#### 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 9, 2017

#### 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.)

> 92121 (Zip Code)

4242 Campus Point Court, Suite 200, San Diego, CA (Address of principal executive offices)

Registrant's telephone number, including area code (858) 251-4400

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

#### Item 7.01 Regulation FD Disclosure.

On August 9, 2017, Heron Therapeutics, Inc. (the "Company") issued a press release announcing initiation of the Phase 3 program for HTX-011 in postoperative pain following successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration, as described in the press release furnished herewith as Exhibit 99.1.

A copy of presentation materials describing a Company update, 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.	
Exhibit No.	Description
99.1	Press Release, dated August 9, 2017
99.2	Corporate Presentation, dated August 9, 2017

#### SIGNATURES

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.

Heron Therapeutics, Inc.

Date: August 9, 2017

/s/ David L. Szekeres David L. Szekeres Senior Vice President, General Counsel, Business Development and Corporate Secretary



#### Heron Therapeutics Announces Initiation of Phase 3 Program for HTX-011 in Postoperative Pain Following Successful End-of-Phase 2 Meeting with FDA

-Phase 3 Program Expected to Enable Broad Indication-

-NDA Filing Planned for 2018-

-Final Phase 2 Results Demonstrate Clear Superiority to Bupivacaine Solution across All Surgical Models Evaluated-

-Conference Call and Webcast Today at 5:00 p.m. ET-

SAN DIEGO, Calif.— (BUSINESS WIRE) – August 9, 2017— Heron Therapeutics, Inc. (Nasdaq: HRTX) (the Company or Heron), a commercial-stage biotechnology company focused on developing novel, best-in-class treatments to address some of the most important unmet patient needs, today announced the positive outcome of a recent End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's investigational agent, HTX-011, to prevent postoperative pain for the first 72 hours after surgery.

General agreement was reached with the FDA on the design and key elements for HTX-011's Phase 3 program that will be required to support a New Drug Application (NDA). The program includes two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair, representing a bony model and a soft tissue model, respectively.

Heron recently initiated patient enrollment in the HTX-011 Phase 3 program and anticipates completing the Phase 3 program in the first half of 2018. Heron expects to file an NDA for HTX-011 in 2018.

The Phase 3 program is designed to achieve a broad indication for the reduction in postoperative pain for 72 hours following surgery. The primary endpoints of the Phase 3 efficacy studies will be the difference in mean area under the curve (AUC) of pain intensity scores through 72 hours compared with placebo. The first key secondary endpoints will be the difference in mean AUC of pain intensity scores through 72 hours compared with bupivacaine. Additional key secondary endpoints measuring reduction in opioid use and proportion of subjects who are opioid-free are included to support an opioid-sparing claim. In addition to the Phase 3 efficacy studies, approximately 200 patients will be enrolled in a Phase 3 safety and pharmacokinetics study to meet the target patient numbers established by the FDA and to provide further evidence of the broad utility of HTX-011 across multiple surgical models. Importantly, the FDA noted that, beyond the agreed-upon Phase 3 studies, no additional clinical work is needed to meet the "Combination Rule" for fixed-dose combination products.



"Inadequate pain management during the first 72 hours following surgery may lead to chronic post-surgical pain and an increased risk of opioid addiction. This places a greater economic burden on the healthcare system, and it potentially results in millions of opioids flooding our communities," said Harold S. Minkowitz, MD, Diplomat American Board of Anesthesiology, Department of Anesthesiology, Memorial Hermann Memorial City Medical Center. "New treatments, such as HTX-011, are addressing how we can prevent, not just react to, the overuse and abuse of opioids in so many of our neighborhoods. HTX-011 provides a highly effective, non-opioid analgesic option before the problem starts. Effectively managing post-surgical pain and prioritizing treatments that can reduce the need for opioid prescriptions are critical steps toward getting ahead of the opioid epidemic."

