



## Noramco World Wide Narcotics Franchise

Overview prepared for the sale of Noramco World Wide Narcotics Franchise global product portfolio including Noramco Wilmington, Tasmanian Alkaloids, and Athens Technical Center

October 2015



Confidential

Exhibit

**s1048**

State of OK v. Purdue

**s1048.0001**

# Presenters



## **Matthew Martin** General Manager

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- 32+ Years of industry experience
- Joined Noramco in 2006
- Experience includes CFO, CIO, VP Marketing and Business Unit Leader for several J&J Pharma, Supply Chain and Med Device Companies

## **Anthony Ambrosini** WW Controller

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- 26 years of industry experience
- Joined Noramco in 2006
- Experience includes Centocor biologics, Nabisco, Avon, and General Chemical

## **Bill Grubb** Group Product Director

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- 24 years of industry experience
- Joined Noramco in 1997
- Experience includes development, regulatory, operations, and commercial with J&J and GlaxoSmithKline

## Important Notice



Management believes the information provided in this presentation on the narcotic active pharmaceutical ingredients business and related manufacturing operations (the “Business”) conducted by Noramco, Inc. (“Noramco”) and Tasmanian Alkaloids Pty. Ltd. is accurate and reliable as of the date of this presentation unless another date is indicated. However, neither Noramco nor any of its affiliates in the Johnson & Johnson Family of Companies make any representation or warranty, express or implied, as to the accuracy or completeness of such information. Only those agreements, representations and warranties contained in a definitive written purchase agreement between Noramco and the successful bidder shall have any legal effect. Prospective purchasers are expected to conduct their own due diligence investigation and analysis, and not rely on the information and description of the Business provided herein. In addition, this presentation contains forward-looking statements and information. Neither Noramco nor its affiliates make any representation or warranty, express or implied, as to the accuracy or completeness of such forward-looking statements and information in this presentation. The audience should not rely upon any forward-looking statement or information in this presentation because Noramco and its affiliates give no assurance such statements or information will be realized. Each potential purchaser is expected by Noramco to do its own analysis as to the future prospects of the Business.



## Agenda

▪ Opportunity and Strategic Rationale	Matthew Martin	4
▪ Market and Commercial Overview	Bill Grubb	12
▪ Manufacturing and Supply Chain	Bill Grubb	26
▪ Pipeline	Bill Grubb	39
▪ R&D Agricultural and Chemical	Matthew and Bill	45
▪ Key Financials	Anthony Ambrosini	58
▪ Human Resources	Matthew Martin	62
▪ Deal Structure and Timelines	Barry Fitzsimons	66

## Strategic Rationale For Seller



Johnson & Johnson is exploring the sale of the Global Narcotics business for the following reasons:

- J&J strategy **no longer includes narcotic analgesics**
- J&J Pharma **supply chain is focused on manufacturing internal products**
- Allows J&J to **focus on producing novel pharmaceuticals**

By focusing on this business from the field to the customer formulation we believe a purchaser can enhance the Noramco value proposition.

# Opportunity For Purchaser



Acquire the **#1 supplier of Narcotic APIs** in the United States, the world's largest market

Gain a **global presence** with marketing authorizations filed in 30+ countries

Inherit a **strong pipeline** of new products and filed customer product opportunities

Become a **key supplier** to the world's largest multi-source generics

Acquire fully integrated **facilities and personnel** and **external supply network**



*Wilmington, Delaware  
Active Pharmaceutical Ingredients*



*Westbury, Tasmania  
Extraction, Ag R&D*



*Athens, Georgia Building 6  
Small Scale Manufacture + R&D*

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# Noramco Global Product Portfolio



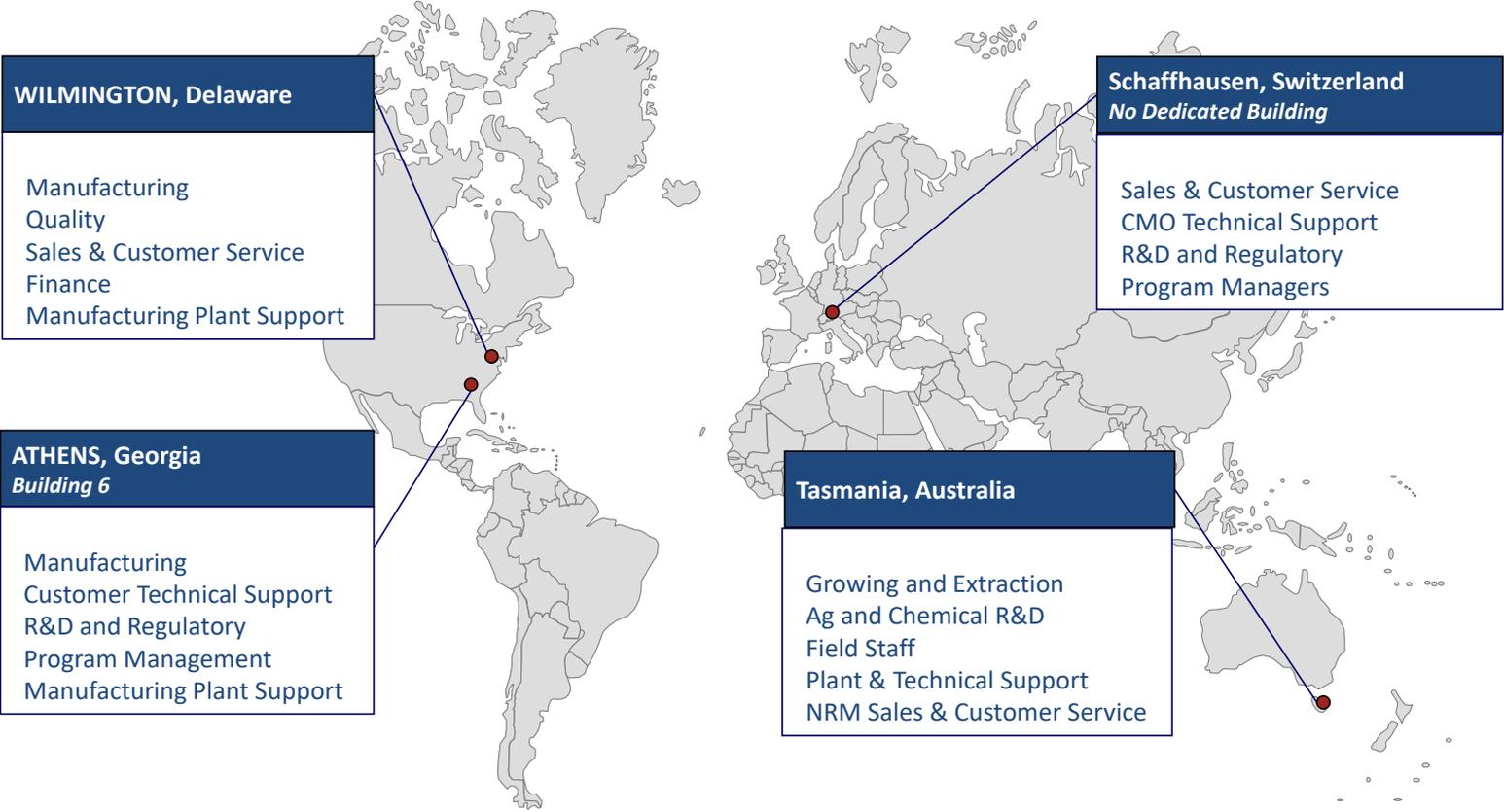
Noramco Family of Active Ingredients	Representative Brand Drug Product	Indication	Net Trade Sales* 2014 in USD MM
Oxycodone	Oxycontin <sup>®</sup> , Percocet <sup>®</sup> , Roxicodone <sup>®</sup>	Pain	\$94
Hydrocodone	Vicodin <sup>®</sup> , Lortab <sup>®</sup>	Pain	52
Buprenorphine	Bu-trans <sup>®</sup> , Norspan <sup>®</sup> Suboxone <sup>®</sup> , Subutex <sup>®</sup>	Pain or addiction	20
Morphine	MS Contin <sup>®</sup> , Embeda <sup>®</sup>	Pain	20
Codeine	Laudanon <sup>®</sup>	Pain	18
Hydromorphone	Dilaudid <sup>®</sup> , Exalgo <sup>®</sup>	Pain	9
Naloxone	Narcan <sup>®</sup> , Evzio <sup>®</sup>	Overdose or abuse	2
Other / Intermediates		ADHD and Pain	23
Narcotic Raw Materials			20
<b>Global 2014 Net Trade Sales value</b>			<b>\$258</b>

