# making medicines better™



# Robert Apple

Executive Vice President, Chief Operating Officer

# **Deutsche Bank 40<sup>th</sup> Annual Health Care Conference**May 6, 2015





NASDAQ: ATRS

### 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 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, anticipated operating losses, uncertainties associated with research, development, testing and related regulatory approvals, outcomes of clinical trials and timing of release of data therefrom; unproven markets, future capital needs and uncertainty of additional financing, competition, uncertainties associated with intellectual property, complex manufacturing, quality requirements, dependence on third-party manufacturers, suppliers and collaborators, outcomes of litigation, lack of sales and marketing experience, the impact of moving from a contract sales force to hiring field-based sales representatives, loss of key personnel, uncertainties associated with market acceptance and adequacy of reimbursement, technological change, 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.



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

#### PROPRIETARY PRODUCTS

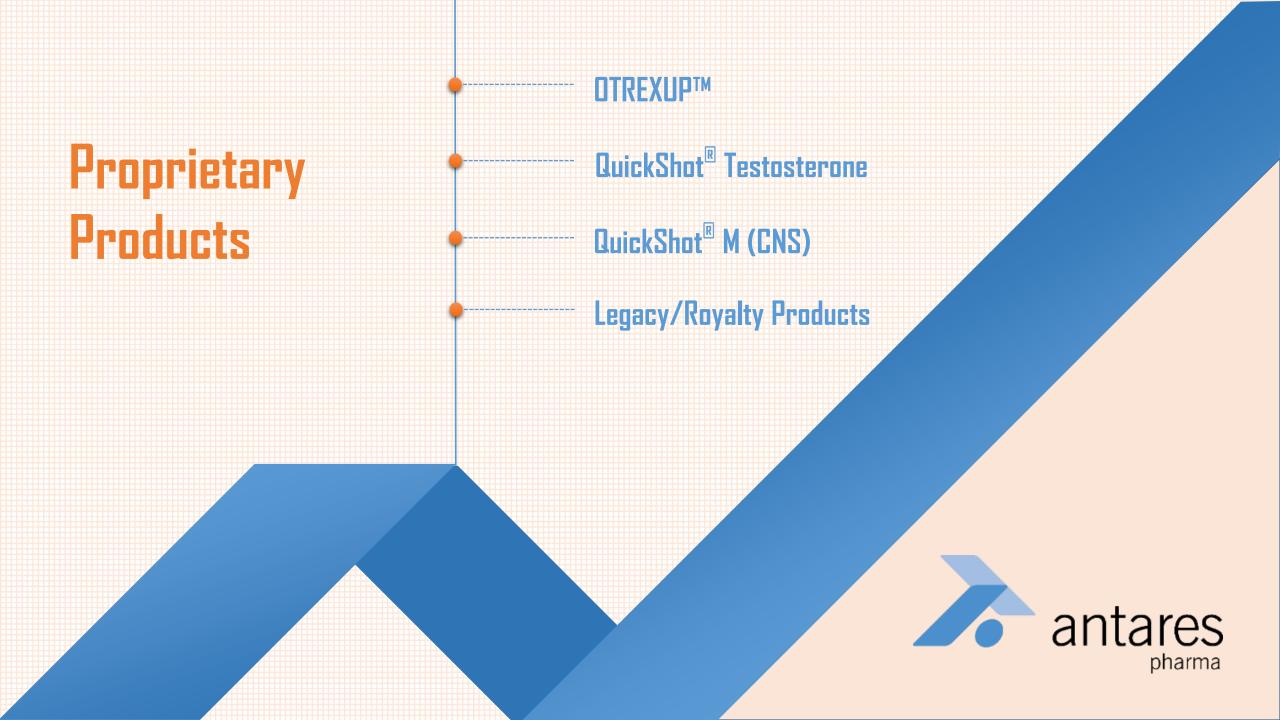
- OTREXUP™
- QuickShot® Testosterone
- QuickShot $\mathbb{R}$  M (CNS)
- Elestrin<sup>®</sup>
- Gelnique 3%™

#### **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<sup>TM</sup>** 

Approved in U.S. and launched by Antares Q1 2014 for the treatment of rheumatoid arthritis ("RA"); LEO Pharma A/S is currently promoting the psoriasis indication, but will return the rights to Antares in June 2015.

