

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

Hello Bryan,

Please see the attached.

Thank you,

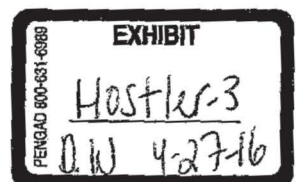
Ashwini

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.
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CIP2079
Argentum Pharmaceuticals LLC v. Cipla Ltd.
IPR2017-00807

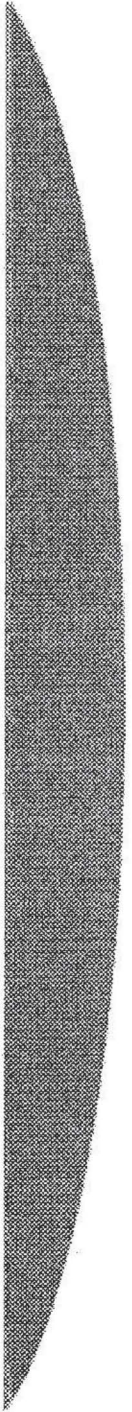


2012 DYMISTA Strategic Plan

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

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Where we are today: Product churn



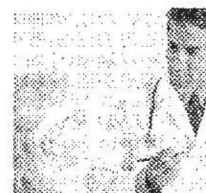
Patient tries 1 OTC