*\*Net Trade Sales reflect internal data and are unaudited*

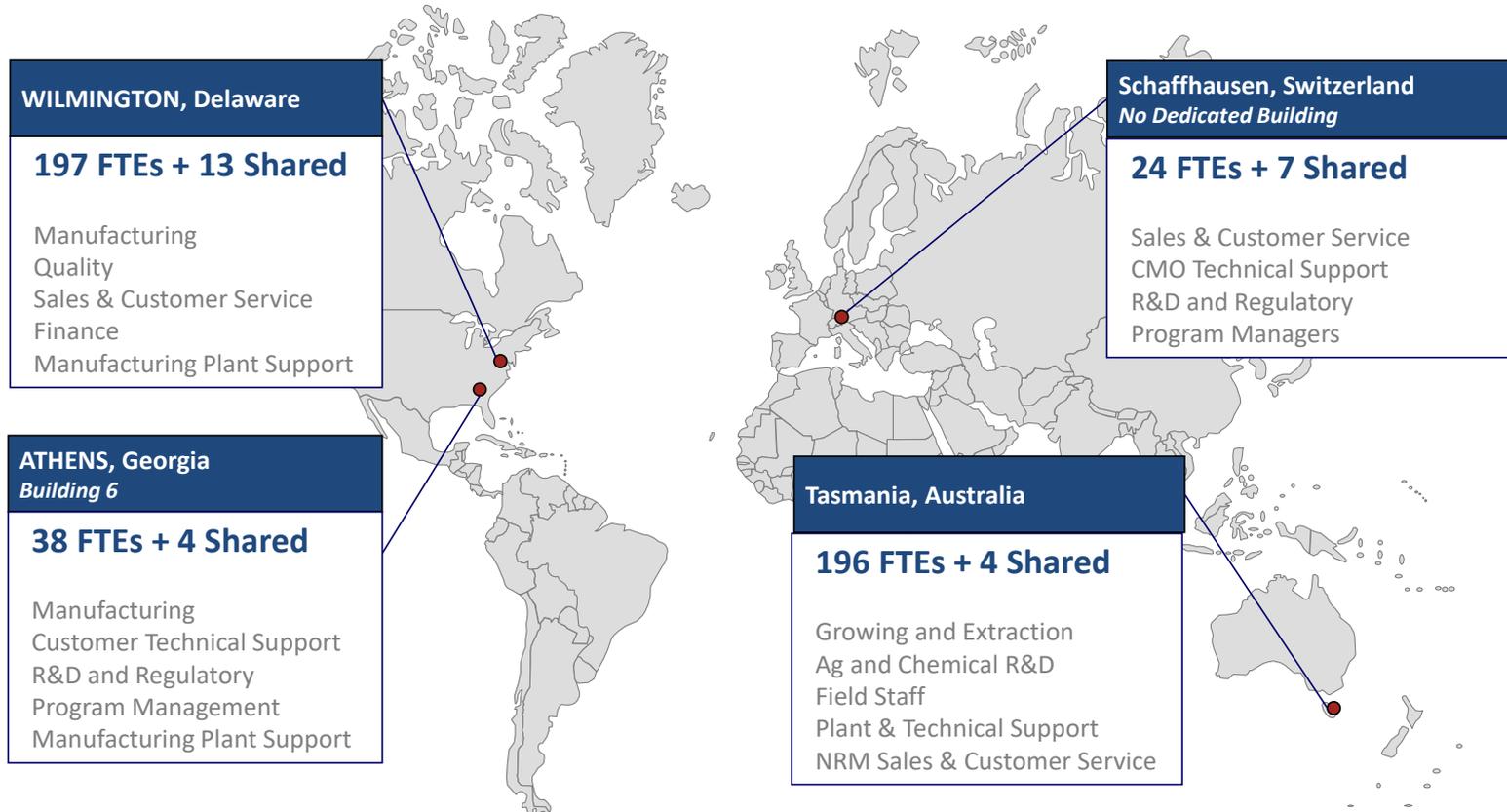
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# Locations and Functions Included in Transaction



# 483 Full Time Equivalents Support the Franchise (455 direct and 28 shared with J&J\*)



\* The 28 shared resources are leveraged with J&J and are required to operate the business.  
2 employees located in UK included within Schaffhausen headcount.  
The shared resources are included with Cost of Goods.

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# Products to Be Transferred to Purchaser

*Transition Supply Agreements are Anticipated*



**Core Products**

**Wilmington**

Oxycodone HCl  
 Hydrocodone Bitartrate  
 Morphine sulfate  
 Codeine Phosphate  
 Oxymorphone HCl

**Tasmania**

CPS-Codeine  
 CPS-Oripavine  
 CPS-Thebaine  
 CPS-Morphine

**Athens**

Hydromorphone HCl  
 Buprenorphine Base  
 Buprenorphine HCl  
 Methylphenidate HCl  
 Tapentadol HCl

**CMO/Geel/Other**

Buprenorphine Base  
 Buprenorphine HCl  
 Codeine Phosphate API  
 Naloxone HCl  
 Naltrexone Base  
 Naltrexone HCl  
 Dronabinol

**Intermediates**

T-3028 for Tapentadol  
 Technical Oxymorphone  
 Technical Thebaine

Hydrocodone Intermediates  
 Technical Oripavine

Noroxymorphone  
 Intermediate 5 for Buprenorphine  
 T-424 for Fentanyl  
 T-2955 for Tapentadol

**Pipeline**

Amphetamine Aspartate  
 Amphetamine Sulfate  
 Dextroamphetamine Saccharate  
 Dextroamphetamine Sulfate

Fentanyl in USA

Methylnaltrexone Bromide (Validation)  
 Oxycodone HCl (Validation)  
 Cannabidiol

# Noramco's Offering



Direct Access to  
Narcotic Raw  
Material



Secure focused  
manufacturing  
network



Comprehensive  
global product  
support



*From Our Fields to Your Formulations*



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# The Noramco Story



## Our Start...

- Johnson & Johnson formed Noramco **36 years ago** for **security of supply for Tylenol® with Codeine**
- In the **mid-80s, J&J acquired Tasmanian Alkaloids**, to secure another piece of the value chain
- Noramco since **developed processes for** and registered **a dozen APIs**



