

**Sender:** Dumaswala, Ashwini </O=CARTER-WALLACE/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ASUMASWALA>  
**Sent:** Wednesday, November 2, 2011 3:40:52 PM  
**Recipient:** Roecklein, Bryan <Bryan.Roecklein@meda.us>  
**Subject:** RE: ET Dymista presentation  
**Attachments:** 2012 Dymista Strat Plan for ET Final.pptx

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Hello Bryan,

Please see the attached.

Thank you,

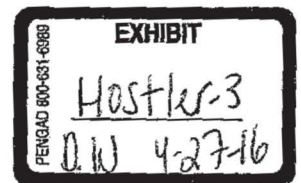
Ashwini

**From:** Roecklein, Bryan  
**Sent:** Wednesday, November 02, 2011 11:25 AM  
**To:** Dumaswala, Ashwini  
**Subject:** ET Dymista presentation

Ashwini, can you send me an electronic copy of your slides.

Thanks, Bryan

**Bryan Roecklein, Ph.D.**  
Vice President, Marketing and Business Development  
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CIP2079  
Argentum Pharmaceuticals LLC v. Cipla Ltd.  
IPR2017-00807



# 2012 DYMISTA Strategic Plan

Presented: October 28, 2011

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## Today's objectives

- Present the Dymista 2012 Strategic Plan
- Gain ET alignment
- Determine action steps to answer any outstanding questions

# Executive Summary

## Objective

- Establish Dymista as the branded TRx and sales leader in SAR

## 2012 Financials:

- TRx: 448K
- Net sales : \$33.1MM
- EBITDA: (\$36MM)
- Gross/net %: 61.5%

## 2012 Commercial Support:

- Personal & Nonpersonal Promotion
- KOL initiatives
- Managed Care
- Public Relations
- CRM/Digital

## Goals

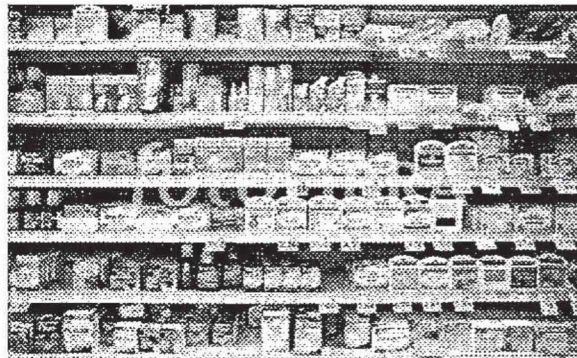
- Take share from other prescription SAR products (specifically, intranasal steroids and intranasal steroid/antihistamine combinations)
- Achieve 4.5% share of the nasal spray market by the end of 2013
- Deliver positive cash flow by the end of 2013 and Net Sales of \$199 million (with 375 sales force expansion in 2013)

## Key Strategies:

- Ensure access to Dymista by eliminating managed care and trade barriers
- Drive early trial and repeat use of Dymista via successful first experience
- Maximize exposure of Dymista and drive efficiencies across communication touchpoints

**TEVA**

# Where we are today: Product churn



Patient tries 1 OTC



Patient tries 2nd OTC

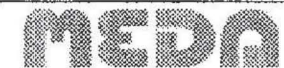


**First Rx:** Patient goes to Dr. and receives INS (in addition to their OTC) and/or Xyzal replaces their OTC



**Second Rx:** Patient returns to Dr. and receives Singulair or patient goes to allergist and receives INS<sub>4</sub> + INAH

**Third Rx:** Patient returns to Dr. and gets INS + INAH



## Where we are today: The current situation

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1. HCPs recognize that while products in their current armamentarium treat the symptoms of SAR, their patients are not receiving “complete relief”

- Patients and physicians often “churn” through several OTC and Rx products
- Generic fluticasone is the “easy-to-Rx” product when oral antihistamines alone are not enough
- There is a disconnect between HCP perception of SAR symptoms and patient perception

2. INS + INAH therapy is the 2<sup>nd</sup> or 3<sup>rd</sup> Rx in the current treatment algorithm (mild patients are treated with OTCs)

- The natural HCP positioning for INS + INAH therapy is for moderate to severe patients
- Positive patient feedback is key to changing the algorithm and establishing a new standard of care
- To date, there has been little new news in the INS or INAH category to change the algorithm

