# making medicines better™

NASDAQ: **ATRS** 



**Ladenburg Thalmann 2015 Healthcare Conference** 

September 29, 2015



### Safe Harbor Statement

This presentation may contain forward-looking statements which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding the timing of actions by the U.S. Food and Drug Administration ("FDA") regarding the Company's product candidates and those of its thirdparty partners; continued growth in prescriptions and revenue for OTREXUP; the timing and results of the phase 3 supplemental safety study for QuickShot Testosterone ("QS T"); FDA approval of QS T and the potential for QS T to be the first at-home auto injector for the subcutaneous treatment for low testosterone, approval by the FDA of and the therapeutic equivalence rating for Teva's epinephrine pen and the timing thereof; the size of the market for the epinephrine pen and future sales by Teva; the approval by FDA of third-party products and the timing thereof; the Company's ability to adequately address and timely respond to the FDA's complete response letter and the approval by FDA of VIBEX Sumatriptan and the timing thereof; the approval by FDA of the exenatide pen and the timing thereof; and the plans, objectives and future financial performance of Antares Pharma, constitute forward-looking statements which involve risks and uncertainties. The Company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including sales growth of OTREXUP, timing of regulatory approval of products in development and the clinical benefits of those products, actions of third-party partners and regulatory actions related to their products, uncertainties associated with research, development, testing and related regulatory approvals, outcomes of clinical trials and timing of release of data therefrom, unproven markets, competition, dependence on third-party manufacturers, suppliers and collaborators, and government regulation. For a more detailed description of the risk factors associated with the Company, please refer to the Company's periodic reports filed with the U.S. Securities and Exchange Commission from time to time, including its Annual Report on Form 10-K for the year ended December 31, 2014. Undue reliance should not be placed on any forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to update any forward-looking information contained in this presentation.

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### Three Strategic Areas of Focus Leveraging Technology for Growth

#### **PROPRIETARY PRODUCTS**

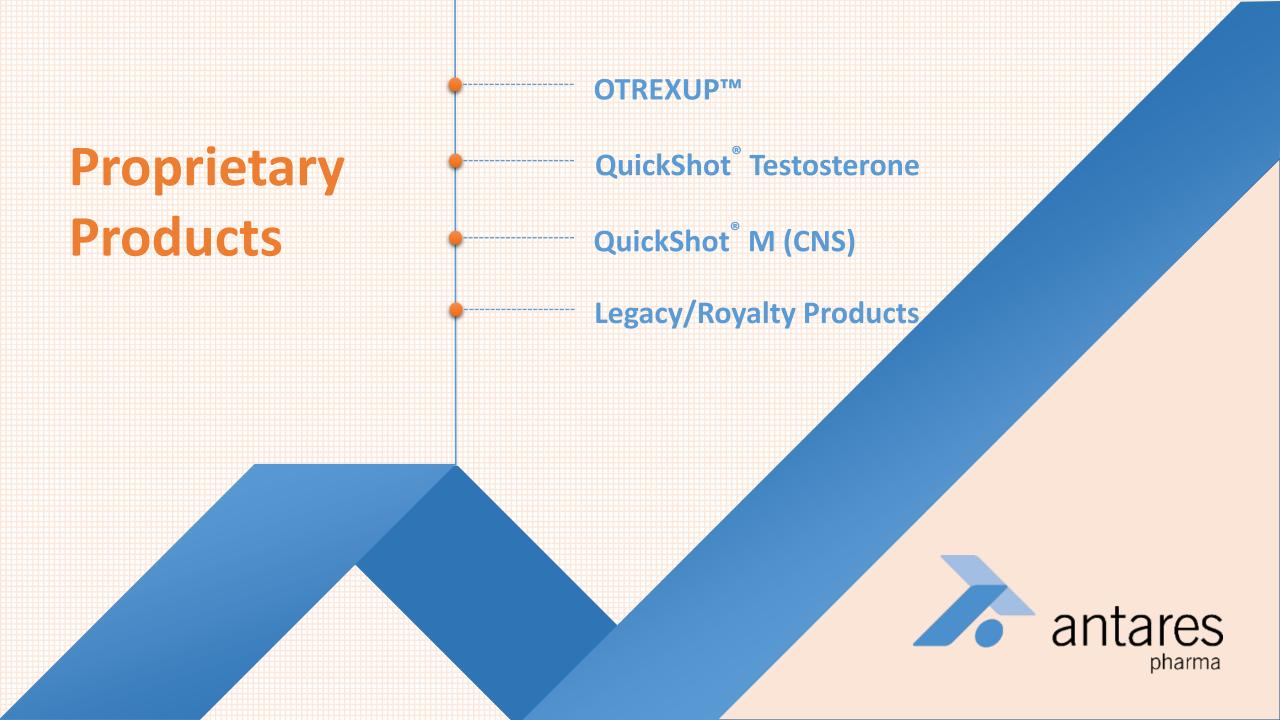
- OTREXUP™
- QuickShot® Testosterone
- QuickShot® M (CNS)
- Elestrin®
- Gelnique 3%™