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# The Noramco Story



## Our Focus...

- C-II Controlled Substances: People, Processes, Procedures
- **Exceptional support.** Over 45 chemists and analysts dedicated to **assisting customers** to bring their products to market and developing new products
- Compliance. **Exemplary** FDA, DEA, and EPA compliance **records**



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# The Noramco Story



## Today...

- The largest narcotic API supplier in U.S.
- Focused expansion of synthetic controlled substances for ADD/ADHD
- Rapidly growing ROW footprint for sales and manufacturing
- Exceptional compliance record
- Recognized for superior customer and technical service



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# Franchise Strategy



- Leverage our vertical integration to deliver the best cost, highest quality, controlled substance APIs
  - Codeine from Tasman poppy
  - Partner with best-cost technology focused manufacturers
  
- Enter new markets for existing products
  - Target closed markets by supplying API to customers
  - Strategic countries and regions of interest for existing portfolio
  
- Maintain a leadership position in agricultural R&D
  - Increase alkaloid content to generate capacity and lower costs
  - Breeding programs to assure robust and stable crops
  
- Participate in growth through partnerships



***Focus. Execute. Deliver.***

## Narcotics US & Global Volume Drivers



- API volume growth linked to expanded use of analgesics driven by aging population and OUS expanded access
- API volume growth linked to generics of Branded drugs, new delivery systems & abuse prevention claims
- No revolutionary new narcotic NRM /API but new uses found
  - Naloxone as a combination for abuse deterrent
  - Methylnaltrexone for constipation
  - Naltrexone for weight loss, drug addiction
- Buprenorphine showing global growth for drug abuse and pain

## Over 80% of Noramco's Sales are via Long-Term Supply Agreements



Noramco has long-term agreements and/or majority controlled substance share with all 7 of the top US generic companies

Typical supply agreement terms

- Covers multiple controlled substance products (4 or more)
- Agreements are for more than 80% of customer's volume
- Terms are for 3 to 5 years minimum with rolling renewals

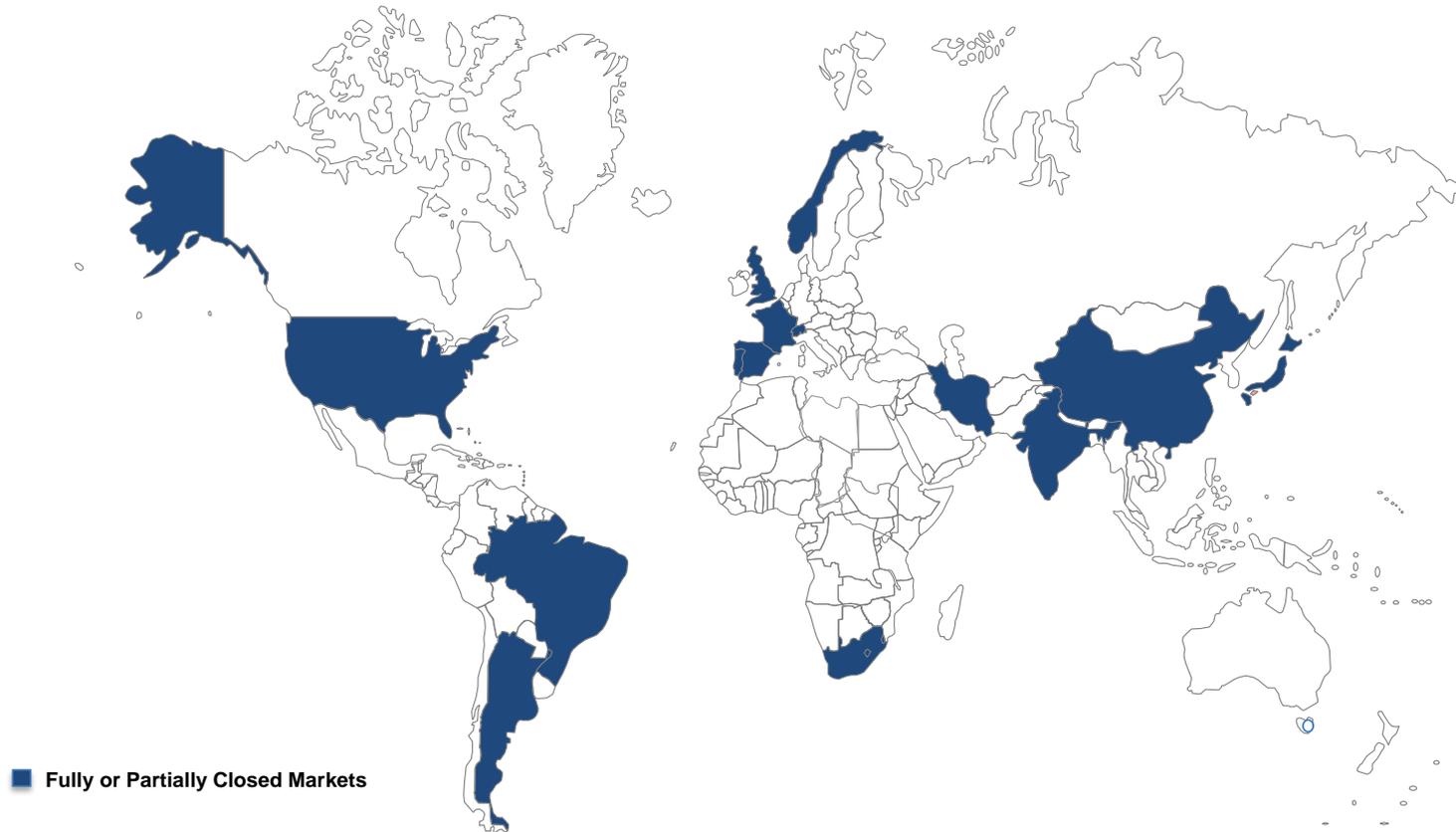
*Note: Existing agreements are not a guarantee of future business or renewal, purchaser must assess value*

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# Key Narcotics Markets are Fully or Partially Closed To the Import of Controlled Substance Narcotics

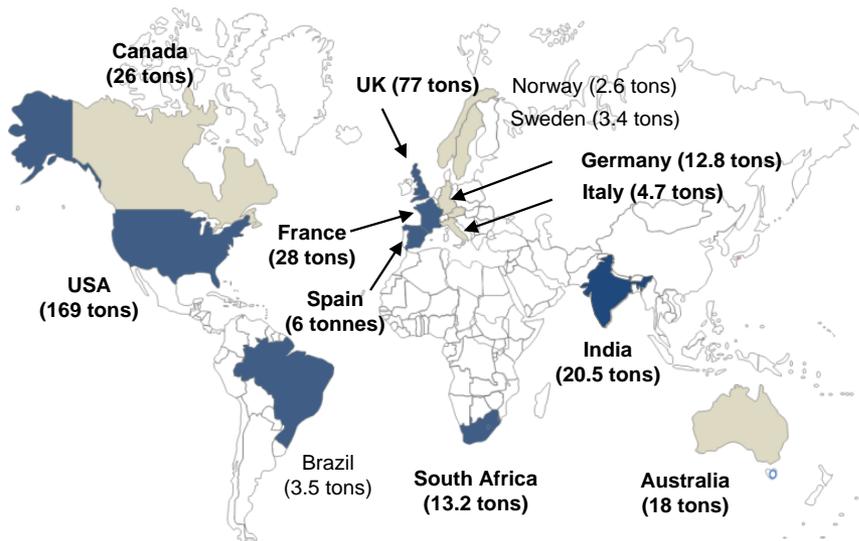


API must be produced in fully closed markets, including the US (the world's largest market)