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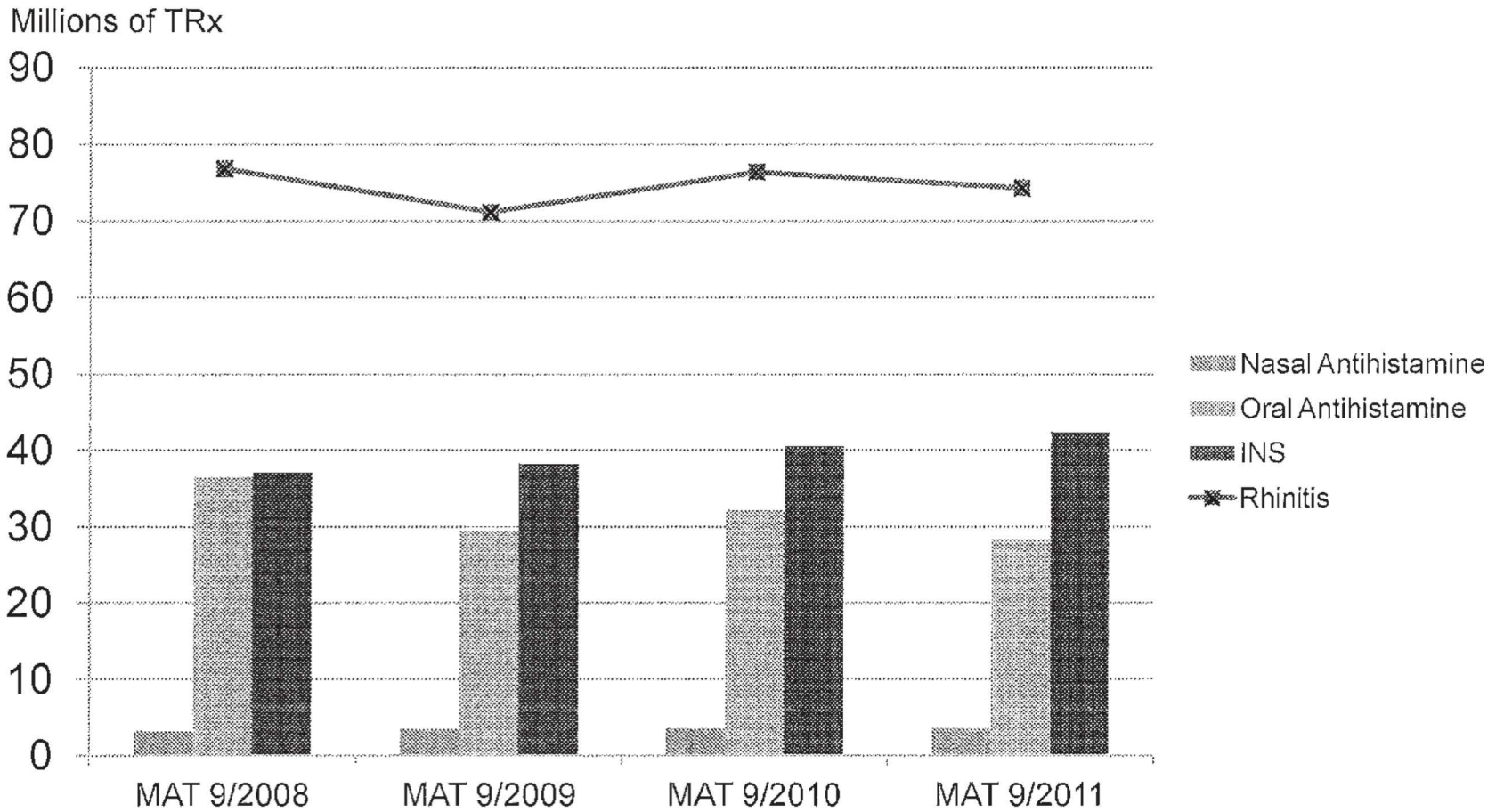
## Where we are today: The current situation

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3. Impact of managed care and cost continue to be the main concern of HCPs
  - Patient out-of-pocket cost is an increasingly important decision criterion in prescribing decisions,
  - Obstacles at point of purchase would significantly impact prescriptions
    - Any payor restrictions would significantly impact prescriptions and will drive negative feedback
    - Unless there is meaningful product differentiation, HCPs Rx the product that is easiest, not always best

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The overall Rhinitis market is flat; The nasal steroid market is growing 5% per year, increasing the opportunity for Dymista; Growth is being driven by fluticasone





# Dymista Challenges & Opportunities

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## Challenges

- Current treatment algorithm places INS + INAH therapy 2 or 3<sup>rd</sup> Rx
- SAR is considered a nuisance condition by HCPs
- Lack of supportive data for INS+INAH combo
  - vs. oral antihistamines
  - vs. single entities used in combination
  - Pharmacoeconomic data
- Managed care supports low cost generics as the “easy-to-Rx” product and supports allergy treatment guidelines
- Limited Meda sales force reach
- Limited KOL advocacy

## Opportunities

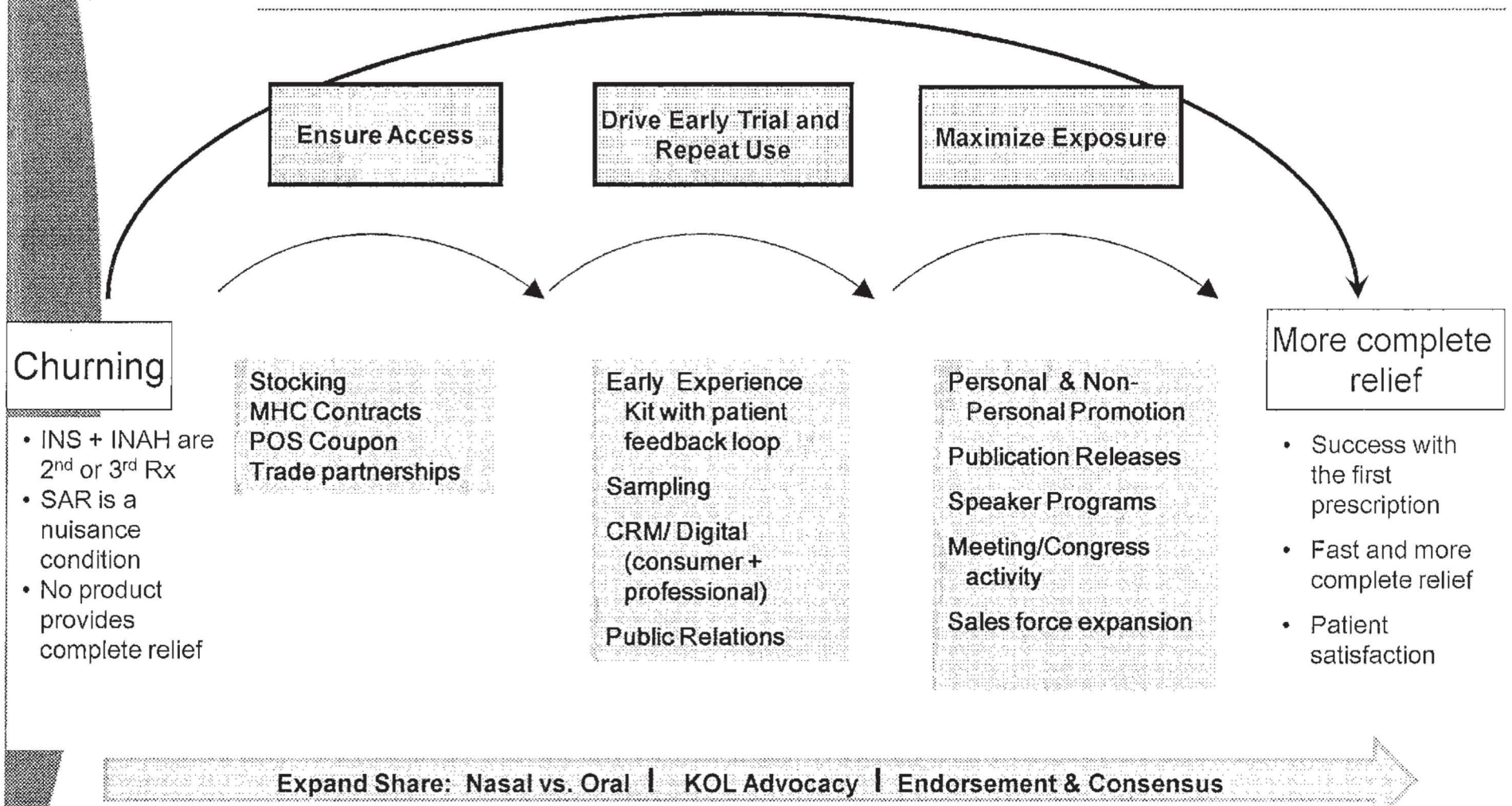
- There is a significant unmet need in the treatment of SAR
- Robust head-to-head clinical data for additional data mining (N=4633)
- Efficacy superior to market leader
- Rapid onset of action and more complete symptom relief vs. single entity therapies
- First combination spray
- Meda Allergy expertise
- Branded market leaders leaving space

