no nausea or infrequent nausea with SUSTOL and SUSTOL patients reported a significantly greater satisfaction with therapy
  - SUSTOL, as part of a three-drug regimen, is the first 5-HT<sub>3</sub> antagonist to demonstrate superiority to a standard-of-care, three-drug regimen in delayed nausea and vomiting in patients receiving HEC
- NDA resubmitted to FDA July 17, 2015
- PDUFA goal date January 17, 2016
  - Because SUSTOL is under active review, we will not discuss the NDA or answer any questions regarding the NDA



# SUSTOL Has the Potential to be the Next Generation 5-HT<sub>3</sub> Receptor Antagonist

5-HT₃ RAs	1 <sup>st</sup> generation	2 <sup>nd</sup> generation	3 <sup>rd</sup> generation
Products	ondansetron granisetron	palonosetron	SUSTOL
Duration of action	Short acting ~ 8 hr half-life	Longer acting ~40 hr half-life	Long acting PK profile 5-7 days
Indications	Prevention of CINV in emetogenic chemo including high-dose cisplatin	MEC – acute & delayed CINV HEC – acute CINV	MEC – acute & delayed CINV HEC – acute & delayed CINV*

\*Obtaining an indication for delayed nausea and vomiting after HEC will be based on FDA's assessment of MAGIC trial results



# HTX-019



- HTX-019 is a proprietary intravenous (IV) formulation of aprepitant, an NK<sub>1</sub> receptor antagonist and is distinguished from EMEND IV<sup>®</sup>, the only IV NK<sub>1</sub> receptor antagonist presently approved in the U.S., in that it does not contain polysorbate 80, which may cause infusion site reactions, hypersensitivity or other adverse reactions in some patients.
  - Bioequivalency study comparing HTX-019 to EMEND IV (fosaprepitant) conducted in late 2015, pk analyses underway
  - Rapid development utilizing the 505(b)(2) registration pathway is anticipated to achieve NDA submission in 2H2016
- Direct competitor to the approximately 1 million units of EMEND IV used annually



# HTX-019 Demonstrated Bioequivalence to Fosaprepitant

HTX-019 Pharmacokinetics of Aprepitant in Rats



# **HTX-019 Potential Tolerability Benefit**

- Fosaprepitant is currently the only injectable NK<sub>1</sub> RA approved in the USA
- Fosaprepitant contains polysorbate 80, which may cause:
  - Hypersensitivity eactions, including flushing, itching or shortness of breath, and has the potential to cause severe anaphylaxis reactions
  - Infusion site reactions, including infusion site pain, erythema, swelling, superficial thrombosis, infusion site hives, and phlebitis/thrombophlebitis
- In review of cancer drugs containing polysorpate 80, hypersensitivity reactions linked to at least 23 deaths in spite of premedication
- HTX-019 does not contain polysorbate 80 and may have a lower incidence of certain adverse reactions than reported with fosaprepitant

Sources: Leal et al, Support Care Cancer, 22:1313–1317, 2014; Norris et al, Community Oncology, 7:425-428, 2010



### HTX-019 vs EMEND IV Human BE Study: HTX-019 Shows Clear Safety Advantage

 100 subjects received HTX-019 and EMEND IV in standard cross-over design

SAFETY	HTX-019	EMEND IV
All AEs	28%	56%
AEs considered at least possibly related	20%	52%
Moderate AEs	0	6%
Hypersensitivity Reactions	0	3%
Premature Discontinuations	0	2%

Conclusion: HTX-019 was clearly better tolerated than EMEND IV, with 62% fewer AEs at least possibly related to treatment, no AEs of greater than mild severity, no premature discontinuations and no hypersensitivity reactions



# CINV FRANCHISE COMMERCIAL OPPORTUNITY



# The Management of CINV Remains a Significant Clinical Challenge

- In the U.S., over 1 million people receive CINV therapy each year
- > On average, they each receive 5-6 cycles of CINV therapy