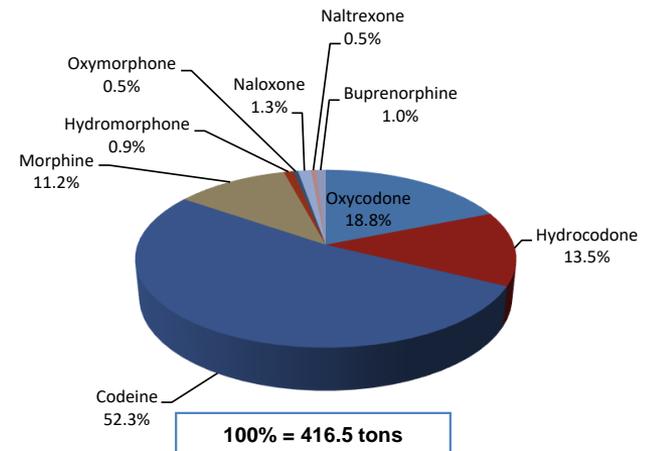
# Ten Markets Account for 90% of Global Consumption of Narcotic API's



**Key Narcotics Consumption by Region**



**Global Narcotics Consumption by Volume**

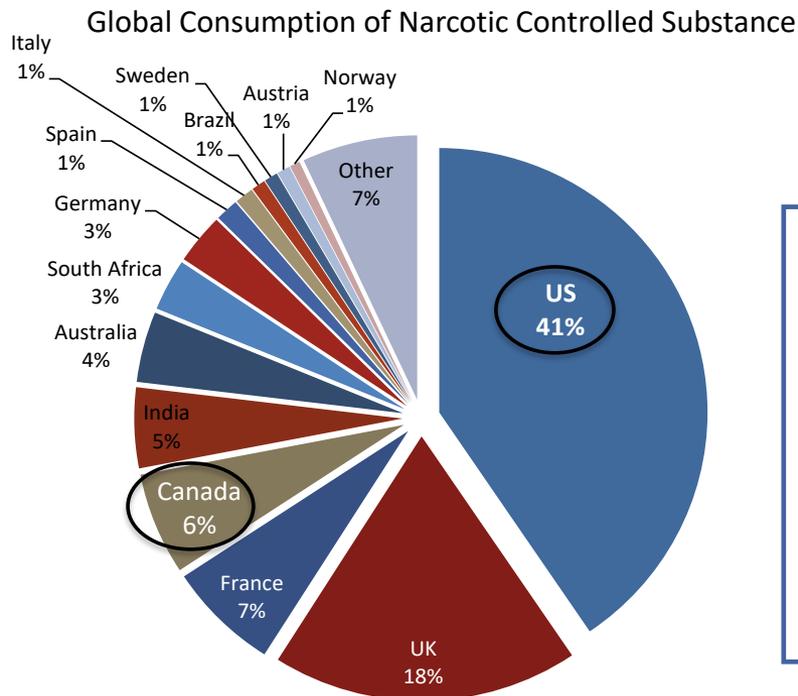


**■ Closed markets** (fully or partially)  
Narcotic APIs must be manufactured in Closed Markets. Exports are allowed but often have restrictions.

**■ Open Markets**  
Imports allowed but are highly regulated.

Source: IMS and INCB 2014  
Narcotic APIs includes some narcotic derived API (Naltrexone, Naloxone, etc.)

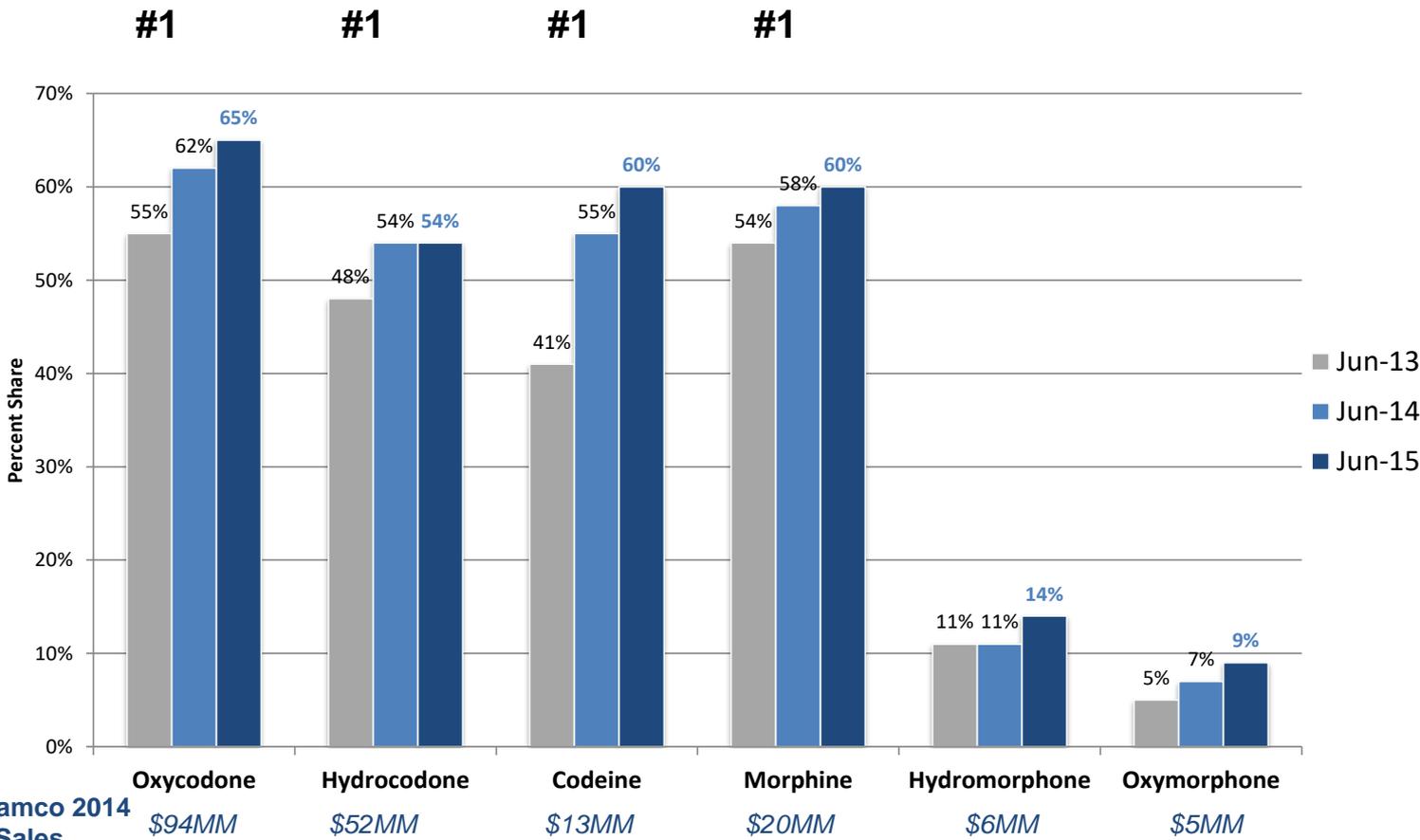
# North America is 47% of Global Consumption and is The Key Controlled Substance Market



- North America consumes:
- 82% of the worlds Oxycodone
  - 99% of the Hydrocodone
  - 99% of the Oxymorphone
  - 79% of the Hydromorphone
  - 66% of the Buprenorphine
  - 61% of the Morphine
  - 14% of the Codeine