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# Dymista Marketing Strategy



# Dymista is the seasonal allergic rhinitis solution

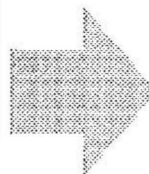
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## HCP NEEDS

Product that provides fast and more complete symptom relief the first time

Product that is easy to Rx

Product that makes patients happy



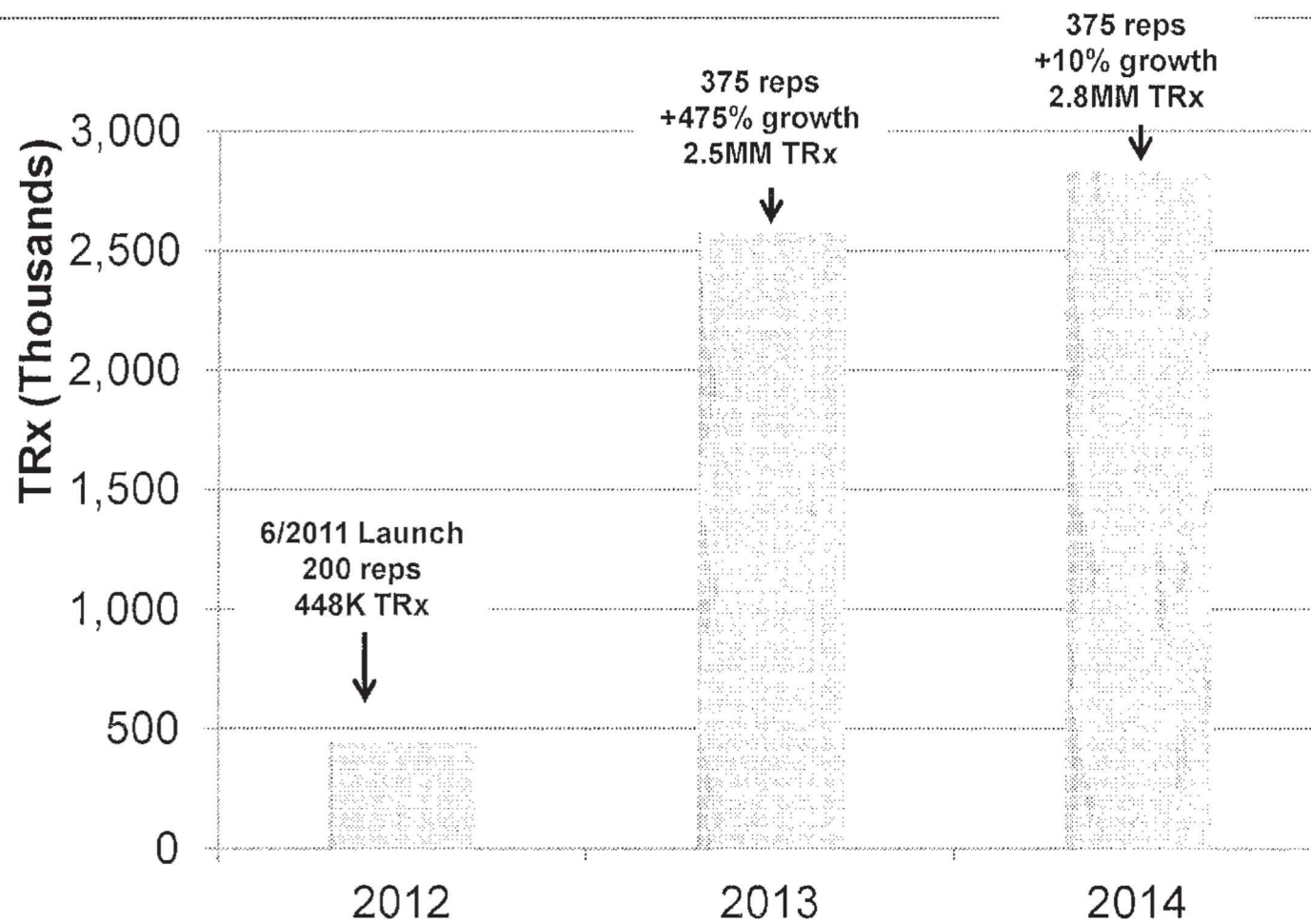
## SOLUTION

**Dymista** provides—rapid and more complete symptom relief—that HCPs & patients can rely on

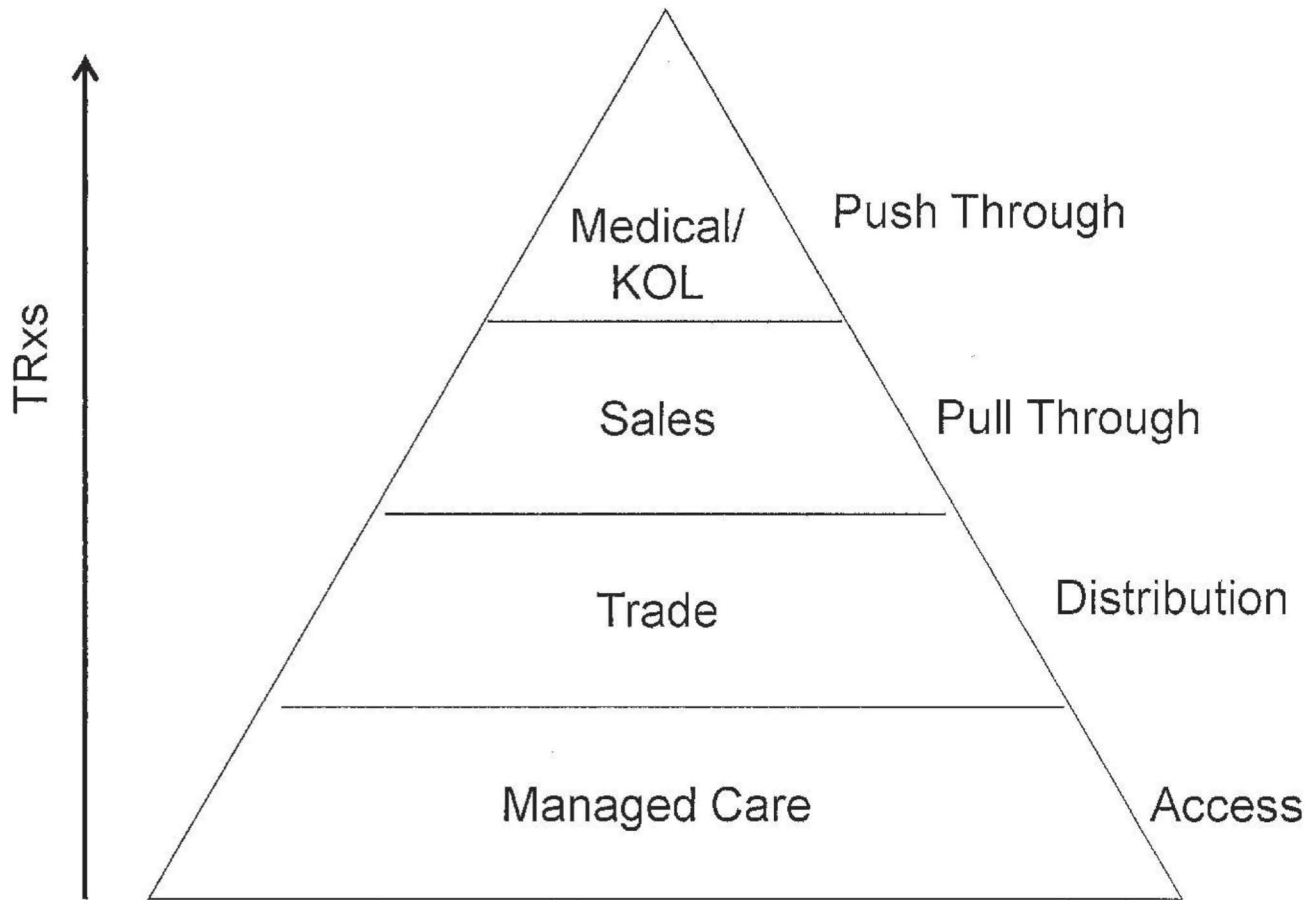
**Dymista** is the first and only prescription medication to combine the effective anti-inflammatory relief of a corticosteroid coupled with the rapid multi-symptom relief of a nasal antihistamine

**So that:** patients can have fast, superior symptom control in a single spray

## Dymista Growth in TRx with the 375 rep expansion



# Launch success is based upon a strong foundation



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## Managed Care: Situation Analysis

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- Astepro 0.15% covered on 2<sup>nd</sup> tier on the majority of plans as a result of line extension strategy and high rebates (35-40%)
- 2<sup>nd</sup> tier status for Astepro 0.15% has had minimal impact on market share gains
- Rhinitis market has shifted to OTC (Orals) and generic Rx in recent years decreasing the size of the category
  - Historically, MHC payers relied upon Tiered copays to manage the category
  - Currently, MHC would prefer not to actively manage the category any more than they do now
- Net cost of new branded entrants will be compared to the overall net cost of currently available products
  - Convenience is not a reason to demand higher price
  - Solid outcomes or pharmacoeconomic rationale is key

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## Managed Care Driving Principle: Maximize Profitability

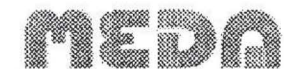
Without rebates, Dymista coverage is at risk however rebates similar to Astepro 0.15% will impact profitability

Example:	<u>Dymista</u>	<u>Astepro 0.15%</u>
WAC	\$120	\$104
AWP	\$150	\$130
AWP-17%	\$124	\$108
Copay	\$ 50	\$ 25
Cost to plan	\$ 74	\$ 83
Rebates		\$ 36
Net cost to plan	\$ 74	\$ 47

\*Rebating (35%) to achieve Tier 2 status for Astepro; Assumes Tier 3 coverage for Dymista