### **ALLIANCE PRODUCTS**

- Epinephrine Pen
- Exenatide Pen
- Teva "Pen 1"
- Pfizer OTC Gel
- Undisclosed Life Cycle Management
- Zomacton™/ZomaJet®

#### **COMPLEX GENERICS**

VIBEX® Sumatriptan



## **Antares Proprietary Products**

**OTREXUP™** 

Approved in U.S. and launched by Antares Q1 2014 for the treatment of rheumatoid arthritis ("RA")

QuickShot® Testosterone

Phase 3 pharmacokinetic ("PK") study enrollment complete and topline data reported February 25, 2015. Finalized protocol design to secure an additional 70 subjects exposed to QS T for six months. First patients were enrolled in the supplemental phase 3 safety study in Q3 2015.

QuickShot® M

Undisclosed neurology product currently in preclinical development.

Legacy / Royalty Products

Elestrin® is marketed in the U.S. by Meda Pharma, and Gelnique 3%™ is marketed by Actavis PLC in the U.S.







### OTREXUP™ (methotrexate) Injection for Subcutaneous ("SC") Use

< First approved methotrexate for SC injection in the U.S. >

# OTREXUP'S UNIQUE DESIGN AND FUNCTION



Single-use, disposable & easy to use

Collar activated, no push button, easy to grip and virtually painless

Needle guard prevents accidental sticks

Audible click followed by red indicator to confirm injection is complete

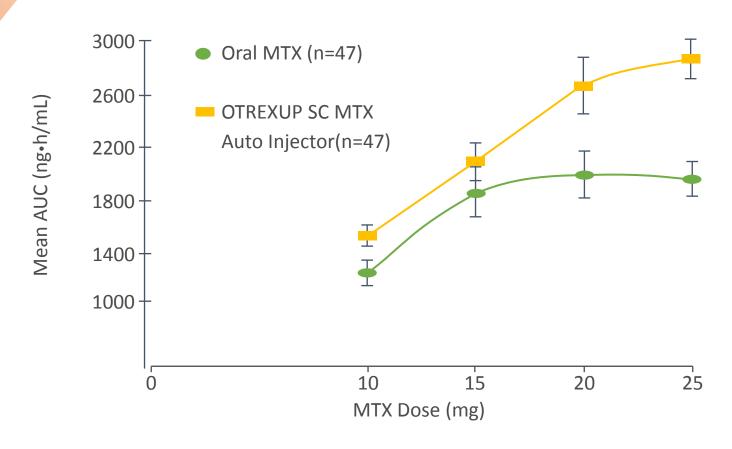
Approved in 7.5, 10, 15, 20 & 25 mg color-coded doses. 10 mg device shown

See full prescribing information for OTREXUP™ (methotrexate) injection [prescribing information]. Ewing, NJ: Antares Pharma, Inc; 2013