HTX-011 is the first and only long-acting anesthetic designed to address both postoperative pain and inflammation in a single administration at the surgical site. HTX-011 leverages meloxicam in our proprietary polymer formulation to potentiate the local anesthetic activity of bupivacaine over 72 hours. The unique synergy of bupivacaine and meloxicam in HTX-011 has been shown to reduce pain significantly better than placebo or bupivacaine alone in three diverse surgical models: bunionectomy, hernia repair and abdominoplasty.

#### Final Phase 2 Results from Bunionectomy, Hernia Repair and Abdominoplasty Studies for HTX-011

As part of our End-of-Phase 2 meeting update, Heron is presenting final Phase 2 results for HTX-011 using the doses, route of administration and statistical methodology that will be used in the Phase 3 studies. These results indicate that HTX-011 has consistently demonstrated superiority over placebo and bupivacaine, the current standard-of-care, in all surgical models evaluated.

- Bunionectomy: HTX-011 60 mg reduced pain through 72 hours significantly better than placebo (P=0.0003) and bupivacaine 50 mg (P=0.0166)
  - HTX-011's pain reduction through 72 hours, as compared to placebo, was 24 times greater than a similar dose of bupivacaine
- Hernia Repair: HTX-011 300 mg reduced pain through 72 hours significantly better than placebo (P=0.0045) and bupivacaine 75 mg (P=0.0427)
  - HTX-011's pain reduction through 72 hours, as compared to placebo, was more than 4 times greater than bupivacaine
- Abdominoplasty: HTX-011 400 mg reduced pain through 72 hours significantly better than placebo (P=0.0041) and bupivacaine 100 mg (P=0.0399)
  - HTX-011's pain reduction through 72 hours, as compared to placebo, was more than 5 times greater than bupivacaine



The final Phase 2 results seen in bunionectomy and hernia repair correspond with the primary and first key secondary endpoints for the Phase 3 efficacy studies agreed to by the FDA.

"We are pleased to announce the positive outcome of the End-of-Phase 2 meeting for HTX-011 and the recent initiation of patient enrollment in our Phase 3 program," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "In bunionectomy and hernia repair, the surgical models planned for Phase 3, we have demonstrated consistent efficacy against both placebo and bupivacaine solution, the standard-of-care used for local administration in more than 11 million surgical procedures per year for postoperative pain control."

#### **Conference Call and Webcast**

Heron Therapeutics will host a conference call and webcast today, August 9, 2017, at 5:00 p.m. ET (2:00 p.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 67789688 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 <a href="http://www.herontx.com">www.herontx.com</a> under the Investor Relations section. The conference call will also be available via webcast under the Investor Relations section of Heron's website. 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 Postoperative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer® drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. The Phase 2 development program for HTX-011 was designed to target the many patients undergoing a wide range of surgeries who experience significant postoperative pain. Heron has recently initiated the HTX-011 Phase 3 program and expects to file an NDA in 2018.

#### About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments that address some of the most important unmet patient needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-



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approved pharmacological agents for patients suffering from cancer or pain. For more information, 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, including, but not limited to, those associated with: whether the HTX-011 Phase 2 study results are indicative of the results in future studies, the timing of completion and results of the Phase 3 trials for HTX-011, the timing of the NDA filing for HTX-011, the progress in the research and development of 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:

David Szekeres Senior VP, General Counsel, Business Development and Corporate Secretary dszekeres@herontx.com 858-251-4447

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# **Company Update**

August 2017



### **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: the potential market opportunity and net sales for SUSTOL<sup>®</sup>, CINVANTI<sup>™</sup> and HTX-011, whether the HTX-011 Phase 2 study results are indicative of the results in future studies, the timing of initiating Phase 3 studies for HTX-011, the timing of completion and results of the Phase 3 trials for HTX-011, the timing of the NDA filing for HTX-011, the timing of NDA approval for CINVANTI™, the projected sufficiency of our capital position for future periods, the progress in the research and development of HTX-011 and our other programs, including the timing of preclinical, clinical, and manufacturing activities, safety and efficacy results from our studies, 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.