### Hybrid Strategy

- Unrestricted Tier 3 access on plans where we do not currently offer heavy rebates
- On plans where we do, we would offer a 22% rebate to achieve unrestricted Tier 3 access
- On the 4-5 top national plans, rebate to get 2<sup>nd</sup> tier coverage
- Note: Strategy will be confirmed through ZS research



# Pricing options and recommendation (Pro/Con analysis)

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**\$120 WAC** - Increase Astepro 0.15% in January and again in June to minimize the disparity in pricing between Dymista and Astepro 0.15% (+15% premium to Astepro 0.15%)

- **Pro's:** With little price disparity between the two brands, a line extension strategy could be employed that avoids a full P&T Review. Access expected to be similar to Astepro 0.15%.
- **Con's:** Rebates would be 35%-40% at launch affecting gross to net similar to Astepro 0.15% now (41.6% overall G2N)

**\$114 WAC** - Increase Astepro 0.15% in January and again in June to minimize the disparity in pricing between Dymista and Astepro 0.15%. Increase Dymista by 5% in January 2013 prior to spring allergy. (+15%/10% premium to Astepro 0.15%)

- **Pro's:** Line Extension strategy easier to employ with little difference in cost between Dymista and Astepro 0.15%
- **Con's:** Lost revenue of 5% from launch in 2012 to start of 2013

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## Next steps for Managed Care

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- Strategy & Pricing Finalization (Nov 2011)
  - ZS to validate strategy and co-pay acceptability
  - Estimate on tier status for Dymista by plan
- P&L impact of hybrid approach (Dec 2011)
- Pharmacoeconomic Data Conclusions (Dec 2011)

# Executive Summary: Trade

- Will leverage previous success in Trade with Astepro 0.1% and Astepro 0.15%
- Anticipate similar launch deal terms for Dymista as we did for Astepro 0.15%
  - 7.5% off invoice, 7.5% distribution allowance, 60 days additional dating
- Retail will want to see our promotional efforts behind the product (Sales Reps, DTC, etc.) and understand managed care formulary status
- We will need to differentiate Dymista by partnering with pharmacies to ensure patient access to Dymista

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## Trade Objective / Strategy

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- **Objective:**
  - Attain stocking better than Astepro 0.15% (approx 30,000 retail outlets) while limiting excess inventory in warehouses at a discount
  - Develop Advocacy with key stakeholders in differentiating standard of care treatment
- **Strategy:**
  - Leverage Meda best practice in launching both Astepro 0.1% and Astepro 0.15%.
  - Differentiate Dymista from other SAR products by partnering with the retail pharmacies to remove barriers and leverage opportunities

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## Next steps for Trade

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- Meet with key pharmacy chains to understand partnership opportunities (Nov/Dec)
- Develop tactical plan to reach pharmacists (Nov/Dec)

## Sales: Situation Analysis

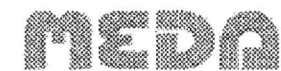
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- There are fewer competitive details in the SAR space
  - Antihistamine details from Merck and sanofi-aventis (main competitors are OTC and generics) have declined vs. PY
- To date there has been limited new noise in the SAR space however 2 new branded entries are expected by 2013 (Teva and Sunovian)
- Meda sales force will be realigned to Dymista targets as of Jan 2012 however there is still a need to optimize sales force size
- In 2012, there will be a gap between approval of Dymista and when product is available

## Sales Guiding Principle: Launch with Excellence

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- LAUNCH: With 200 rep sales force
  - Realign from current 80/120 structure effective January 2012
  - Territories optimized geographically for Dymista; Targets optimized for Astepro 0.15% until 1 month prior to launch
  - Training: assign 2 training managers to Dymista (add headcount for an additional training manager)
- EXECUTE: Plans with excellence
  - Measure performance against reach, frequency and sample targets
  - Structure IC plan to support execution (Astepro 0.15% until Dymista launch)
- EXPAND: Effective January 2013
  - Recruitment & training beginning in Fall 2012
  - Consider utilizing outside resources for recruitment and interviewing so as to minimize field management disruption during the Fall allergy season



# Expansion

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## Assumptions

- Incremental 175 representatives
- Fully trained and integrated into sales force so that impactful selling occurs during 2013 Spring allergy season

## Timing

- Complete sales force alignment analysis by August 1, 2012
- Management team selections completed by Sept. 1, 2012
- Begin representative interviewing Sept. 2012
- On-board the week of Oct. 29, 2012
- 2 month training program
- New alignment effective January 1, 2013
  - December 2012 – new alignment POA meetings

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# Expansion

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## Resources

- Outside services
  - Identifying, contacting, and managing the recruiting process
  - Building the interview process, identifying teams, and provide any additional training around the process
  - Contracting for interview site services and managing the logistics of scheduling, travel, hotels, meals, etc.
  - Being on the interview sites as interviewers and managing the sites
  - On-boarding support (i.e. offer letters, reference checks, background checks, etc.)
  - Training support

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## Risk of not starting recruitment in 2012

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- Sales not maximized for 2013 spring allergy season
- P&L at risk and suboptimal growth trajectory
- Decrease in share of voice in an environment with increased noise (Teva and Sunovian launches)

## Executive Summary: Medical Marketing

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- Objectives
  - Leverage KOLs to establish Dymista as the standard of care
  - Provide avenues to discuss product development and remove any obstacles to early trial and repeat use of Dymista
  - Build credible, evidence-based platform to be communicated for Dymista, surrounding 2012 launch and into 2013
- Strategy
  - **Disseminate** our clinical and economic data to build a body of knowledge for the use of Dymista and establish as a standard of care
  - **Discuss** through case based learning and real world experience the benefits of Dymista to drive trial and repeat use as well as maximize exposure
  - **Displace** churn by exchanging inferior product offerings with Dymista

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Dymista Goal: Deliver \$33MM NR by the end of 2012