Source: IMS FY 2014  
 Includes OXY, HBT, CPH, PMS, OMH, HMM, NLX, NTX, BUP.  
 Excludes synthetics and ADHD/ADD drugs

# Noramco Has Steadily Gained US Market Share



**Noramco 2014 US Sales**

Source for Share: IMS sales data,  
Source for Noramco US sales: unaudited company financials

# Competitive Landscape

Noramco Has A Focused API Portfolio Backed By Secure Internal Supply Of Narcotic Raw Material



	Focus Area	Narcotic Raw Material Capability	Primary Markets
<b>Noramco</b>	API Supplier to Largest Generics	<b>Major Supplier</b>	<b>Global NRM and API</b>
<b>Mallinckrodt</b>	Branded dosage	No	Primarily US
<b>Rhodes Tech</b>	Internally focused API for Purdue	No	Primarily US
<b>J. Matthey</b>	CRO and CMO and FDF	Limited	Global
<b>Francopia</b>	Brand and Generic API	Yes	Primarily OUS
<b>Siegfried</b>	CMO and FDF	No	Global
<b>Cambrex</b>	CMO and Generic API	No	Global
<b>Alcaliber</b>	NRM supplier limited API	Yes	OUS
<b>Others</b>	Sun, Aspen, AMRI	Varies	Varies

# Narcotics Global Trends And Future



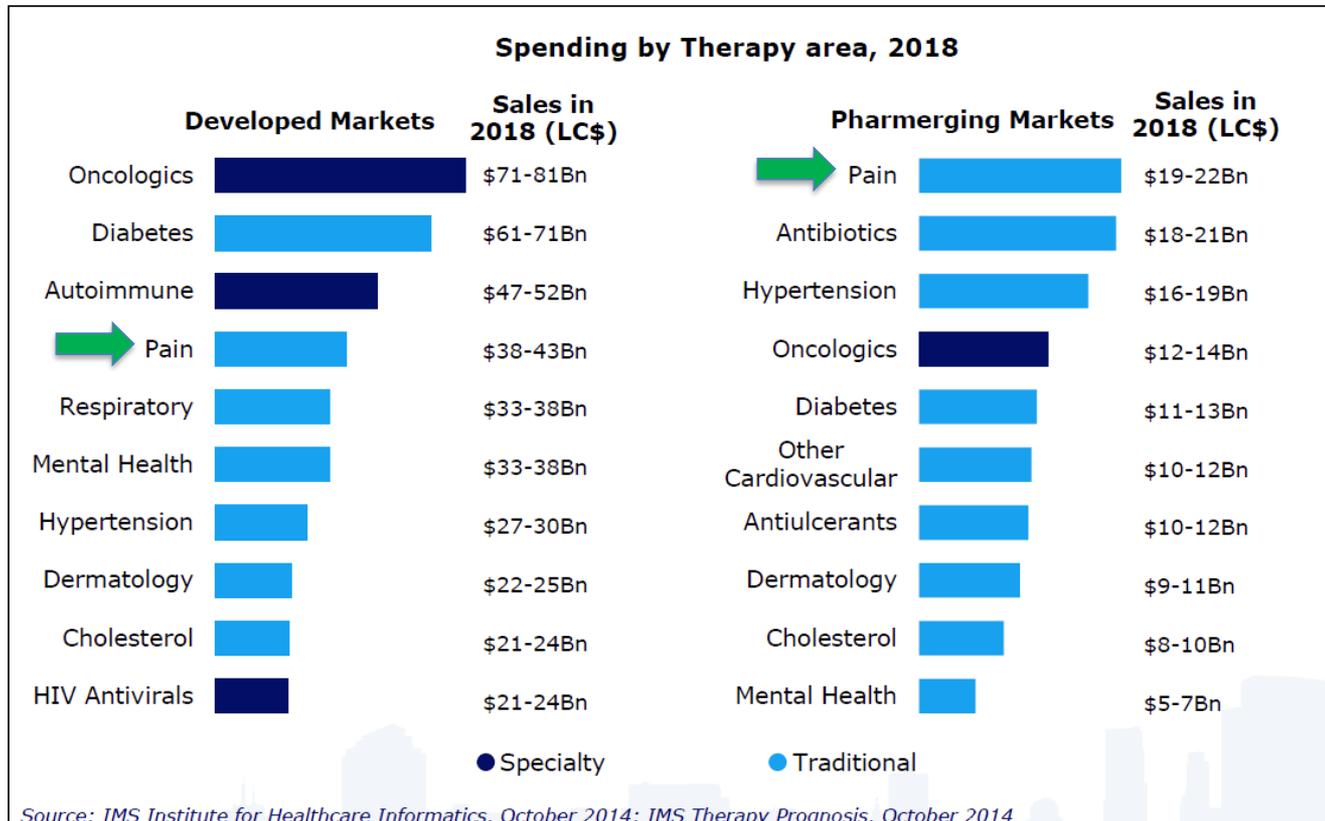
## *Global Market Past*

- Codeine and Morphine primarily used for analgesics OUS
- Enforcement reduced market size by ~2% per year from 2011 to end of 2014, appears to be stabilizing
- Stronger analgesics (Oxycodone, Hydromorphone, Oxymorphone) reformulated for Extended Release presentations

## *Global Market Future Trends*

- Aging population and increasing wealth increase analgesic demand
- Stronger analgesics in Abuse Deterrent presentations will gain more acceptance in new markets
- US Multinationals will continue to expand pain franchises OUS with Generics and Branded Generics

# Pain Finished Dose Sales Are Projected To Increase To \$57 To \$65 Billion By 2018



Today Pain Is The Number One Therapy Area For Generics Both In Value And Volume In Pharmerging Markets

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# Fully Integrated Supply Chain Provides Security