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 INS₄ + INAH



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

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Where we are today: The current situation

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

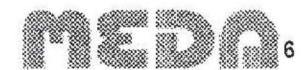
2. INS + INAH therapy is the 2nd or 3rd Rx in the current treatment algorithm (mild patients are treated with OTCs)

- 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

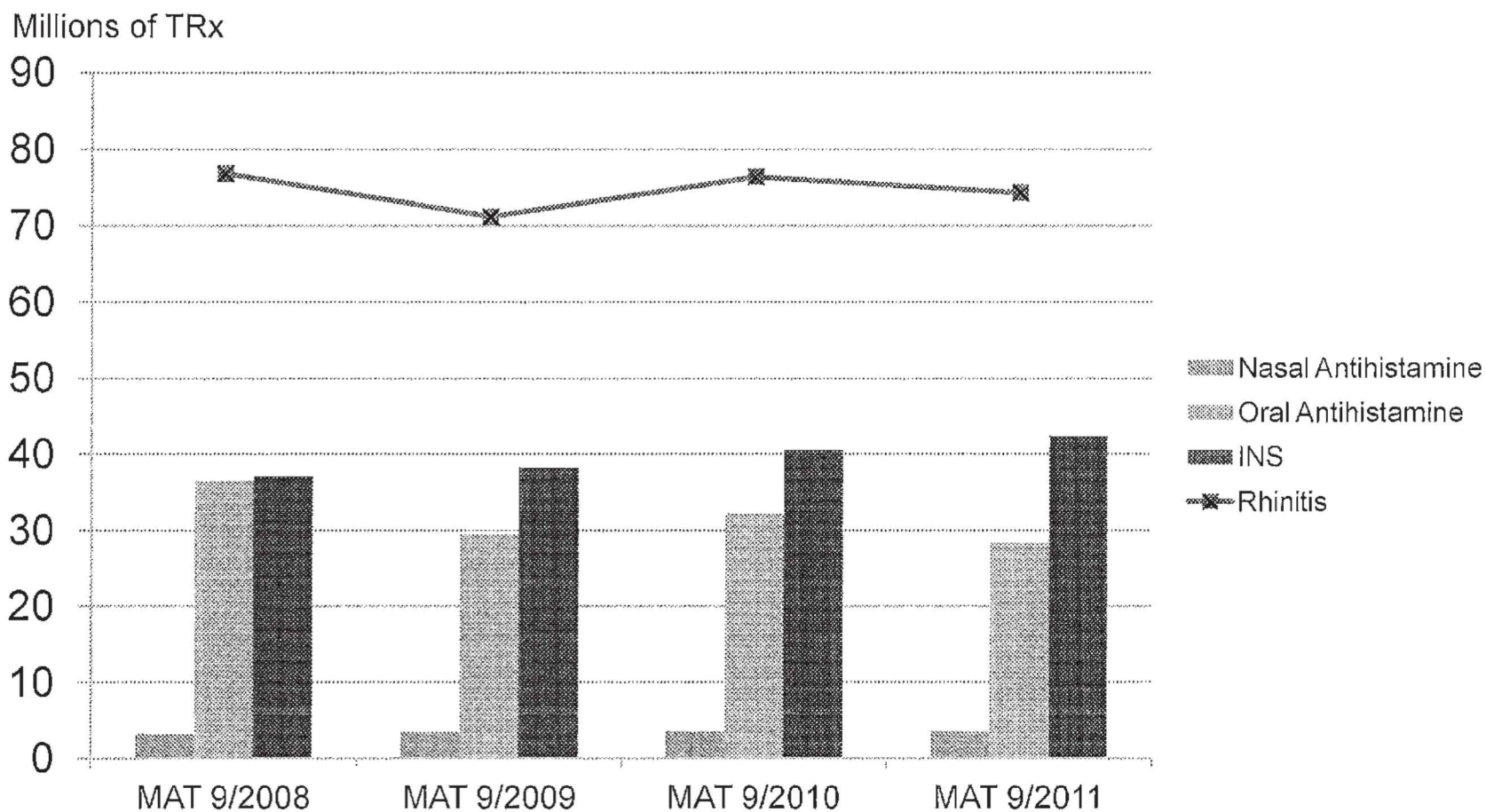
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Where we are today: The current situation