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### **2012 Forecast & P&L Assumptions**

- Supply available and trade stocked for launch in June 2012
- 200 reps at launch
- WAC \$120/Rx
- 5% Nasal market growth (driven by fluticasone)
- Limited restrictions from Managed Care
- 61.5% Gross to Net
- EBITDA reflects launch investment
  - Trade unit cost at 16% of NR
  - Sample unit cost at \$4 and \$6

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## 2012 P&L

Item	2012 P&L
TRx	448K
Gross Sales	\$53.8MM
Net Sales	\$33.1MM
Sample Cost	\$ 9.0MM
A&P	\$30.0MM
EBITDA	(\$36.0MM)
PDEs	154K
Sales force size	200

\*Note: 2012 assumes a June launch

2012 includes the cost of DTC exploration and sales force recruitment for +175 reps

PDEs calculated based upon a 3 product detail

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# Revised Contract Having A Large Impact on Sample Costs And P&L

	2017 Q3	2018 Q3	% Change
TRx	448K	448K	475%
Net Sales	\$33.1MM	\$33.1MM	503%
COGS Trade Units	\$1.5MM	\$5.2MM	247%
COGS Sample Units	\$3.6MM	\$9.0	150%
EBITDA	(\$26.5MM)	(\$36.0MM)	
PDEs	154K	154K	
Sales force size	200	200	

## Revised Contract

- Trade Units increased from \$3.25/unit to 16% of Net sales
- Sample unit costs increased from \$2 to \$4 & \$6



# Critical Success Metrics

Provided unrestricted access to >80% of patient lives	✓	✓	
Gain distribution at >30,000 pharmacies	✓	✓	
Shipments & Daily Net Sales per plan	✓	✓	
NRx & TRx per plan		✓	
Coupon redemption at launch > Astepro	✓	✓	✓
50% awareness 6 months post launch among HV Targets; Aided awareness +80% post launch			✓
Sales force achievement against reach, frequency and sample targets			✓
Deliver targeted reach and lift via speaker programs			✓
Achieve ROI $\geq$ benchmark for non personal promotion tactic		✓	✓

## IMMEDIATE NEXT STEPS

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- ET Brand Plan Alignment (Oct 28<sup>th</sup>, 2011)
- ZS Forecast Validation (Oct 31<sup>st</sup>, 2011)
- Supply Dates Confirmed (Oct 31<sup>st</sup>, 2011)
- Final Positioning (Oct 31<sup>st</sup>, 2011)
- Final Managed Care Strategy & Pricing (Nov. 2011)
- Final Creative Concept (Dec. 2011)
- Final inputs for Dymista Target List (Dec. 2011)
- Final date for launch meeting (Nov. 2011)
- Budget approved by Sweden (Dec. 2011)
  
- Reinstitute Bi-Monthly Steering Committee Updates

In order to be successful we need to...

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Continue the strong integration across cross functional teams

Stay focused against the strategies

Communicate a consistent single-minded message

Maintain communication between the US and Global

Differentiate ourselves internally and externally

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Appendix

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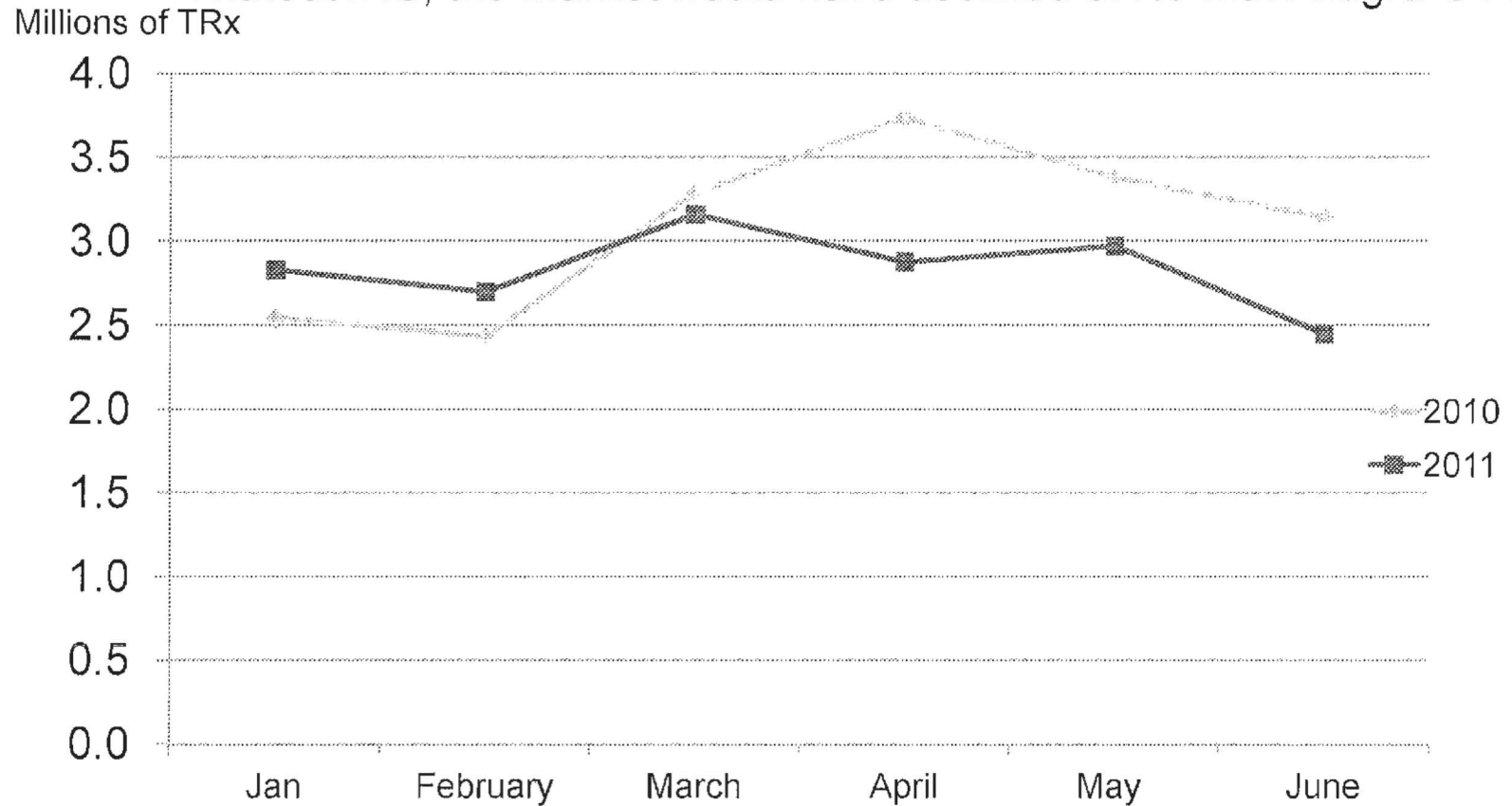
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BR34