QuickShot® Testosterone

Phase 3 pharmacokinetic ("PK") study enrollment complete and top-line data reported February 25, 2015; working with FDA to determine next steps toward registration.

QuickShot® M

Undisclosed neurology product currently in preclinical development.

Legacy / Royalty Products

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





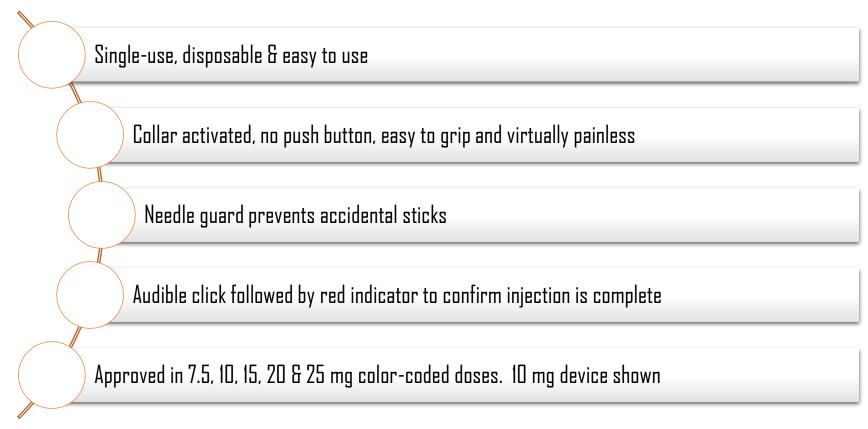


# OTREXUP™ (methotrexate) Injection for Subcutaneous ("SC") Use

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

# OTREXUP'S UNIQUE DESIGN AND FUNCTION



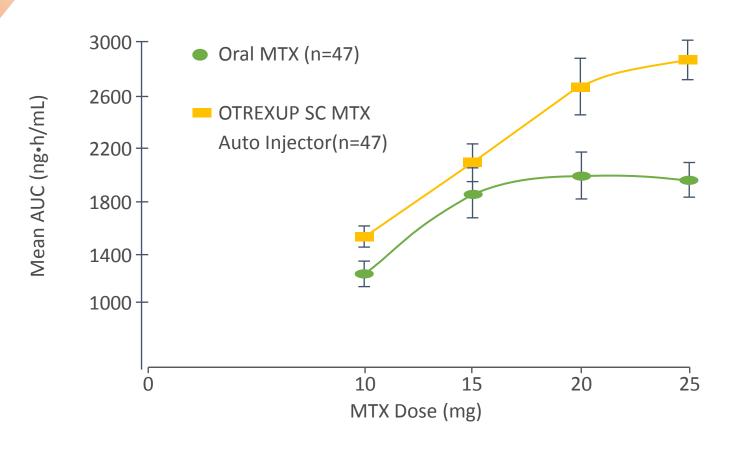


OTREXUP<sup>TM</sup> (methotrexate) injection [prescribing information]. Ewing, NJ: Antares Pharma, Inc; 2013