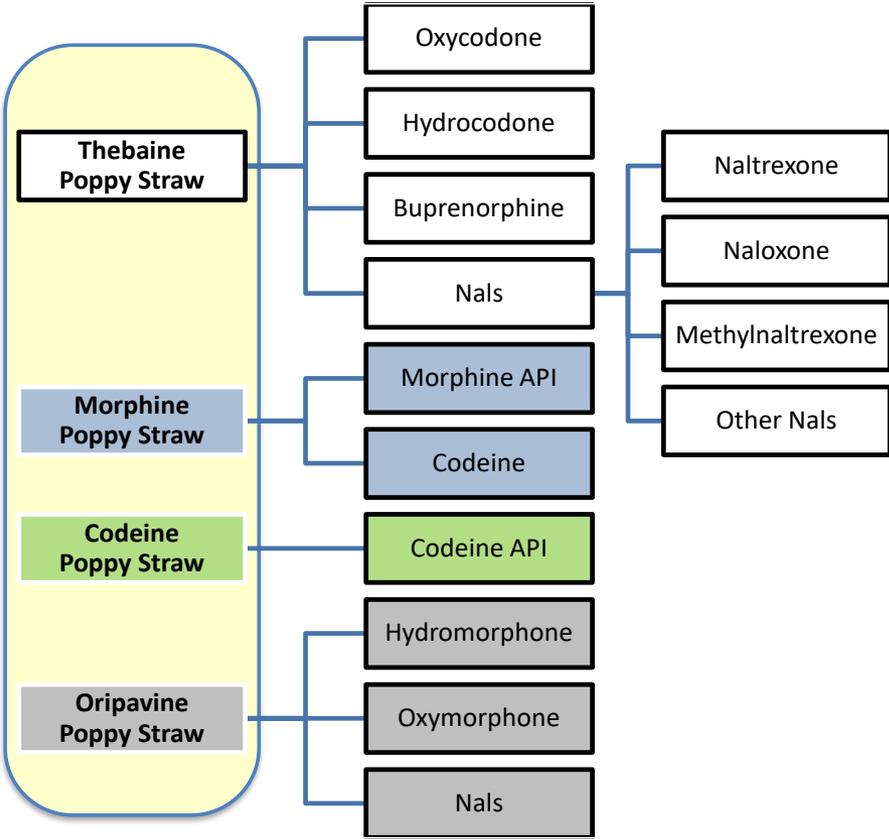
Rolling 12 months

6 to 12 months



**Generally Field to Formulation is 2 years**

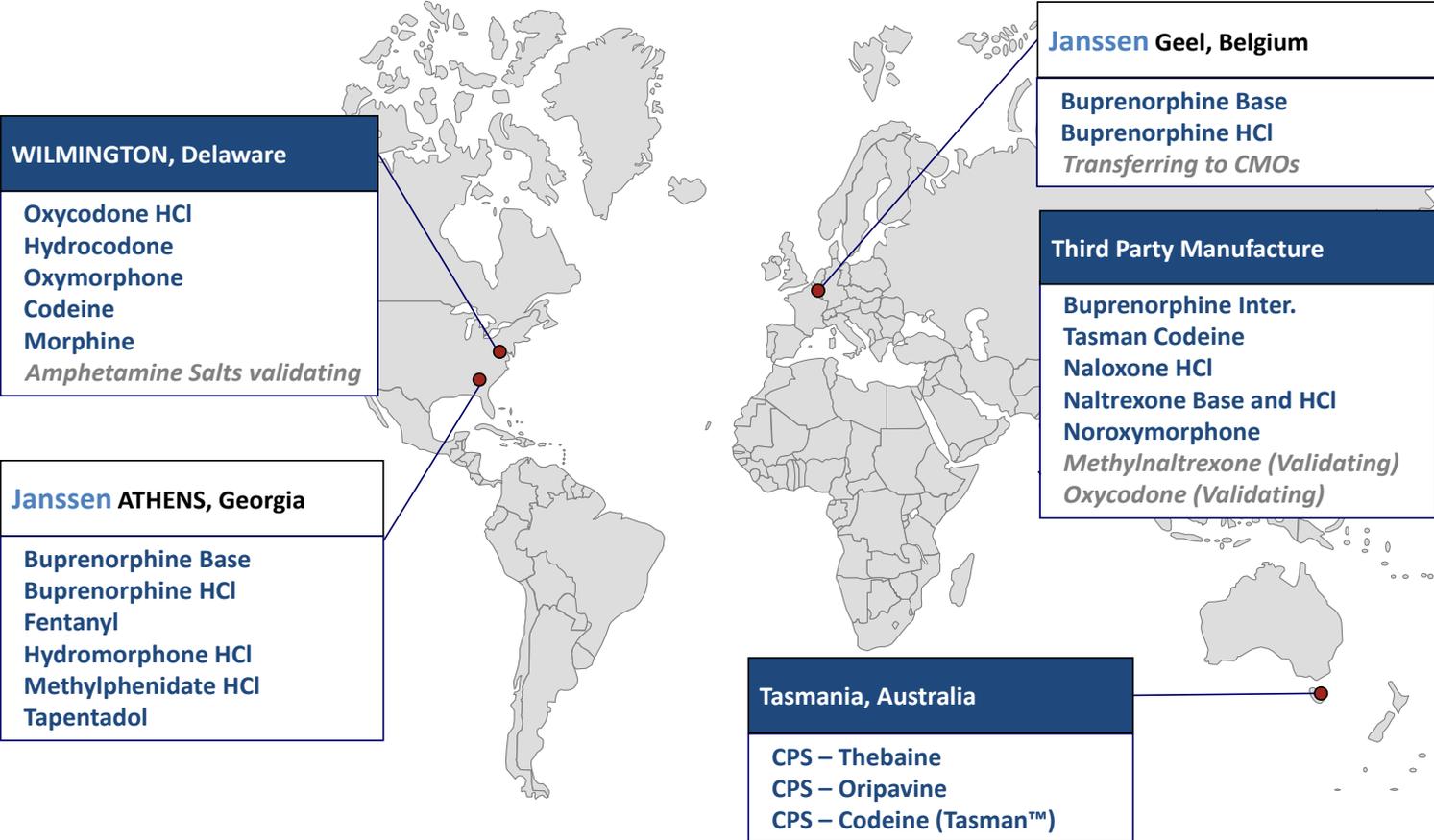
# Narcotic Raw Material Is A Critical Foundation In A Complex Supply Chain



- Tasmanian Alkaloids produces over 40% of the world’s supply of Narcotic Raw Materials
- Tasmanian Alkaloids has the highest content poppies for key alkaloids
- Many APIs may be made via different routes of synthesis

INCB report issued March 2015 notes that Tasmania produces 77% of the World thebaine

# Noramco Manufacturing Network



Note: This is a summary, not intended to show all office relationships

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# Excellent Compliance: Quality



## Tasmania

- Most recent FDA inspection was February 2013
- **No Form 483** was issued

## Wilmington

- Most recent FDA inspection was November 2014
- **No Form 483** was issued
- Over 5 years since the last inspection in which a Form 483 was issued

## Athens Total Site

- Most Recent FDA inspection was February 2014
- **No Form 483** was issued
- There has never been a Form 483 related to any part of API or intermediate manufacturing in Athens

Noramco and Tasmanian Alkaloids host customer audits by the world's largest brand and multisource generics routinely

## Excellent Compliance: DEA



### Wilmington

- Most recent DEA inspection was July and August 2015
- 5 week inspection with zero observations based on the review of prior three years of transactions

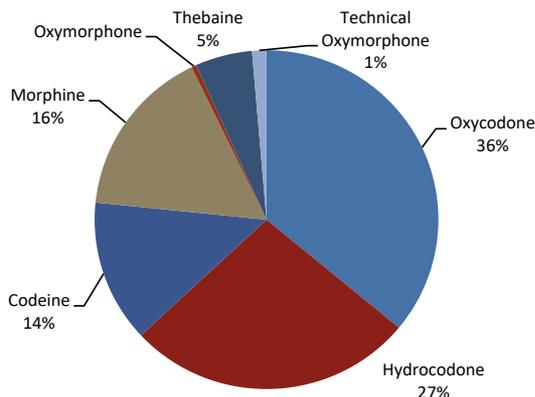
### Athens (total site)

- July 2015 DEA inspection of Importer registration zero observations
- Most recent manufacturing inspection was 2013

# Noramco, Wilmington, DE



**750+ tons per year Finished API and Intermediates**



**Key Products % by Kgs produced**

### Facility Size:

- 81,000 sq ft.
- 140 m3 reactor capacity

### Other:

- Approximately 30 minutes from Philadelphia Airport
- Located on Wilmington, DE waterfront

### People Total 197

177 Supply Chain Personnel

- 24 hrs x 7 days
- Non-Union Site

20 Off-Site Business Personnel

- Sales, Customer Service, Finance, Logistics

### Capabilities

- Over 750,000 Kg/year produced
- GMP chemical processing
- DEA secure manufacturing
- Multiple Vaults
- Hydrogenation Chemistry
- 1,100 to 10,500 L Reactors
- Multiple dryer technologies
- Milling & Custom Packaging