#### Source: IPSOS Q2 2015 Cancer Tracking

#### **Unmet Need**

- Despite treatment with existing therapies, many patients experience breakthrough CINV particularly in the delayed phase (days 2-5)
- CINV has a high clinical burden impacting patients' QOL and cancer treatment
- Historically, there have been no single-agent 5-HT<sub>3</sub> antgonists indicated to prevent delayed CINV in HEC (including palonosetron)
- HCPs cite the need for new therapies that deliver long-acting CINV prevention in both MEC and HEC



### Despite Available Therapies, a Large Percentage of Patients Experience Breakthrough CINV

#### % of MEC/HEC patients with breakthrough CINV despite prophylaxis

Community practice observational study



Data from a prospective observational study enrolling chemotherapy-naive patients who received single-day HEC or MEC at four oncology practice networks, all using electronic medical record (EMR) systems, in Georgia, Tennessee, and Florida. CINV = emesis or clinically significant nausea on days 1-5. For HEC=5-HT3+NK-1+CS on Day 1; NK-1 on Days 2-3; CS on Days 2-4; For MEC=5-HT3+NK-1+CS on Day 1; 5-HT3, NK-1, or CS on Days 2-3.



#### % of MEC/HEC patients with breakthrough CINV despite prophylaxis

Physician perception



Source: Instar Market Research, Dec 2015, N=75 oncologists



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### CINV Has a High Clinical Burden – Impacting Patients' QOL and Cancer Treatment



### 87% of Oncologists Believe New Agents are Needed to Address Unmet Needs in CINV Prevention







SUSTOL was non-inferior to IV palonosetron in preventing acute and delayed CINV in MEC and acute CINV in HEC





Because the study was designed to show non-inferiority, P=NS indicates that the endpoint of non-inferiority was reached, and that SUSTOL was as effective as IV palonosetron

Raftopoulos H et al. Support Care Cancer. 2014 Epub; Sep 2:1-10; Fig 2; p6 col2, ¶5.



THERAPEUTICS

MAGIC STUDY

### MAGIC is the First Pivotal HEC Trial to Incorporate a Guideline-Recommended 3-Drug Regimen in Both Arms

- In MAGIC, the efficacy advantage of SUSTOL vs. the standard-of-care 5-HT<sub>3</sub> was similar to the benefit shown in recent trials of adding an NK-1
- SUSTOL is the first 5-HT<sub>3</sub> to demonstrate superiority vs. another in HEC

			Delayed CR		
HEC Studies	Study Arm	Comparator Arm	Absolute Difference	Relative Difference	
SUSTOL* (SC) <sup>1</sup>	3 drug	3 drug	8.0%	14.2%	
NEPA* (PO) <sup>2</sup>	3 drug	2 drug	7.4%	10.6%	
NEPA (PO) <sup>2</sup>	3 drug	2 drug	10.3%	12.9%	
Rolapitant* (PO) <sup>3</sup>	3 drug	2 drug	9.8%	15.7%	
Rolapitant (PO) <sup>3</sup>	3 drug	2 drug	14.3%	24.5%	
Rolapitant (PO) <sup>3</sup>	3 drug	2 drug	8.2%	13.2%	

**3 drug** = 5-HT<sub>3</sub> receptor antagonist, NK-1 receptor antagonist, dexamethasone **2 drug** = 5-HT<sub>3</sub> receptor antagonist, dexamethasone

\*Predominately anthracycline/cyclophosphamide

1 Heron data on file; 2 NEPA PI; 3 rolapitant PI



40%

0%

20%

2 = Disagree 3 = Neither agree nor disagree

4 = Agree

Mean score

4.0

Scale 1-5 where 1 is not

at all meaningful and 5 is highly meaningful

5 = Strongly agree

**Clinically meaningful results:** the 8.1% absolute CR difference (P=.014) makes Product X the first 5-HT<sub>3</sub> to show superiority vs. another in HEC



% Strongly agree or agree

60%

80%

100%

#### % Highly meaningful or meaningful

Source: Instar Market Research, Dec 2015, N=75 oncologists



### SUSTOL was Rated Higher than Aloxi<sup>®</sup> on Most Clinical Attributes Including Those That Influence Product Choice the Most