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

#### The OTREXUP™ Value Proposition = Increased Bioavailability

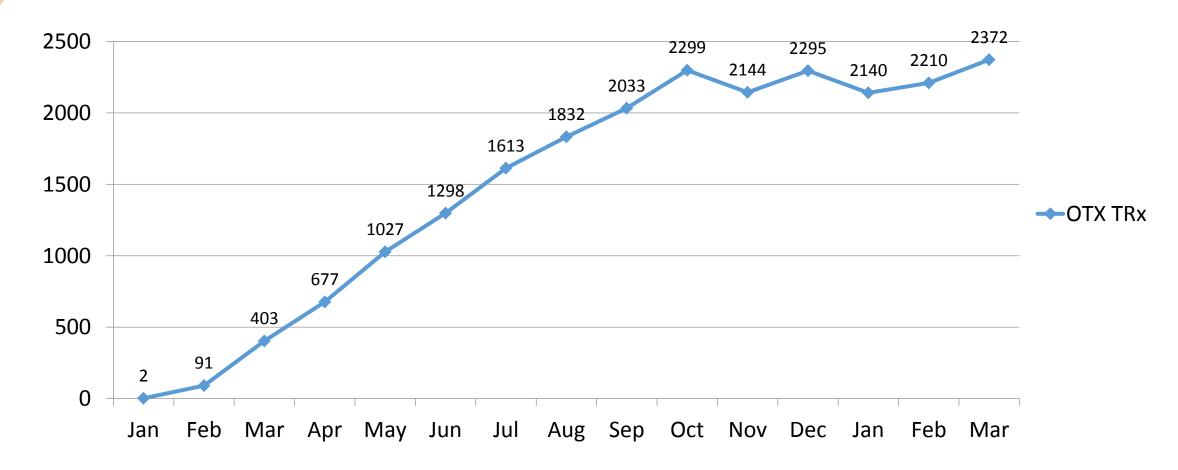


- Oral MTX has GI absorption limitations
- Bioavailability following oral dosing showed a plateau effect at doses of 15mg and greater<sup>1</sup>
- The systemic exposure of MTX from OTREXUP™ at doses of 10, 15, 20, and 25mg was higher than that of oral MTX by 17, 13, 31, and 36%, respectively¹

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



#### OTREXUP™ Month-Over TRx Growth 2014 - 2015



Source: Symphony Health Solutions



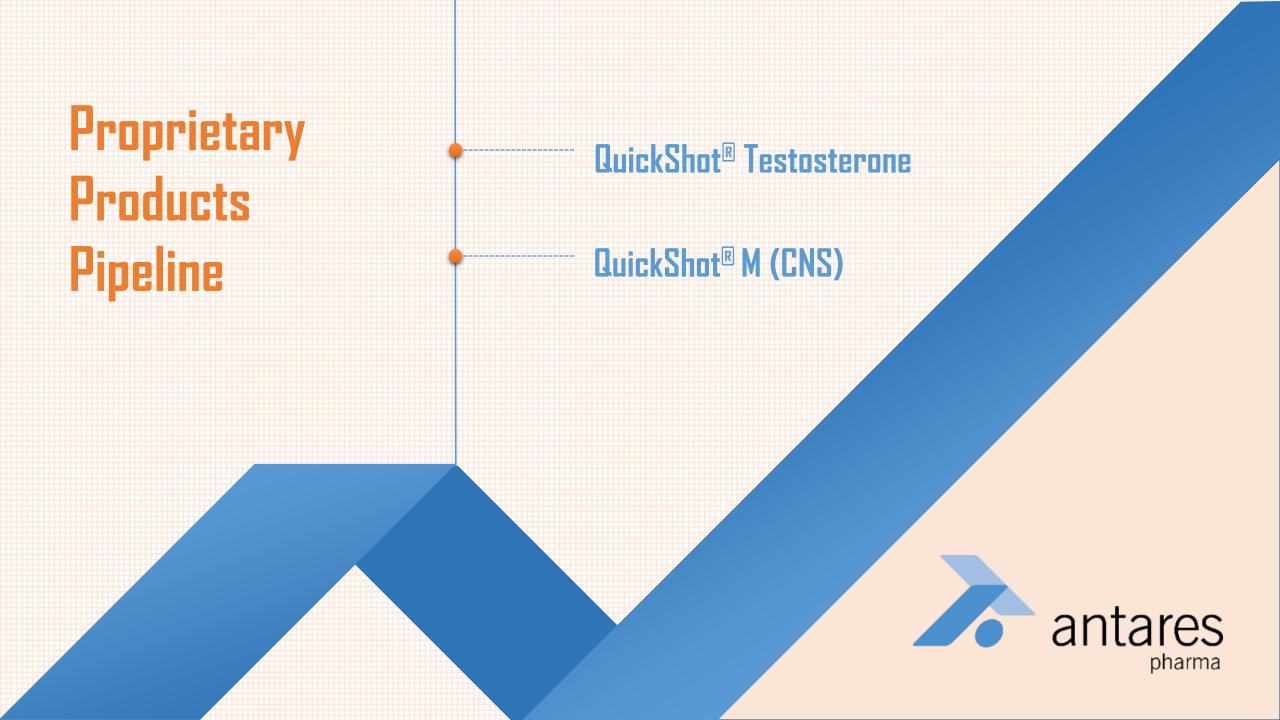
## Plans to Grow OTREXUP™ Scripts in 2015