### OTREXUP™: Oral MTX Exposure Plateaus ≥15 mg/week



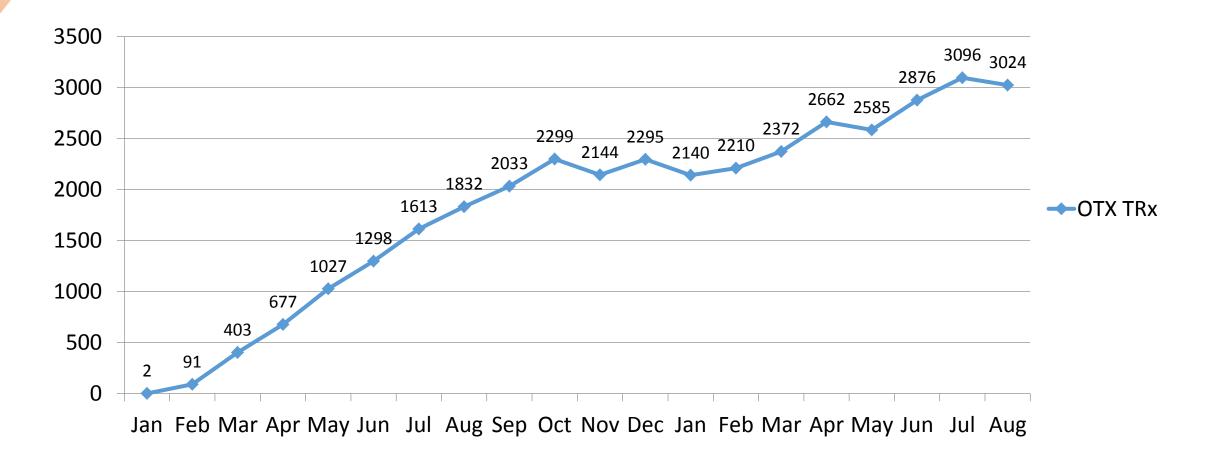


- Oral MTX has GI absorption limitations
- Bioavailability following oral dosing showed a plateau effect at doses of 15mg and greater<sup>1</sup>
- The systemic exposure of MTX from OTREXUP™ at doses of 10, 15, 20, and 25mg was higher than that of oral MTX by 17, 13, 31, and 36%, respectively¹

1. OTREXUP<sup>TM</sup> [prescribing information], 2013. 2. Schiff MH, et al. Arthritis Rheum. 2013; 65 (10 suppl): S337-338/Phase 2 data



### OTREXUP™ Monthly TRx Growth Jan 2014 – Aug 2015



Source: Symphony Health Solutions



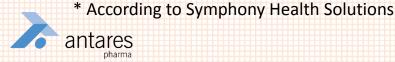
### **Plans to Grow OTREXUP™ Scripts in 2015**