Postoperative Pain Program HTX-011: Proprietary Extended-Release Combination of Bupivacaine + Meloxicam



### Market Is Large and Local Anesthetic Use Is Common, but Long-Acting Anesthetics Have Not Fulfilled the Promise





#### Key Limiters of Liposomal **Bupivacaine Market Penetration**

- · Perceived inability to achieve marketed duration of efficacy<sup>2</sup>
- · No large scale studies have reproducibly shown superiority versus bupivacaine solution
- · HCPs not persuaded that incremental efficacy is worth the cost
- · Because of the above, there are significant formulary access restrictions<sup>2</sup>
  - Restricted by Specialty
  - Restricted by Procedure
  - Not on Formulary
  - Very low penetration in ASC and outpatient settings1

ERO

<sup>1</sup> DRG claims analysis (2015), DRG Postoperative Pain Pharmacor
 <sup>2</sup> DRG physician and P&T member interviews (2016; n=106)
 \*Based on analysis of current postoperative pain management across 40 target procedures (~28M procedures)



Source: DRG Physician Survey (2016)



**HTX-011** directly blocks transmission of the pain signal, potentially reducing the chance of chronic pain.

Acting on opiate receptors in the brain, opioids can reduce the sensation of pain, but do not block transmission of the pain signals. Occasionally, the affected nerves become hyper-stimulated resulting in chronic pain.

### HTX-011 Designed to Produce Marked Analgesia Through the First 72 Hours After Surgery



### HTX-011 Clinical Experience Shows It Has the Potential to Transform Postoperative Pain Control



#### Phase 2 data has demonstrated:

- Statistically significant reductions in both pain and opioid use lasting up to 72 hours after surgery
- Utility in a broad selection of surgical procedures, including small procedures (bunion), medium size procedures (hernia), and one of the largest incisions (abdominoplasty)
- Synergy between meloxicam and bupivacaine in HTX-011 results in significantly greater analgesia compared to bupivacaine alone



## Product attributes of HTX-011 optimized in Phase 2 for Phase 3 efficacy studies:

- Formulation, where the product has shown the versatility to be used in a wide variety of surgical procedures
- Dose, where the lowest highly effective dose has been chosen for Phase 3
- Route of administration, where instillation, a faster, easier and potentially safer route of administration was demonstrated to be equally effective to standard injections



### **End-of-Phase 2 Meeting Agreements with FDA**



- Two Phase 3 adequate and well-controlled efficacy studies and a Phase 3 safety study of approximately 200 subjects in multiple surgical models are adequate to support an NDA for a broad indication for reduction in postoperative pain for 72 hours
  - Primary and key secondary endpoints for Phase 3 studies are acceptable
  - Adjustment of pain intensity data for opioid use by the wWOCF methodology is acceptable
- Phase 3 efficacy studies with bupivacaine as an active control meets FDA Combination Rule
  - One ingredient is intended to enhance effectiveness of principal active component
  - Factorial design study not required
- Size of proposed safety database adequate
- No renal or hepatic impairment studies or drug-drug interaction studies required for NDA



# PHASE 3 PROGRAM HAS BEEN INITIATED

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### Study 301: Phase 3 Bunionectomy Study Design



#### Study 301 Endpoints

Primary: Pain Intensity AUC<sub>0-72</sub> vs. placebo

1st Key Secondary: Pain Intensity  $AUC_{0-72}$  vs. bupivacaine

2<sup>nd</sup> Key Secondary: Opioid use vs. placebo

3<sup>rd</sup> Key Secondary: Opioid-free vs. bupivacaine

4<sup>th</sup> Key Secondary: Opioid use vs. bupivacaine

The trial design provides at least 90% power to detect a statistically significant difference between HTX-011 and each of the control groups for primary and all key secondary endpoints

HERO

### Study 302: Phase 3 Herniorrhaphy Study Design



#### Study 302 Endpoints

Primary: Pain Intensity AUC<sub>0-72</sub> vs. placebo

1st Key Secondary: Pain Intensity  $AUC_{0-72}$  vs. bupivacaine

2<sup>nd</sup> Key Secondary: Opioid use vs. placebo

3rd Key Secondary: Opioid-free vs. bupivacaine

4<sup>th</sup> Key Secondary: Opioid use vs. bupivacaine

The trial design provides at least 90% power to detect a statistically significant difference between HTX-011 and each of the control groups for primary and all key secondary endpoints