- Convert contract sales reps and build an Antares sales force
- Increased the number of sales territories
- Replaced under-performing reps

- 2
- Improve hub services to assist physicians with reimbursement process
- Launched new patient starter kits for use during the hub reimbursement process

- 3
- Contract with Managed Care Organizations on fiscally responsible basis





## 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<sup>®</sup> 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, and painless Approximately 5 seconds to self-inject
  - Eliminate transference issue associated with gels
  - ✓ Improve patient compliance





Source: Symphony Health Solutions

## 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<br>300 – 1100 ng/dL<br>n (%) | C <sub>max</sub> <1500 ng/dL<br>n (%) | C <sub>max</sub> >1800<br>ng/dL<br>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

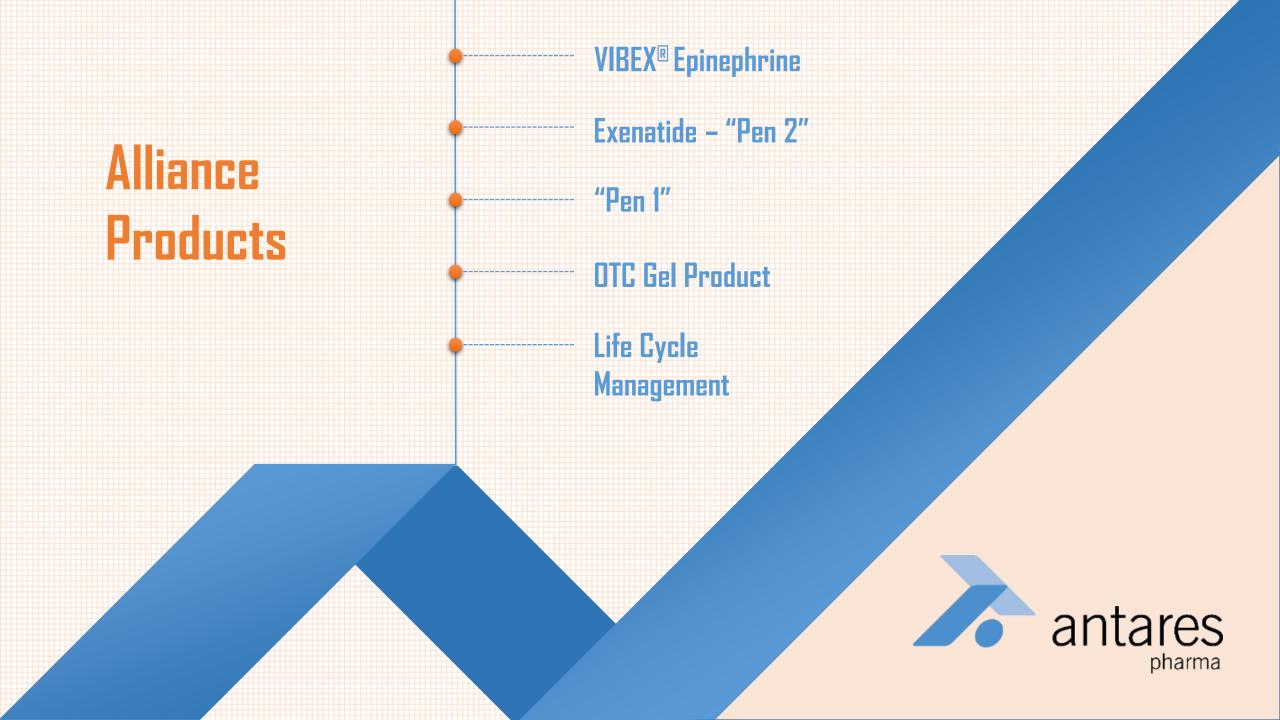


<sup>\*\*</sup>Patients without a  $C_{max}$  determination at week 12 are assigned above 1500 ng/dL