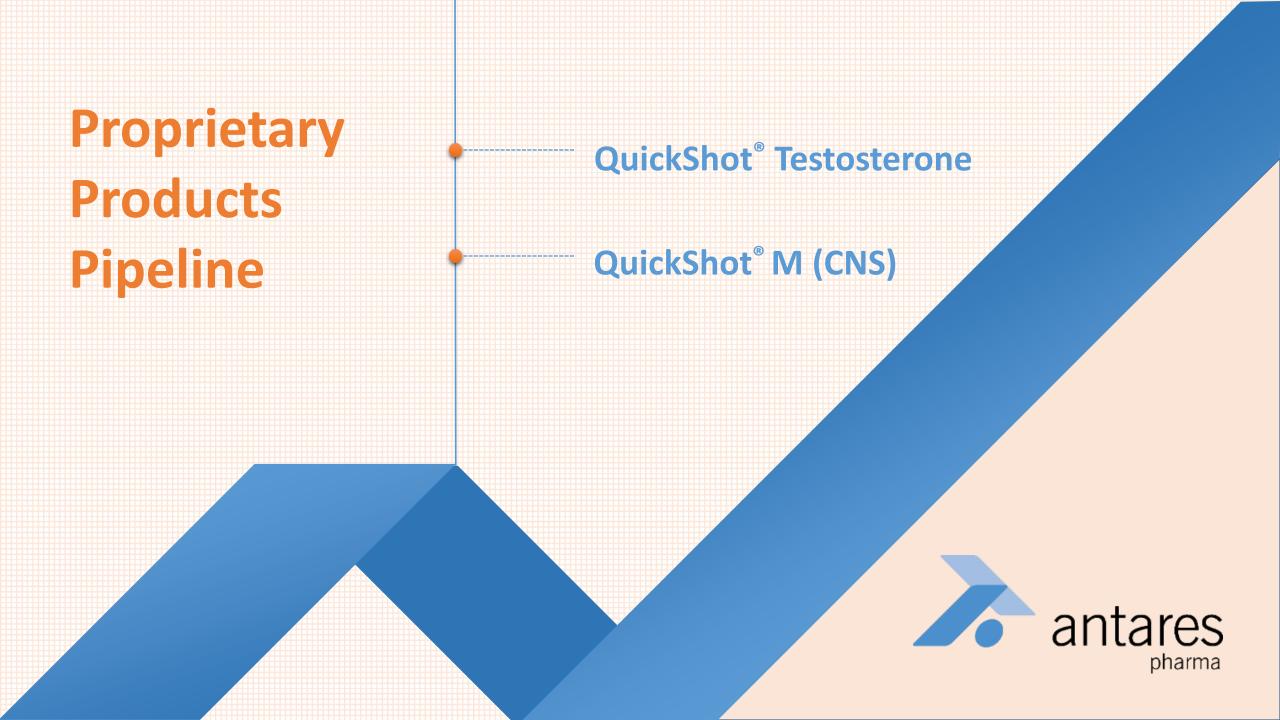
- Converted contract sales reps and built an Antares sales force
  - Increased the number of sales territories
  - Replaced under-performing reps
- Improve hub services to assist physicians with reimbursement process
  - Launched new patient starter kits for use during the hub reimbursement process
- Contract with Managed Care Organizations on fiscally responsible basis



### **OTREXUP Progress**

- OTREXUP TRx's are approximately two-thirds of the subcutaneous market and approximately five percent of the injectable MTX market\*
- Managed Care Coverage continues to improve
- 4.9% price increase July 1 WAC = \$575
- Co-pay card utilization increasing
- Marketing and Medical Affairs Initiatives
- Enhanced OTREXUP web site launched in Q3





## QuickShot® Testosterone

- Potentially the first at-home auto injector for SC treatment of low testosterone (Low T)
  - Total TRT Market of \$2.8 billion in 2014\*
- Single use, disposable QuickShot® device engineered to deliver high viscosity products through fine needle (27 gauge) with 1 ml capacity
- 1x Weekly Injection Peak/Trough ratio reduced versus 1 2x monthly intramuscular injection
- Design Goals:
  - Quick, easy, accurate and painless Approximately 5 seconds to self-inject
  - Eliminate transference issue associated with gels
  - ✓ Improve patient compliance





\*Source: Symphony Health Solutions



Subcutaneous Testosterone Replacement Efficacy and Safety in Adult Men Diagnosed with Hypogonadism

# STEADY Phase III Trial Data Overview





# QST-13-003 Pharmacokinetic Results

Population/Analysis	C <sub>avg</sub> Lower limit of the 95% 2-sided C. I.	C <sub>avg</sub> % in Range 300 – 1100 ng/dL n (%)	C <sub>max</sub> <1500 ng/dL n (%)	C <sub>max</sub> >1800 ng/dL n (%)
Primary analysis* N=150	87.3%	139 (92.7%)	137 (91.3%)**	0%
Completers N=137	94.8%	135 (98.5%)	137 (100%)	0%
Protocol-Required Outcomes	≥65%	75%	≥85%	≤5%

 $<sup>^{*}</sup>$  All patients with 1 or more doses,  $C_{avg}$  0-168 hours post week 12 injection or last measured concentration carried forward