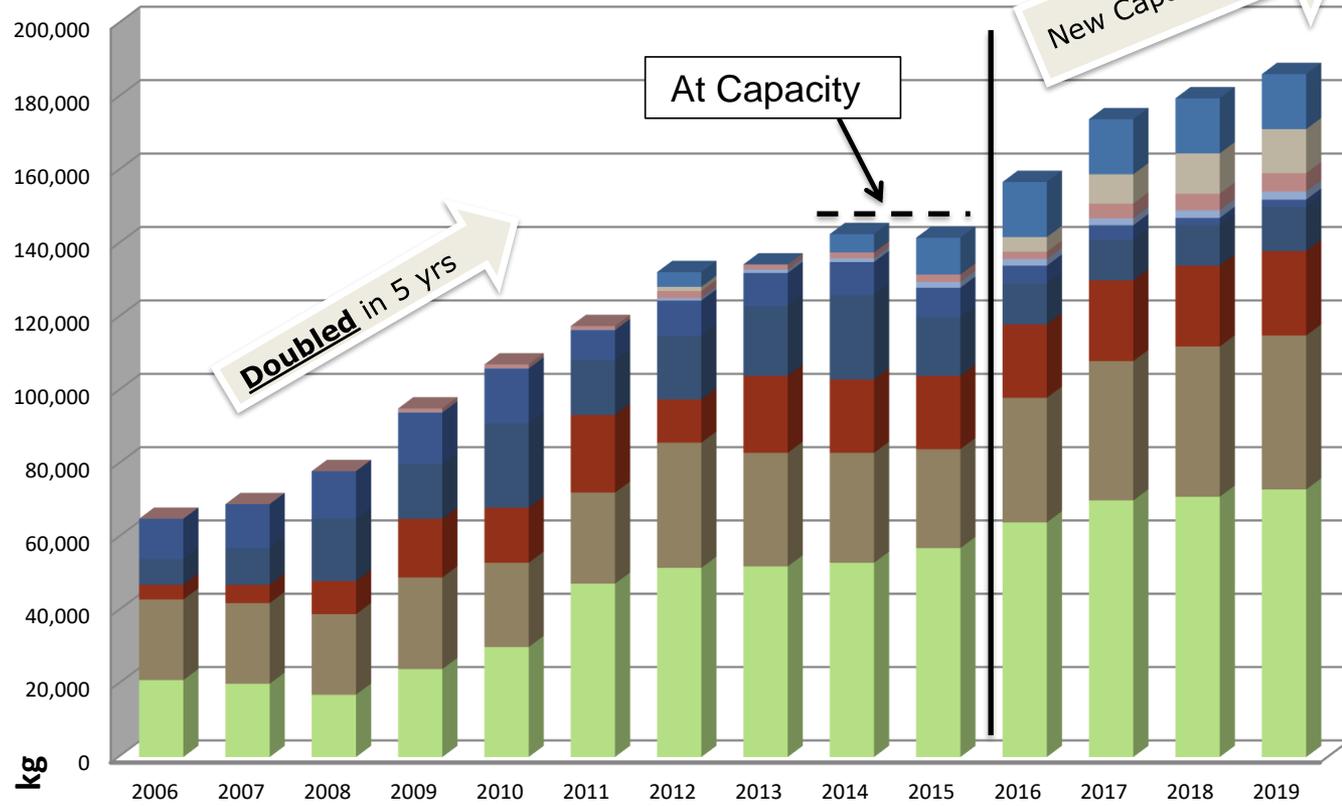
### Regulatory Profile

- FDA, EDQM, DEA, EPA, OSHA, Health Canada, Homeland Security
- Multiple customer audits monthly
- Active US Foreign Trade Zone

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# Wilmington API Volume Growth 2006-2019



- Oxycodone HCl
- Hydrocodone Bitartrate
- Codeine Phosphate
- Morphine Sulfate
- Technical Thebaine
- Oxymorphone HCl
- Oxymorphone, crude (COMd)
- Amphetamines
- Tapentadol Intermediate

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# Recent Wilmington Investments Provide Capacity And Support Growth



- Hydrogenation capacity Complete  
Doubled capacity for Oxycodone and Oxymorphone
  
- Drying capacity Complete  
New 2000L dryer Complete  
New 1000L dryer
  
- Milling capacity Completion 2016  
\$14 MM expansion
  
- Focused Factory In progress 2015 / 2016  
Hydrocodone, Codeine, Morphine

These investments **provide capacity** and room for expansion

# Tasmanian Alkaloids, Westbury, Tasmania



## People: 200 Total

- Site 24 hrs x 7 days

## Capabilities

- 300 tons per annum extraction capacity
- Modern Drying and Packaging
- Spent biomass Solvent Removal

## Regulatory Profile

- FDA, TGA, PMDA, Health Canada, EDQM, DEA, INCB, Australian Federal and State Government Authorities

## Delivery Model

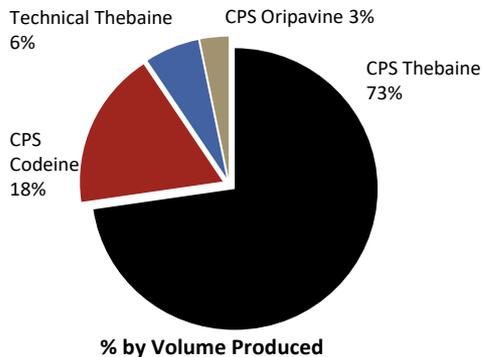
	TasAlk	Contracted
Ag R&D	●	
Growing		●
Harvesting		●
Agriculture Advising	●	
Extraction	●	
Distribution		●

## Key Products

- Concentrate of Poppy Straw (CPS) Thebaine, Codeine, & Oripavine
- Technical Thebaine
- Poppy Seed (Raw Agricultural Commodity)

**Facility Size:** 128,718 sq.ft.  
148 m3 reactor capacity

## 300 tons per year



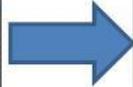
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# Security of Supply: Raw Material From Tasmanian Alkaloids to Noramco



Poppies growing in the field



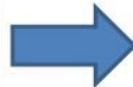
Poppies in Flower



Green Poppies



Ready for Harvest



Harvesting



Receiving the Poppies



Looking Like a Good Harvest!