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



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



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Dymista Challenges & Opportunities

Challenges

- Current treatment algorithm places INS + INAH therapy 2 or 3rd 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

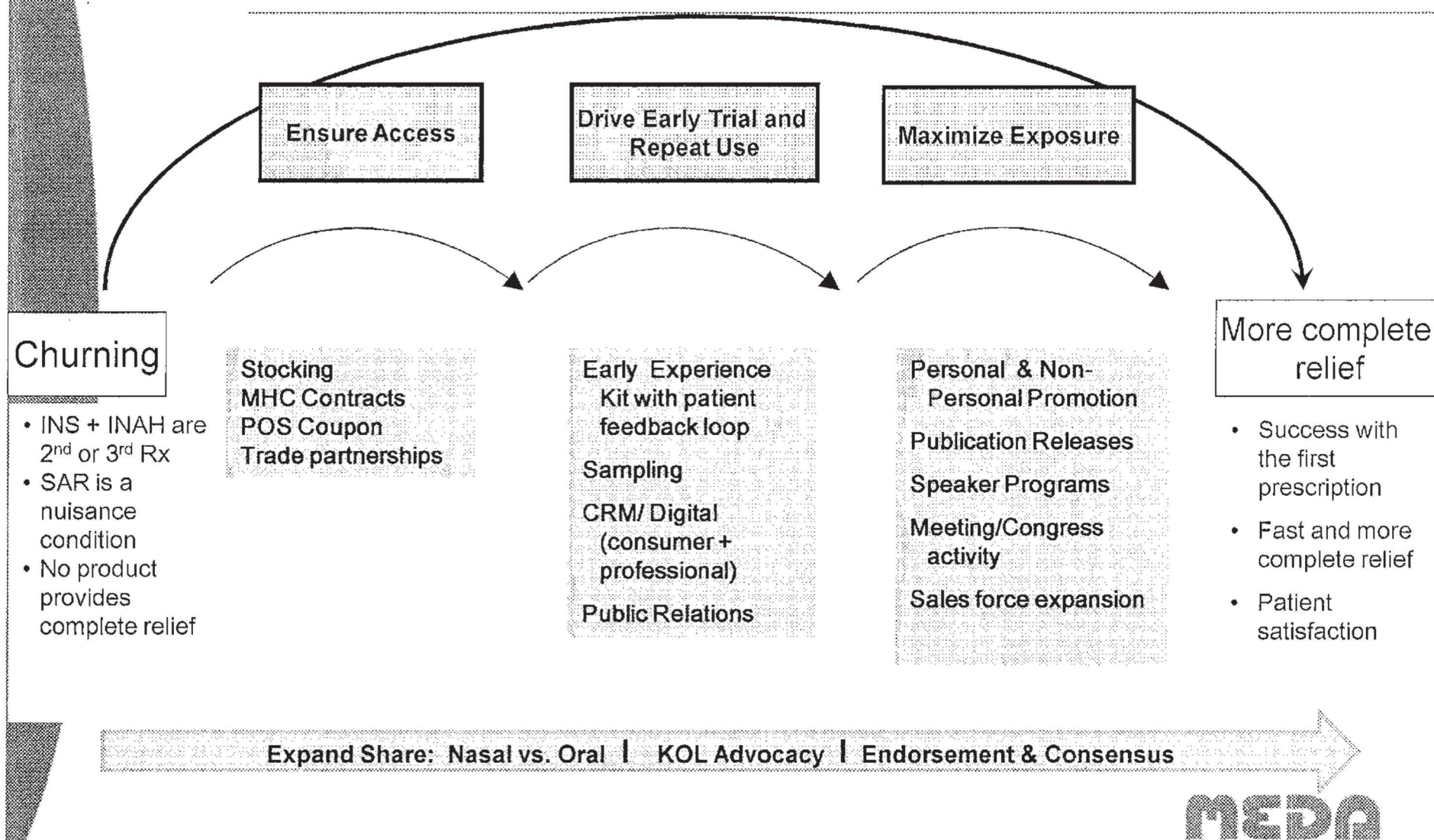
Opportunities

- 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



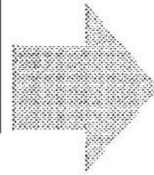
Dymista is the seasonal allergic rhinitis solution