#### SUSTOL vs. Aloxi Product Attribute Ratings



# The Branded 5-HT<sub>3</sub> Market (Aloxi) Consists of 2.6 Million Units



20 Source: Symphony Health Solutions data, 2015

### Despite No Promotion to Date, Significant Awareness of SUSTOL Exists Among Oncologists Surveyed

#### Awareness of CINV products



### Heron's Commercial Plans will Address Traditional Launch Barriers for Providers, Patients, and Payers

	Objectives	The Heron Approach
	Establish SUSTOL as preferred agent	<ul> <li>Differentiated ER technology and broadest clinical data set</li> <li>Robust in-office and peer-to-peer education via multiple channels</li> <li>Antiemetic guidelines inclusion</li> </ul>
Providers	Create "coverage confidence"	<ul> <li>Best-in-class reimbursement support services</li> <li>Extended payment terms</li> <li>Innovative "stand by your drug" program (qualified payer denials)</li> </ul>
	Build differentiated value proposition	Performance-based contract that delivers sustained value
Patients	Educate & optimize access	<ul> <li>Comprehensive in-office and on-line educational resources</li> <li>Zero patient co-pay for commercially insured patients</li> <li>Strong uninsured patient program</li> </ul>
Payers	Optimize access	<ul> <li>Compelling value story (clinical data, guidelines, HEOR data)</li> <li>Proactive payer engagement with traditionally restrictive plans</li> <li>Engagement between community practices and regional payers</li> </ul>



# SUSTOL Pricing Strategy Will Consider CINV Product Benchmarks

Product	WAC
AKZYNEO (NEPA) (300-0.5mg capsule)	\$499.80
EMEND (aprepitant) (TriPack – 1x 120mg and 2x 80mg)	\$539.60
VARUBI (rolapitant) (2x 90mg tablet)	\$533.00
ALOXI (palonosetron) (0.25mg/5mL vial)	\$434.00
EMEND IV (fosaprepitant) (150mg vial)	\$268.52

Source: BluePrint Market Research, Dec 2015





# **POST-OPERATIVE PAIN PROGRAM**



# Biochronomer<sup>®</sup> Bupivacaine Superior to EXPAREL<sup>®</sup> at 24-72 Hours

### Pig Post-Operative Pain Model



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

Acidic Environment Shifts the Balance to Ionized Form Unable to Penetrate Nerve Cell Membrane



 The acidic environment associated with inflammation shifts the balance further to the left, resulting in far less drug penetrating the nerve membrane and reduced anesthetic effects.

ΗE

With a pKa of 8.1, bupivacaine is very sensitive to reduced pH

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

### HTX-011 Significantly Superior to EXPAREL at 24-72 Hours

### Pig Post-Operative Pain Model



Study #1, All studies used the post-operative pair model in pigs non castle et al, 2013 EF 3
 Study #2 compared <1/2 expected human dose of Biochronomer bupivacaine/meloxicam formulation to the human dose of EXPAREL (40% smaller incision used with EXPAREL)</li>

28 (n=4 pigs)



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



# Phase 2a 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

ΗE

# Historical Context: Exparel Pivotal Bunionectomy Study





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







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



# Mean Time to First Use of Opiate Rescue Medication

 488% longer time to first use of rescue medications with 400 mg dose compared to placebo

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



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



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



# **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 with greater volume (potentially up to 20 ml)
- 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