HERO



### HTX-011 STUDY 208: Phase 2 Bunionectomy

Updated Results With the Phase 3 Dose Analyzed by the FDA Requested Methodology (wWOCF) (5 Clinical Sites Enrolled Subjects)



### HTX-011 Reduces Pain Significantly Better Than Placebo or Bupivacaine (Standard-of-Care) After Bunionectomy



#### HTX-011 60 mg Produces 24-Fold Greater Reduction in Pain Compared to Bupivacaine 50 mg Through 72 Hours in Bunionectomy







HTX-011 STUDY 202: Phase 2 Hernia Repair

Updated Results With the Phase 3 Dose Analyzed by the FDA Requested Methodology (wWOCF) (3 Clinical Sites Enrolled Subjects)



### HTX-011 Reduces Pain Significantly Better Than Placebo or Bupivacaine (Standard-of-Care) After Herniorrhaphy



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#### HTX-011 300 mg Produces 4-Fold Greater Reduction in Pain Compared to Bupivacaine 75 mg Through 72 Hours in Hernia Repair





## HTX-011 STUDY 203: Phase 2 Abdominoplasty

Updated Results Using wWOCF (8 Clinical Sites Enrolled Subjects)



### HTX-011 Reduces Pain Significantly Better Than Placebo or Bupivacaine (Standard-of-Care) After Abdominoplasty



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### HTX-011 400 mg Produces 5-Fold Greater Reduction in Pain Compared to Bupivacaine 100 mg Through 72 Hours in Abdominoplasty



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## Summary: HTX-011 Is Poised to Fulfill the Promise of a Long-Acting Extended-Release Local Anesthetic

$\checkmark$
~
$\checkmark$
✓
~
$\checkmark$
✓





# CINV





## **CINVANTI™** (HTX-019) (aprepitant for injection) is an investigational proprietary, surfactant-free intravenous formulation of the NK₁ receptor antagonist aprepitant

PDUFA date November 12, 2017, planned launch Q1 2018

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## CINV FRANCHISE COMMERCIAL UPDATE

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## SUSTOL Launch Performance Aligns Closely With "Buying Process" Insights From Market Research

**<u>Q4 2016</u>**: 56% of MDs said they would evaluate SUSTOL as their potential branded agent of choice over a period of several quarters



Note: In what timeframe do you expect Sustol to become the practice's branded 5-HT3 of choice? Source: Putnam SUSTOL Tracking Surveys (November 2016) **Q2 2017:** 37% of PMs said they have completed trial or are in the process of trialing SUSTOL while 35% plan to do so in next 2 guarters



Note: Which of the following best describes the extent of review and/or trial of Sustol by your practice? Source: Putnam SUSTOL Tracking Surveys (May 2017)

## Since Launch, SUSTOL Has Delivered Triple-Digit Unit Growth Quarter-Over-Quarter



**Purchasing Accounts by Quarter** 105 accounts 120 (291 affiliated sites) 88 accounts 100 (252 affiliated sites) 74 accounts (167 affiliated sites) 80 60 40 20 0 Q4'16 Q1'17 Q2'17

86% (76 of 88) of accounts exhibited double-digit growth from Q1 to Q2 2017



### Account Growth and Penetration Has Enabled SUSTOL to Outperform Recent CINV Launches









**CINV Launches Since 2008** 

Sources: IMS DDD; Heron actuals (distributor 867 reports); due to data availability, Sancuso data includes actuals for launch months 3-9 and estimates for months 1-2

Akynzeo

(2014)

Varubi (2015)

0

Sancuso

(2008)

SUSTOL

(2016)

н

### Market Insights Suggest SUSTOL May Decline Modestly **Through the Arbitrage and Grow Thereafter – Consistent** With Aloxi Analogue