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



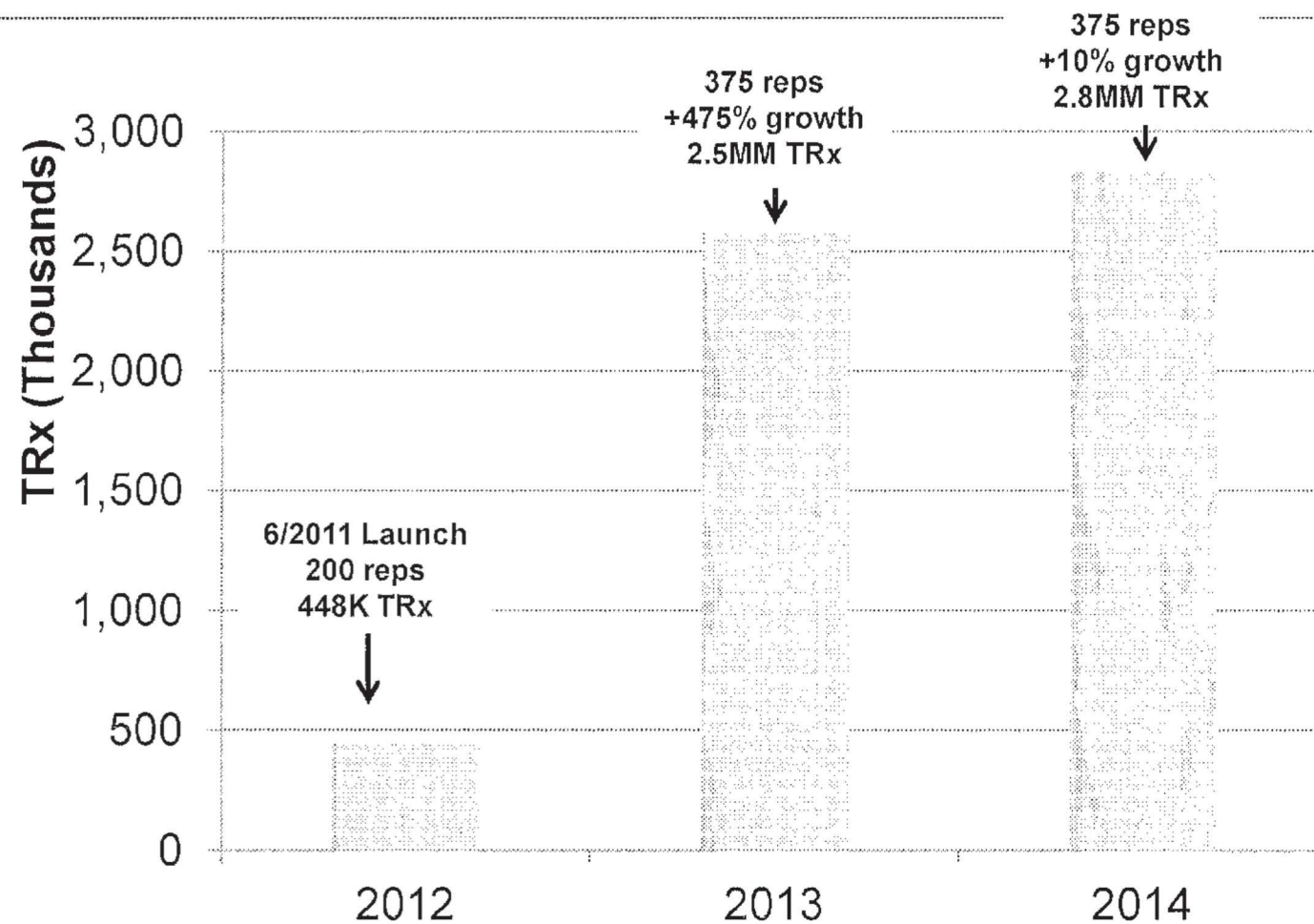
SOLUTION

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

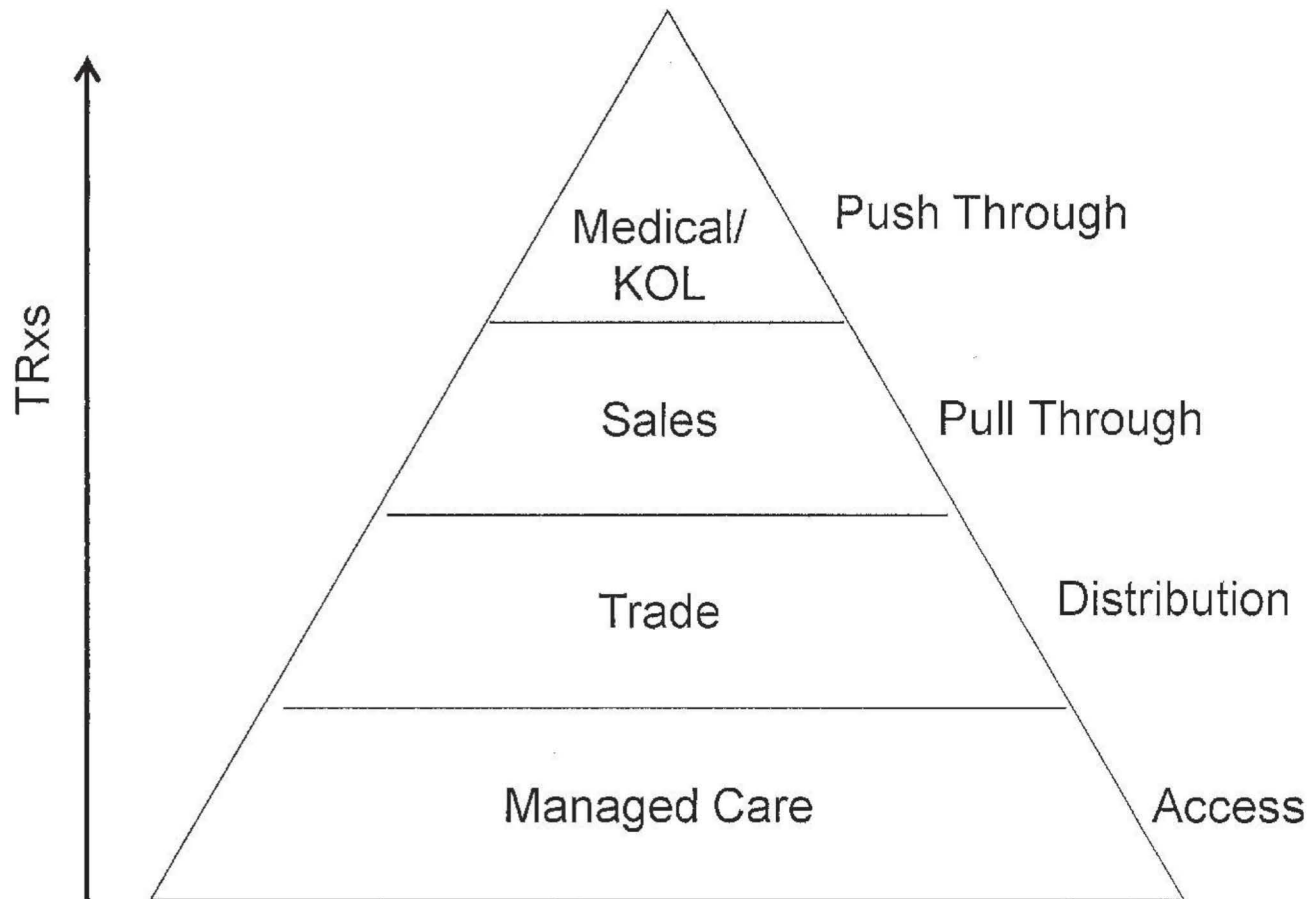
Dymista is the first and only prescription medication to combine the effective anti-inflammatory relief of a corticosteroid coupled with the rapid multi-symptom relief of a nasal antihistamine

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

- Astepro 0.15% covered on 2nd tier on the majority of plans as a result of line extension strategy and high rebates (35-40%)
- 2nd 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	<u>\$ 50</u>	<u>\$ 25</u>
Cost to plan	\$ 74	\$ 83
Rebates		<u>\$ 36</u>
Net cost to plan	<u>\$ 74</u>	\$ 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 2nd tier coverage
- Note: Strategy will be confirmed through ZS research

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Pricing options and recommendation (Pro/Con analysis)

\$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

- 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

- **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

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

Sales: Situation Analysis

- 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

- 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

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Expansion

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

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

- 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

- 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

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

Category	2017 Actual	2018 Actual	2018 Revised
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

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Critical Success Metrics

	Q1	Q2	Q3	Q4	YTD
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

- ET Brand Plan Alignment (Oct 28th, 2011)
- ZS Forecast Validation (Oct 31st, 2011)
- Supply Dates Confirmed (Oct 31st, 2011)
- Final Positioning (Oct 31st, 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...