## INS are fueling the Rx market stability...

Without INS, the market would have declined 8.4% with Allegra OTC



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**Slide 33**

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**BR34**      What am I looking at here? Y axis is what? Total Rx's in category?

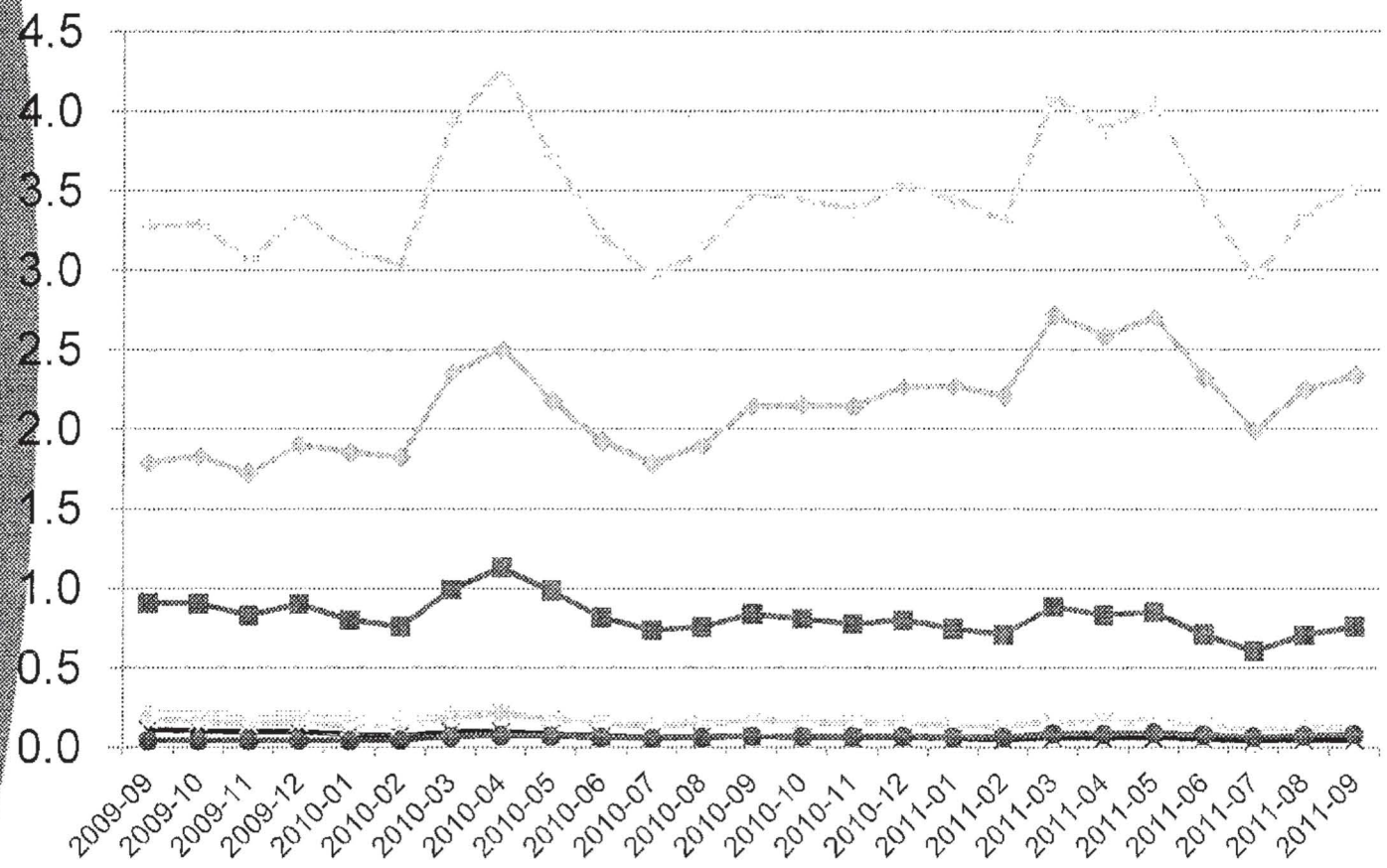
From the graphs I don't see what supports the statements.

what I see is a decline of X percent from 2010 to 2011 of Rx of something.