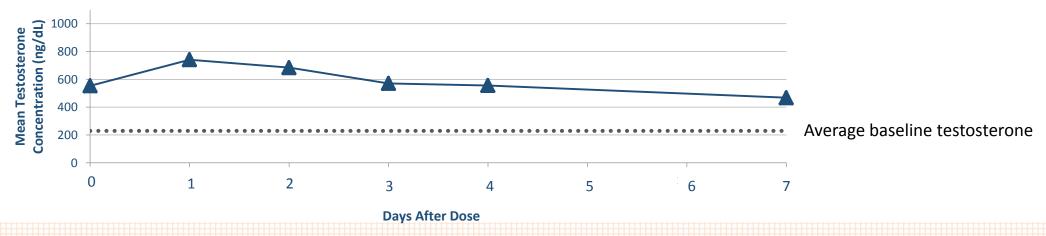


<sup>\*\*</sup>Patients without a C<sub>max</sub> determination at week 12 are assigned above 1500 ng/dL



# QST-13-003 Pharmacokinetic Results

- The PK results of our phase 3 clinical trial showed that patients using QS T had testosterone levels within and not exceeding the normal range
  - Patients experienced steady levels of testosterone with each week's dose
  - We believe the absence of peaks and troughs could mean fewer side-effects



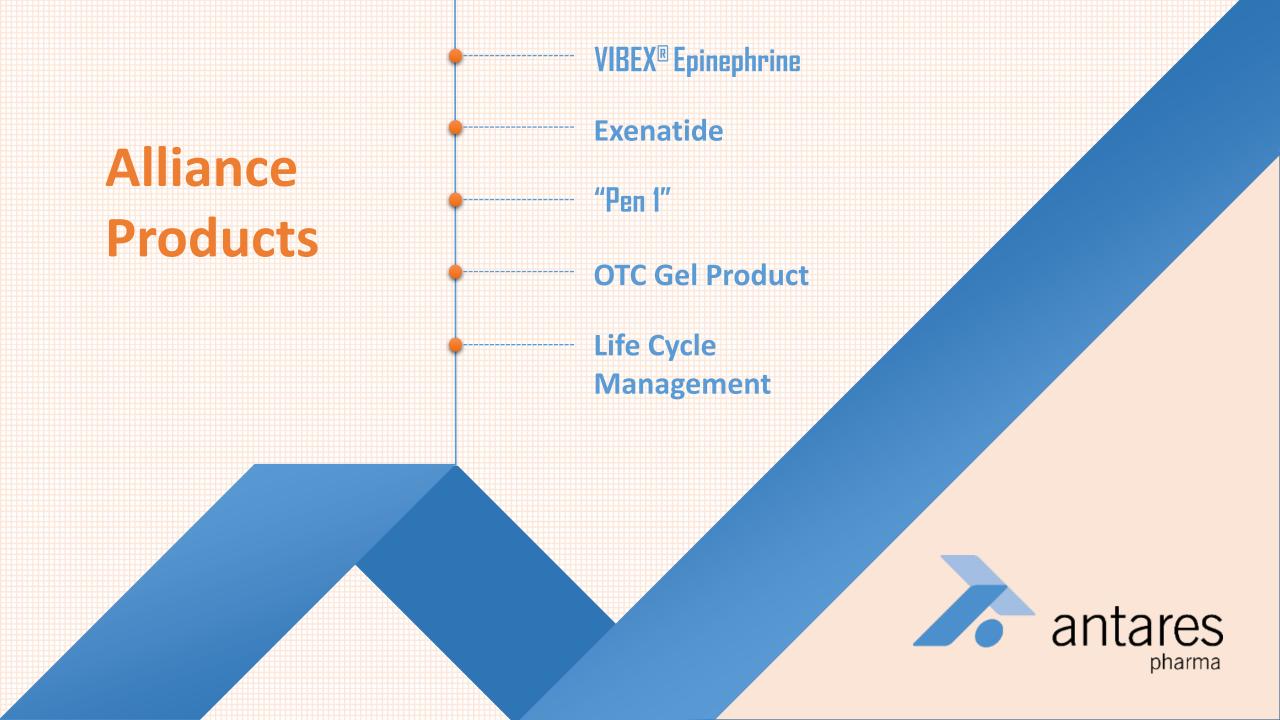




## **Updates to QS T Program**

- Received written recommendations from FDA on January 9, 2015 and May 28, 2015.
- FDA has recommended a larger safety database, including approximately 350 subjects exposed to QS T with 200 subjects exposed for six months and 100 subjects exposed for a year.
  - The Company will need to recruit approximately 70 additional subjects exposed to QS T for six months based on number of subjects in previous studies and in the current phase 3 study.
- Announced August 3, 2015 that the first patients had been enrolled in the supplementary safety study.