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

Appendix

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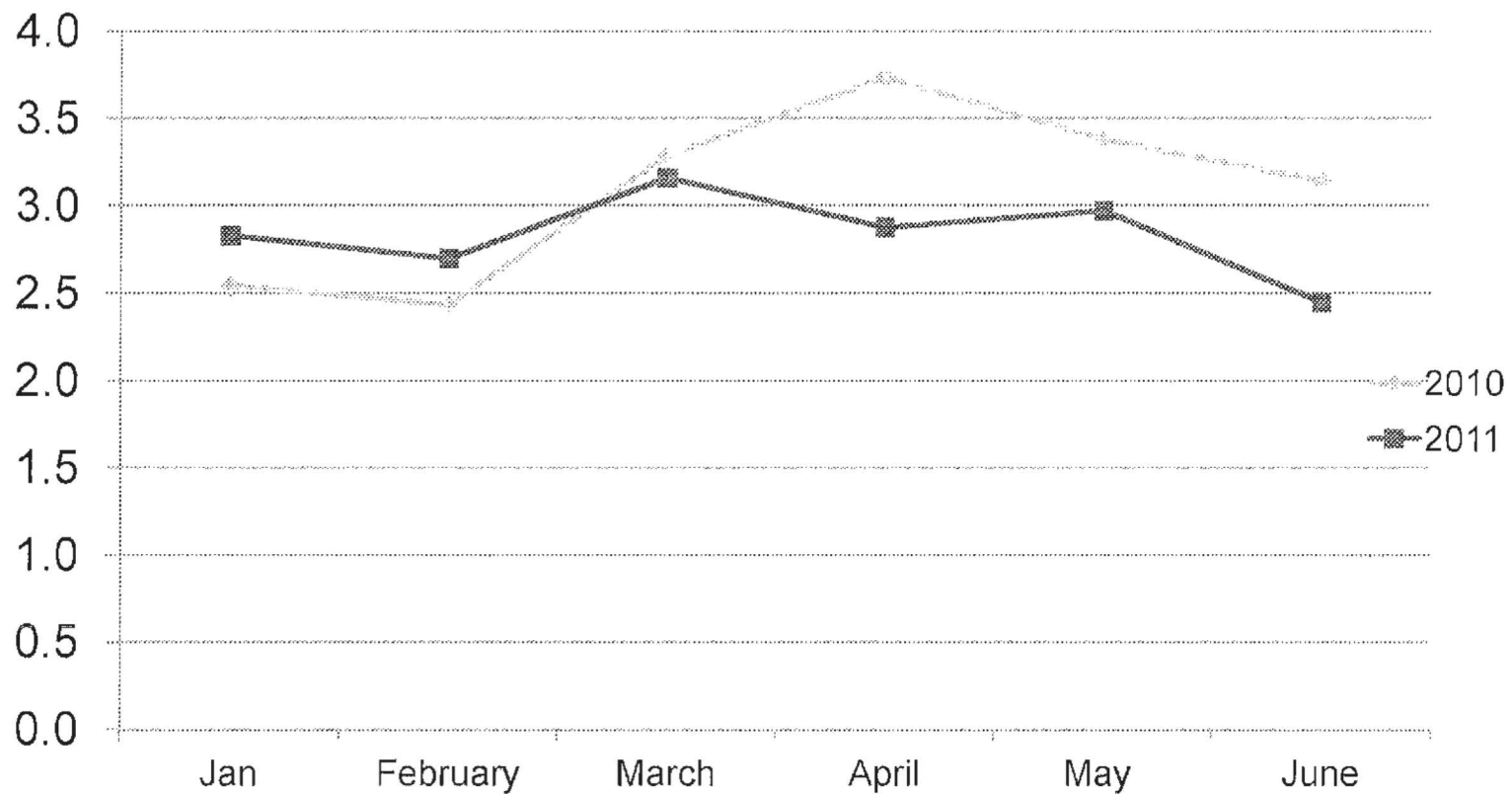
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BR34

INS are fueling the Rx market stability...

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

Millions of TRx



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Slide 33

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.