- Practices that are converting to SUSTOL are likely to maintain use<sup>1</sup>
- ~67% of current "dabblers" likely to stop or reduce use of . SUSTOL during arbitrage<sup>2</sup>
- ~20% of SUSTOL non-users would consider initiating SUSTOL during arbitrage<sup>2</sup>
  - o "If generic Aloxi is available, it's going to allow me to start using SUSTOL without having to worry about maintaining my Aloxi contract" -PM
- · ~55% of HCPs said they would be interested in using SUSTOL post-arbitrage (equating to an addressable market of ~650K units)2
  - "When ASP [erodes], we would switch all patients from generic Aloxi to SUSTOL." PM
  - "SUSTOL usage would increase. There's no reason to keep people on generic Aloxi." PM

Sources: <sup>1</sup> Customer discussions <sup>2</sup> Putnam Associates Qual Research Findings, June 2017



## **CINVANTI Gives Heron a 2-Product CINV Franchise** With Little Incremental Investment

- Significant market opportunity
  - Emend<sup>®</sup> IV accounts for 80% (~1.2M units) of NK-1 market
- Potential for significant growth as NK-1s are underutilized particularly in MEC
- CINVANTI will offer established efficacy without the risk of polysorbate 80-related adverse events

Sources: IMS DDD: IPSOS "US Tandem Oncology Monitor Anti-Emetics Report" is based on chart audit data of 68,437 patient records between 2015 and 2016





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## 2017 CINV Franchise Outlook





Building on the strong momentum built by Heron, we expect steady but measured growth in SUSTOL® trial and adoption

 We are raising our guidance to \$25M - \$30M in SUSTOL net sales in 2017



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CINVANTI™ (HTX-019) program advancing

- PDUFA date November 12, 2017
- Anticipate launch Q1 2018
- If approved, Heron would be the first company to address both mechanisms of action for the prophylaxis of CINV with injectable products
- Offers strong strategic and operational fit with existing commercial organization



**Financial Summary** Cash, cash equivalents and short-term investments of \$109.3 million plus accounts receivable of \$18.6 million at June 30, 2017, along with collections from SUSTOL sales after June 30, 2017 provides enough funding to complete the HTX-011 pivotal Phase 3 efficacy studies in the first half of 2018.

Summary Statement of Operations and Net Cash Used in Operations (In thousands, except per share data)	Three Months Ended June 30, 2017	Six Months Ended June 30, 2017
Net product sales	\$ 8,510	\$ 12,142
Operating expenses <sup>1</sup>	50,565	103,496
Other expenses, net	(744)	(1,774)
Net loss <sup>1</sup>	\$ (42,799)	\$ (93,128)
Net loss per share <sup>2</sup>	\$ (0.80)	\$ (1.79)
Net cash used in operations	\$ (32,030)	\$(82,611)

Condensed Balance Sheet Data (In thousands)	June 30, 2017	
Cash, cash equivalents and short-term investments	\$	109,263
Accounts receivable, net	\$	18,616
Total assets	\$	142,370
Promissory note payable	\$	25,000
Total stockholders' equity	\$	69,075
<ul> <li><sup>1</sup> Includes \$8.2 million and \$16.2 million of non-cash, stock-based compensation expense for the three and six months ended June 30, 2017</li> <li><sup>2</sup> Based on 53.8 million and 52.2 million weighted-average common shares outstanding for the three and six months ended June 30, 2017, respectively.</li> </ul>	7, respectively. respectively.	

## Key Catalysts in Pain & CINV Franchises

HTX-011 for Postoperative Pain	CINVANTI™ (HTX-019) for CINV	SUSTOL <sup>®</sup> for CINV
<ul> <li>✓ Top-line results abdominoplasty</li> </ul>	✓ NDA submission	2017 net sales guidance increased: \$25M - \$30M
✓ Phase 2 program in nerve block initiated	NDA PDUFA Date Nov. 12, 2017	
<ul> <li>✓ TKA study initiated (local administration)</li> </ul>		
✓ End-of-Phase 2 meeting		
✓ Phase 3 program initiated		
Top-line Pivotal Phase 3 results 1H 2018		
NDA filing 2018		
	-	