# Broad Device Collaboration With Teva - VIBEX<sup>®</sup> Epinephrine

- 2014 EpiPen retail total Rx dollars were approximately \$1.8 billion, according to Symphony Health Solutions
- Teva included risk adjusted revenue for the launch of an AB rated generic epinephrine pen in their 2015 guidance
- Mylan also indicated that their financial guidance includes the potential for a second half 2015 launch of an AB rated generic to EpiPen
- Mylan's Citizen Petition and supplement denied by FDA without comment June 15, 2015
- Teva stated on July 27, 2015 that they expect an approval on their epinephrine pen application in the second half of 2015



### **Broad Device Collaboration With Teva**

### VIBEX<sup>®</sup> Epinephrine

- Teva filed final amendment with FDA December 2014
- Antares receives margins on device sales, and mid-to-high single-digit royalty on overall product sales
- Antares to manufacture and ship devices which began in Q2 2015

#### Exenatide

- Teva filed ANDA with FDA in October 2014
- AstraZeneca and Amylin filed Paragraph IV certification in December 2014
- Antares receives margin on supply agreement and single digit to mid-teens royalty on overall product sales

### "Pen 1"

505(b)2 program has completed PK work in Europe



## Additional Partnership Products in Place

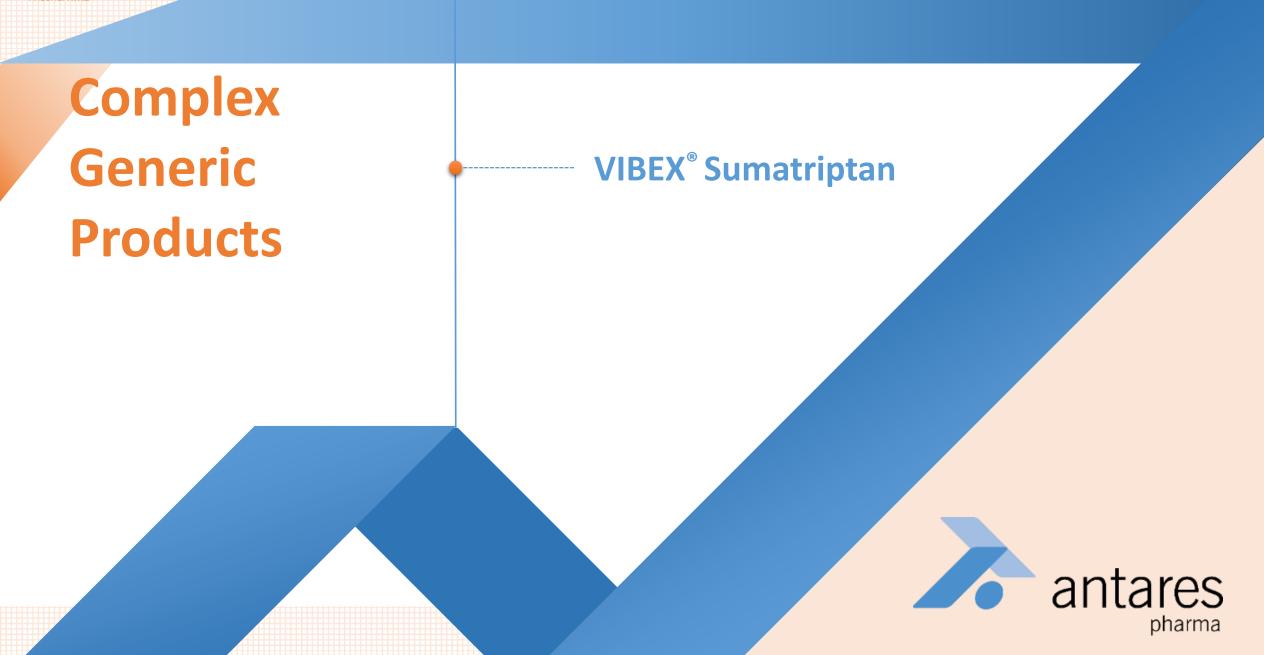
### Pfizer – Undisclosed Branded OTC Gel Product