### Long-Acting Injectable Products Contain Many Times the Single Dose HTX-011 is at the Low End of the Range

		Maximum Approved	Long-Acting Injectable	Maximum Approved LAI	Maximum LAI Dose vs. Maximum Short-Acting Daily
Short-Acting Injectable Drug	Indication	Daily Dose	(LAI) Drug	Dose	Dose Ratio
Sandostatin	Acromegaly	150 mcg	Sandostatin LAR	20 mg Q4W	133.3
Byetta	Diabetes	20 mcg	Bydureon	2 mg QW	100.0
Lupron	Prostate cancer	1 mg	Eligard	45 mg Q24W	45.0
Sandostatin	Carcinoid tumors	600 mcg	Sandostatin LAR	20 mg Q4W	33.3
Abilify	Schizophrenia	30 mg	Aristada	882 mg Q4W	29.4
Nutropin	Pediatric growth hormone deficiency	0.1 mg/kg	Nutropin Depot	2.25 mg/kg Q2W	22.5
Invega	Schizophrenia	12 mg	Invega Sustenna	234 mg Q4W	19.5
Zyprexa	Schizophrenia	20 mg	Zyprexa Relprevv	300 mg Q2W	15.0
Abilify	Schizophrenia	30 mg	Abilify Maintena	400 mg Q4W	13.3
Provera	Endometriosis	20 mg	Depo Provera	200 mg Q4W	10.0
Naltrexone	Alcohol and opioid dependence	50 mg	Vivitrol	480 mg Q4W	9.6
Risperdal	Schizophrenia	16 mg	Risperdal Consta	50 mg Q2W	3.1
Mean					36.2
Bupivacaine	Post-operative pain	175 mg	Exparel	266 mg	1.5
Bupivacaine	Post-operative pain	175 mg	HTX-011	400 mg	2.3

### > 72 hour Duration of Action Seen as "Ideal" by Physicians, With 48 hours Minimally Acceptable



Source: Decision Resources Post-Operative Pain Physician Research Initiative 2014 (N=30 qualitative interviews; N=184 quantitative survey) Minimally Acceptable Duration of Efficacy for Long-Acting Local Anesthetic



THERAPEUTIK

Advancing Medicine In

### Across Procedures, Many MDs Expect the Use of Long-Acting Local Anesthetics to Increase

#### Use of Long-Acting Local Anesthetics in the Future, by Procedure

Arthroplasty knee (inpatient)	3%	49%		48%	
Hernia (inpatient)	7% <mark>6</mark>	47%	46%		
Hip replacement, total and partial	3%	3% 49%		48%	
Hernia (outpatient)	5 <mark>%</mark>	41%	41% 54%		
Arthroplasty other than hip, knee, shoulder, or elbow	7% <mark></mark>	50%		43%	
Cholecystectomy (inpatient)	6 <mark>%</mark>	60%		35%	
Other therapeutic procedures on muscles and tendons	7% <mark></mark>	60%		34%	
Arthroplasty shoulder	2%	44%		53%	
Repair of toe	5 <mark>%</mark>	66%	6	28%	
Other fracture and dislocation procedure	6 <mark>%</mark>	58%		37%	
Treatment, fracture or dislocation of hip and femur (inpatient)	6 <mark>%</mark>	58%		36%	
Other non-OR therapeutic procedures on musculoskeletal	9%	62	%	29%	
Arthroplasty knee (outpatient)	5 <mark>%</mark>	45%		49%	
Cholecystectomy (outpatient)	7% <mark></mark>	60%		33%	
Cesarean Section	10% <mark>&gt;</mark>	53%		37%	
0º Perc	% entage to us	20% 40 of physicians ir se long-acting lo	% 60% ndicating how ocal anestheti	80% frequently the cs in the future	100% y expect
	Less	frequently S	ame amount	More freque	intly

"Minimizing opioid use by using longacting local anesthetics is the trend. I think the long-acting local anesthetics have great promise in the future." – General surgeon

Source: Decision Resources Post-Operative Pain Physician Research Initiative 2014 (N=30 qualitative interviews; N=184 quantitative survey)



# **Financial Summary**

#### \$128.2M raised June 2015 (net proceeds)

Summary Statement of Operations (In thousands, except per share data)	Nine Months Ended September 30, 2015
Revenue	\$ -
Operating expenses	65,865
Other income (expenses)	(484)
Net loss	\$ (66,349)
Net loss per share <sup>1</sup>	\$ (2.07)

Condensed Balance Sheet Data (In thousands)	September 30, 2015
Cash and cash equivalents	\$ 152,989
Total assets	\$ 158,151
Total stockholders' equity	\$ 141,701

<sup>1</sup> Based on 32.1 million weighted average common shares outstanding for the period ended September 30, 2015



## Condensed Balance Sheet Data – December 31, 2015

Condensed Balance Sheet Data (In thousands, Unaudited)

Cash and cash equivalents

As of December 31, 2015

\$ 131,000

### Current cash resources expected to fund operations through 2016, including potential SUSTOL commercial launch