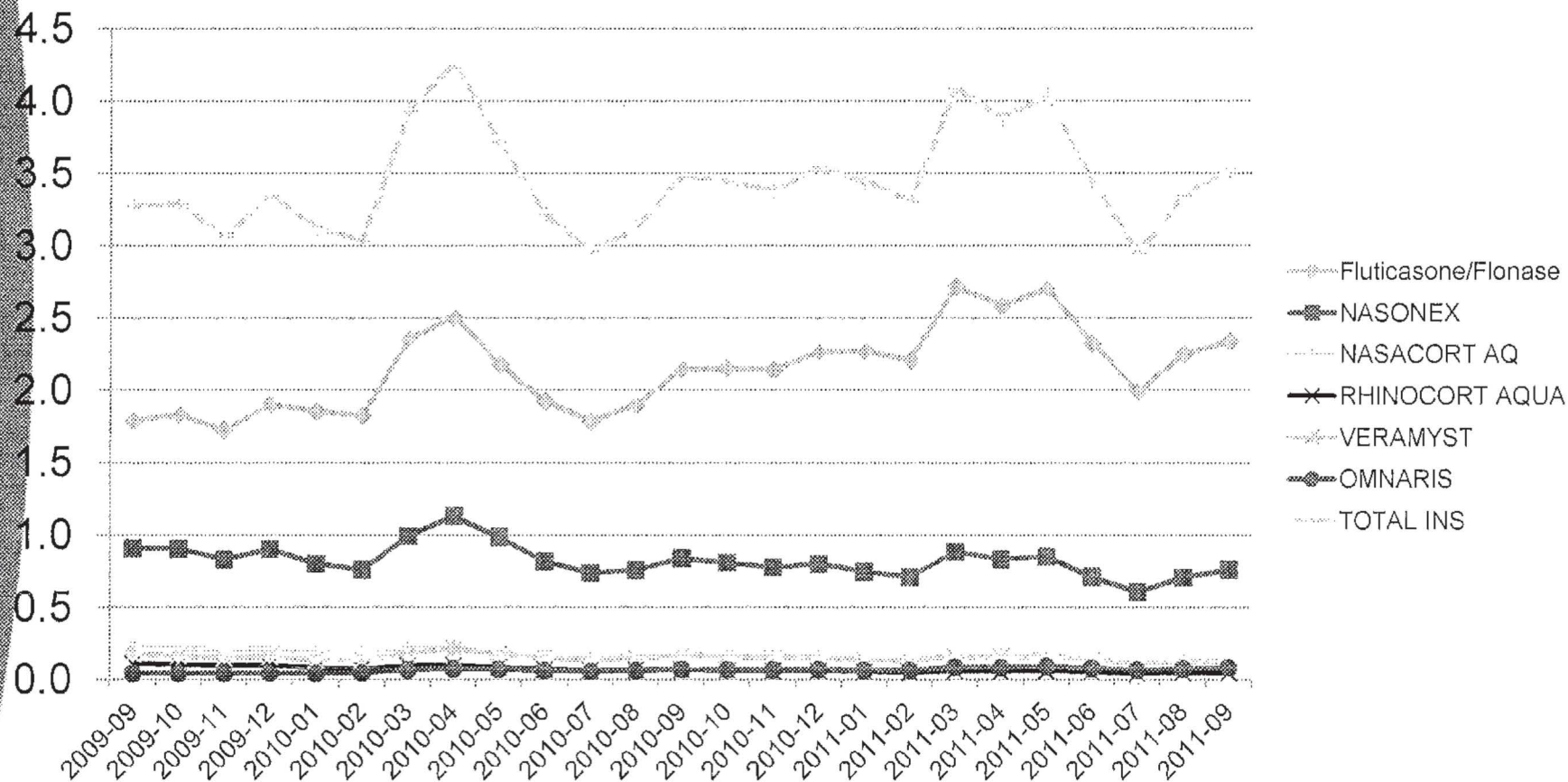
what I see is a decline of X percent from 2010 to 2011 of Rx of something.