- Currently in Phase 3 clinical development
- Pfizer assumes full cost and responsibility for clinical development, manufacturing and commercialization
- Antares receives development and sales based milestones and royalties on net sales for 3 years post launch

### Undisclosed Partnership

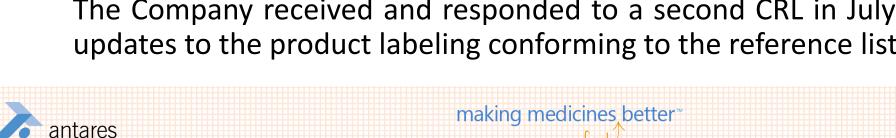
 Life cycle management (LCM) project announced in Q3 2014 – currently in clinical development





## VIBEX<sup>®</sup> Sumatriptan

- ANDA amendments filed with the FDA in the first half of 2014
- Antares will hold marketing authorization
- Teva will be distribution partner
  - Antares to receive undisclosed milestone upon launch
  - Net profit split 50/50 between parties
- Complete Response Letter ("CRL") received January 2015 provided labeling revisions and cited minor deficiencies; Antares responded to CRL in March. The Company received and responded to a second CRL in July with additional updates to the product labeling conforming to the reference listed drug.





## **Second Quarter 2015 Overview**

### Record Revenues

- \$14.4 million + 128% over Q2 2014
- YTD June = \$22.8 million vs. \$26.5 million for entire 2014 year
- Delivering on Four Critical Areas:
  - Growing OTREXUP prescriptions & revenue
  - Epipen devices to Teva \$1.8 million
  - Quick Shot Testosterone Final Study Commenced
  - Sumatriptan Manufacturing investments initiated; continued dialogue with FDA



## **Second Quarter 2015 Revenues**

	Three Months Ended June 30		Increase
	2015	2014	(Decrease)
OTREXUP	\$ 3,346	\$ <b>1,671</b>	100%
Needle-free injector devices and components	725	1,689	-57%
Auto injector and pen device sales	1,769	-	NA
Total Product Sales	5,840	3,360	74%
Development revenue	3,027	1,788	69%
Licensing revenue	5,186	928	459%
Royalties	367	250	47%
Total Revenue	\$ 14,420	\$ 6,327	128%



# **Second Quarter 2015 Financial Results**

	Three Months En	Increase	
	2015	2014	(Decrease)
Total Revenue	\$ 14,420	\$ 6,327	128%
Cost of Revenue	4,708	2,130	121%
Gross Profit	9,712	4,197	131%
% Revenues	67%	66%	
Research & Development	4,569	3,943	16%
Selling, General & Administrative	6,605	9,345	-29%
<b>Total Operating Expenses</b>	11,174	13,288	-16%
Operating Loss	(1,461)	(9,091)	-84%
Net Loss	(1,507)	(9,098)	-83%
Loss Per Share	\$ (0.01)	\$ (0.07)	



### **Antares Pharma – A Compelling Investment Opportunity**

- A Leader in High Performance Combination Products
- Commercial Stage Company with Advanced Pipeline and Several Near-Term Catalysts
  - ✓ VIBEX® Epinephrine Pen (Teva)
  - ✓ QuickShot® Testosterone Phase 3 results
  - ✓ OTREXUP™ prescription and revenue growth
  - ✓ VIBEX® Sumatriptan approval (Antares ANDA)



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