Bryan Roecklein, 10/23/2011

# Growth in the INS market is being driven by fluticasone

Millions of TRx



- Fluticasone/Flonase
- NASONEX
- NASACORT AQ
- RHINOCORT AQUA
- VERAMYST
- OMNARIS
- TOTAL INS

will format slide



**Slide 34**

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**BR35**

Since you have total in the previous slide (I believe), I'd eliminate here and you'll see the dynamic for fluticasone and Nasonex better.  
Bryan Roecklein, 10/23/2011

## P&L

	2012	2013	
TRx	448K	2,578K	475%
Gross Sales	\$53.8MM	\$324.7MM	503%
Net Sales	\$33.1MM	\$199.6.0MM	503%
Sample Cost	\$ 9.0MM	\$41.2MM	358%
A&P	\$30.0MM	\$40.0MM**	33%
EBITDA	(\$36.0MM)	\$39.9MM	NA
PDEs	154K	495K	221%
Sales force size	200	375	87%

\*Note: 2012 assumes a June launch

\*\*2013 Does not include DTC

PDEs calculated based upon a 3 product detail

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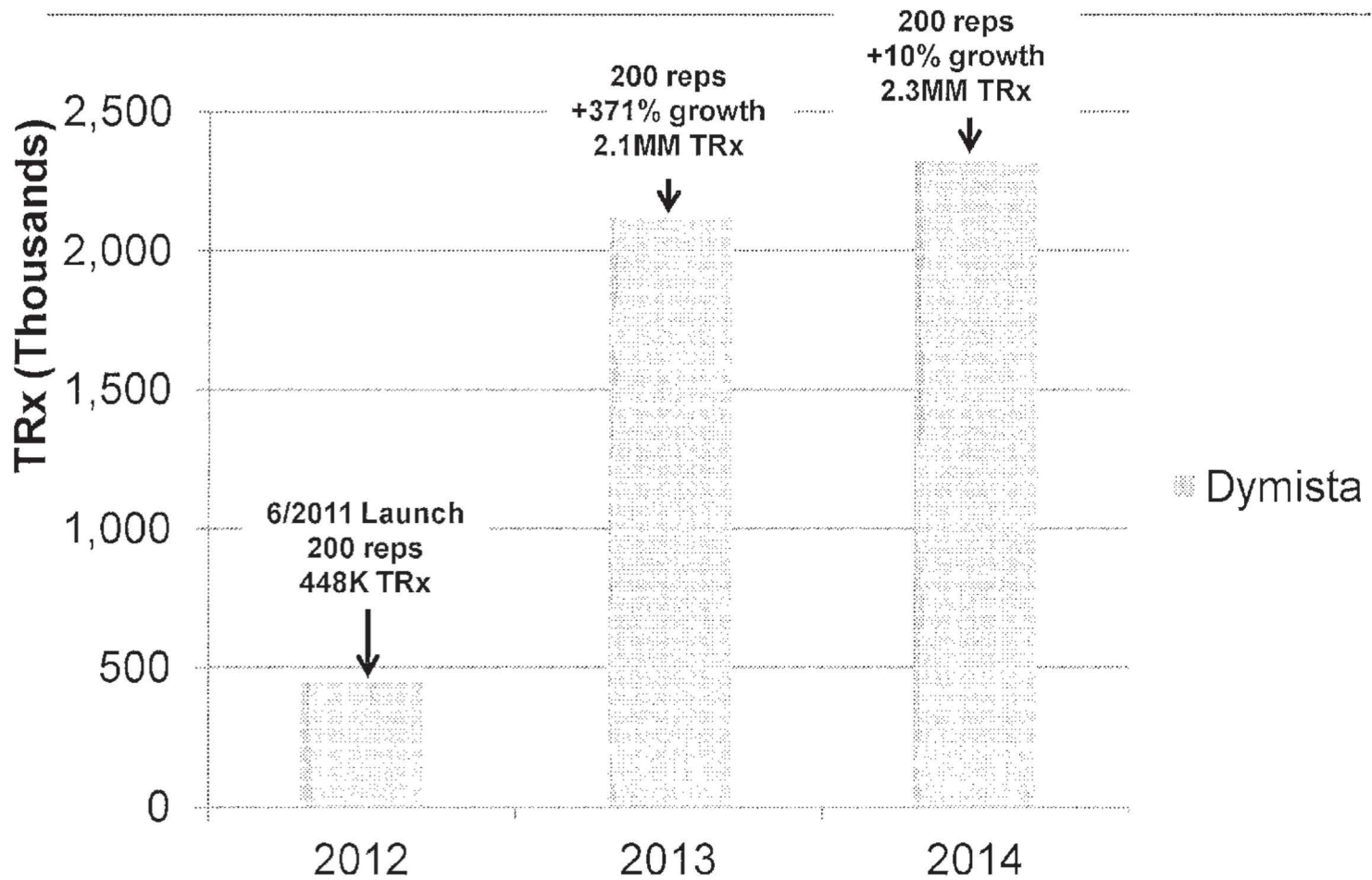
# A&P Breakdown

Remember to  
print out full  
sheet

Samples	\$	9,000,000
Selling materials	\$	5,400,000
Sales Force Expansion	\$	4,926,250
Other promotion	\$	4,815,000
E-Business	\$	4,000,000
DTC Evaluation and Development	\$	2,695,000
Direct Mail	\$	1,500,000
Managed Care/Trade	\$	1,200,000
MLB/KOL/Field Funds	\$	1,050,000
Lunch & Learn	\$	1,000,000
DTP/Patient Ed	\$	900,000
Public Relations	\$	750,000
Conventions	\$	660,000
Strategic support	\$	500,000
Field MicroMarketing Funds	\$	500,000
Total	\$	38,896,250

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# Dymista Growth in TRx with a 200 rep sales force





## New Competitive Product Entries

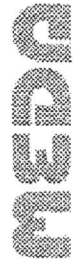
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Sunovian – ciclesonide HFA nasal inhaler – NDA filed 6/2011

Teva – beclomethasone dipropionate hydrofluoroalkane (BDH)  
nasal HFA – NDA filed 8/2011

**Trapdoors**

- Access
- Price
- Breakage – ship tests underway
- Consumption
- Sample/Rx
- Taste/Smell – patient education on how to administer
- Technique – patient education on how to administer



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Peak azelastine franchise sales - MAT 2/2008 – 3.28MM TRx

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