Bryan Roecklein, 10/23/2011

Growth in the INS market is being driven by fluticasone

BR35

Millions of TRx



will format slide

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Slide 34

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

	2011	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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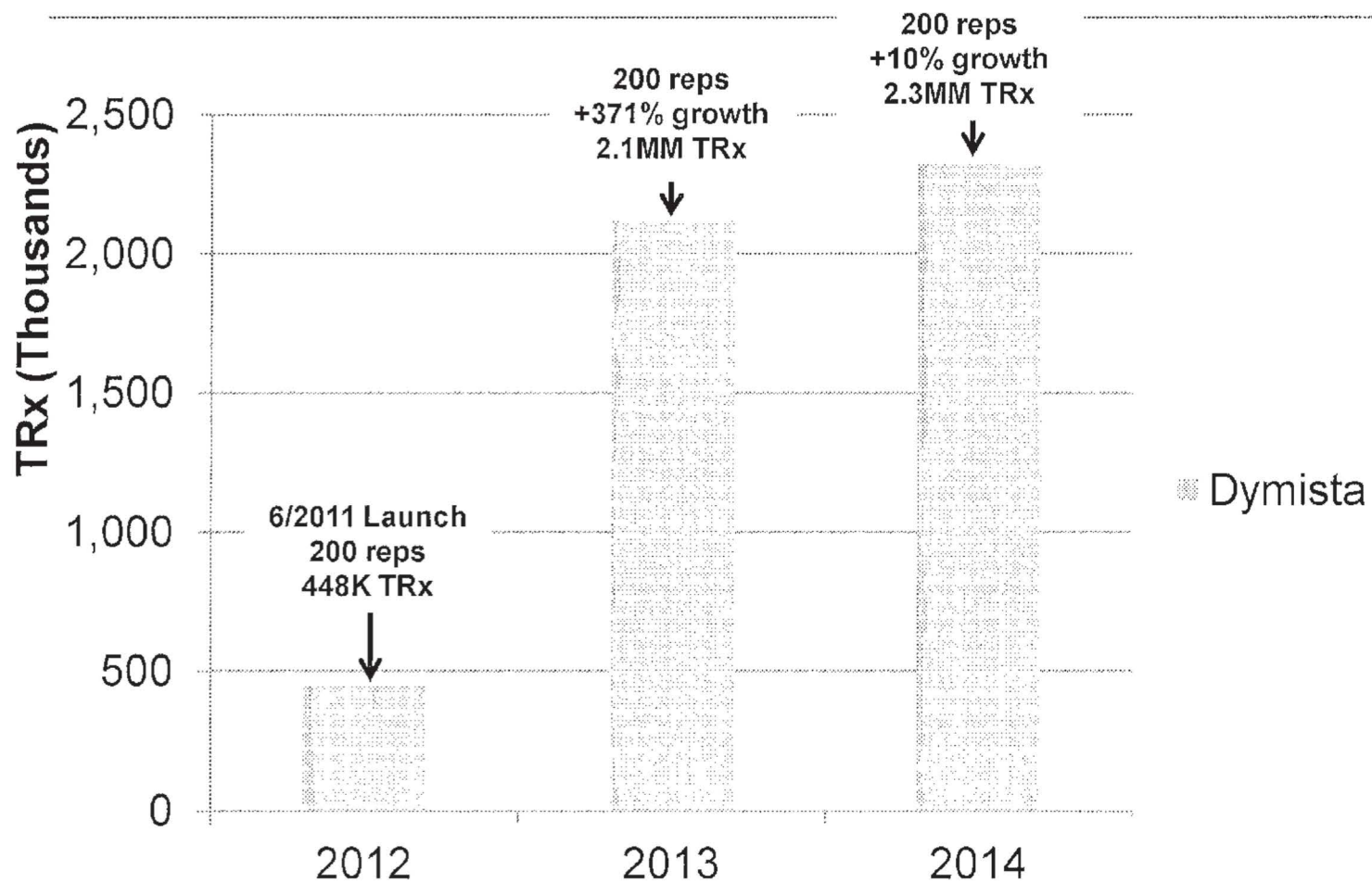
A&P Breakdown

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

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