## Updates to QS T Program

- Received written recommendations from FDA on January 9, 2015.
- Antares believes that many of the recommendations cited in the advice letter are already included in the protocols of the
  ongoing phase 3 study as a result of guidance provided by FDA at the May 2014 Type C meeting.
- Antares Pharma is assessing the FDA's comments in the advice letter and their impact on the timing of the filing of a New Drug Application for QS T with FDA.
  - 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.
  - May need approximately 70 additional subjects exposed to QS T for six months based on number of subjects in previous studies and in current phase 3 study
  - Response to FDA's January 9 letter submitted in early March





## VIBEX® 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.
- Teva has stated they expect an FDA decision 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 – "Pen 2"

- 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

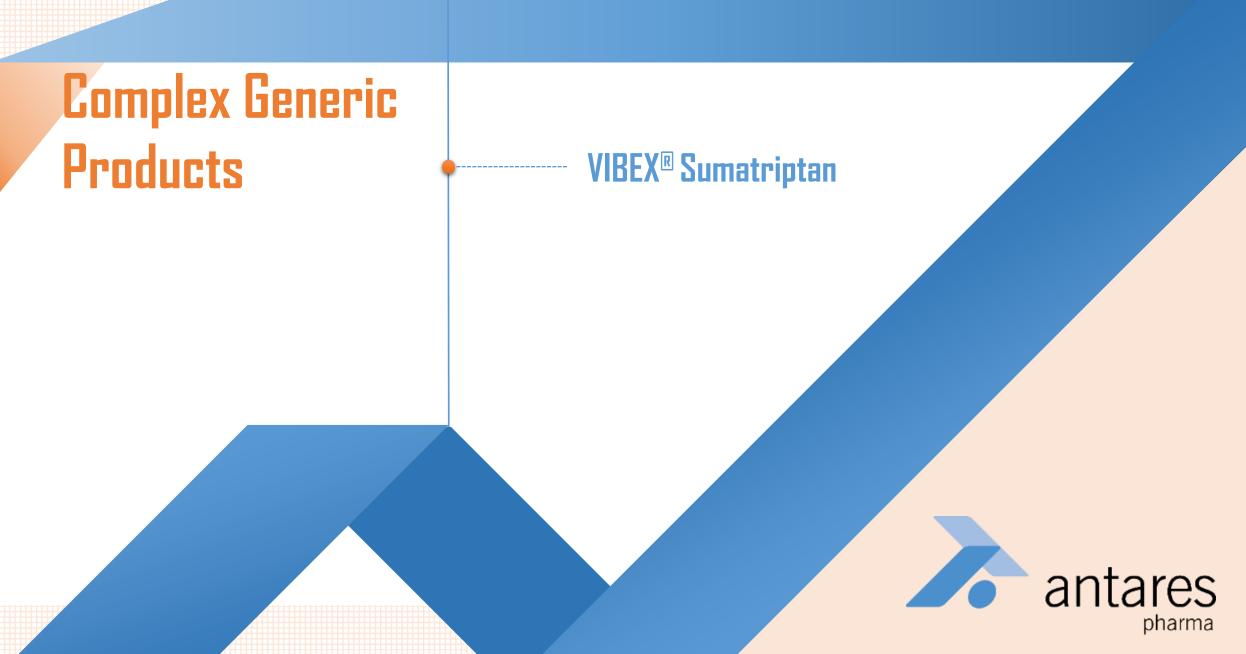
#### Pfizer – Undisclosed Branded OTC Gel Product

- 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®** 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





### 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 Commencement of safety study to meet FDA exposure requirements
  - ✓ OTREXUP™ prescription and revenue growth
  - ✓ VIBEX® Sumatriptan approval (Antares)



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