Reserves for the Future

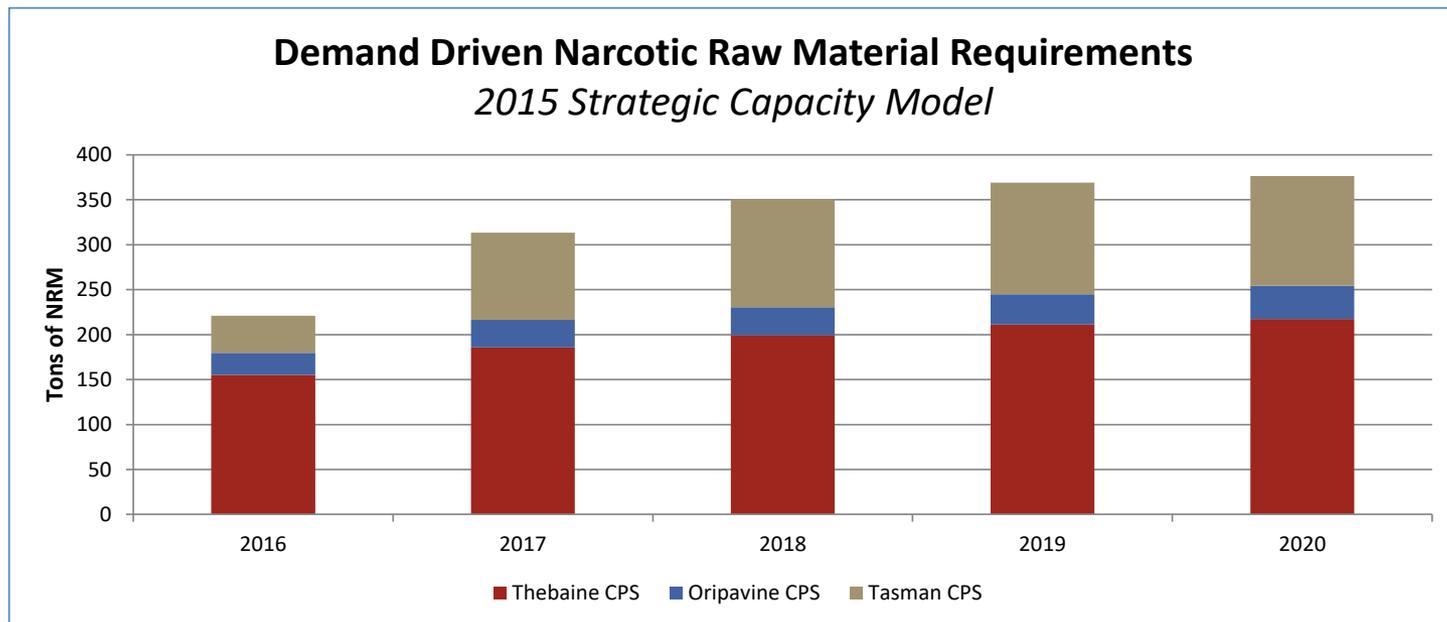
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# Tasmanian Alkaloids Recent Investment of \$27 MM Increased Capacity by 50%



- 300 tons per annum capacity at Tasmanian Alkaloids
- 3<sup>rd</sup> party contract extractor demonstrated and qualified
  - Utilize contract extraction above 300 tons (no capital expenditure)
  - Annual increase in poppy content will boost capacity



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# Noramco's Established External Manufacturing Network



- Efficient access to specialized equipment and technology
- Access to closed markets

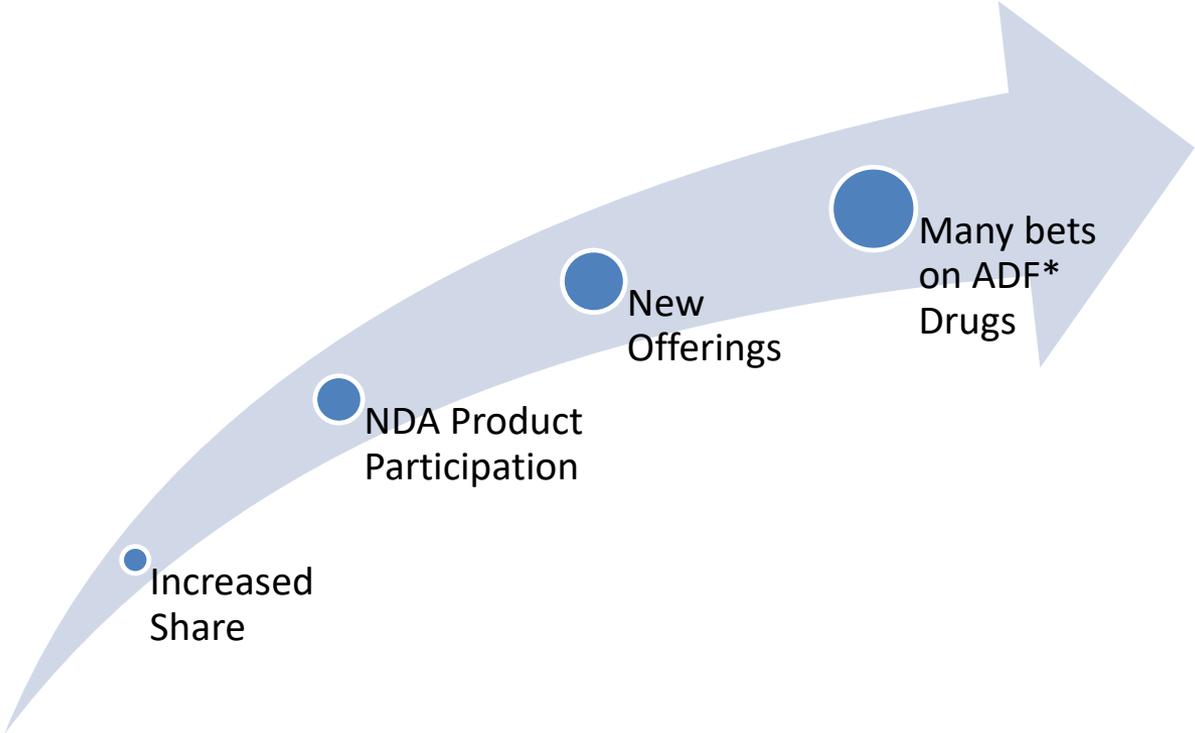




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# Noramco Growth Drivers and Upside



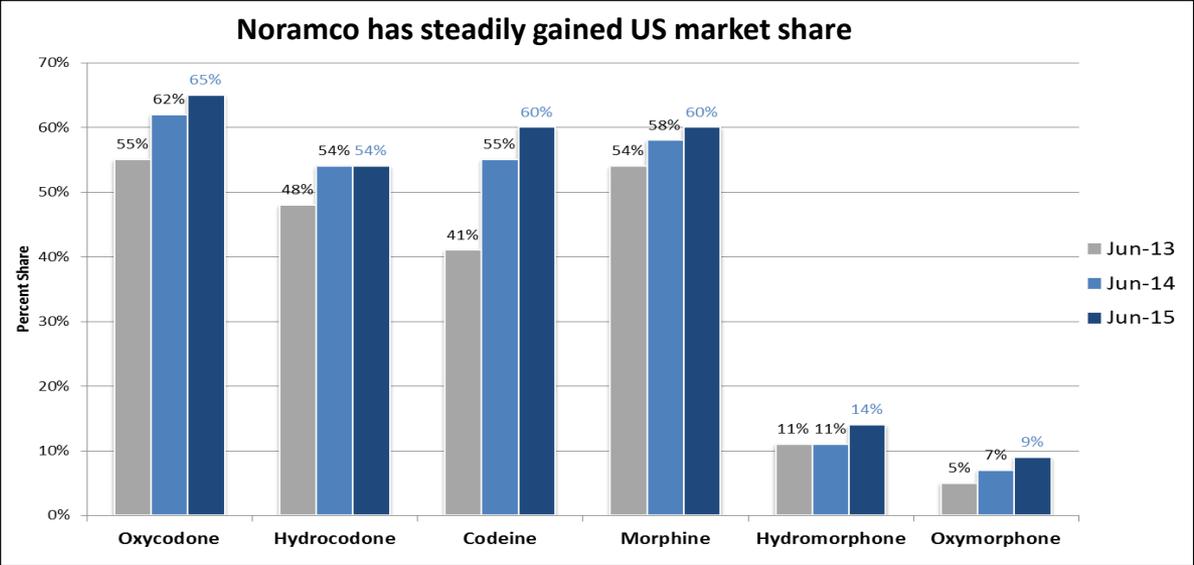
\* ADF = Abuse Deterrent Drug Formulations

# Growth in Noramco Share is Possible



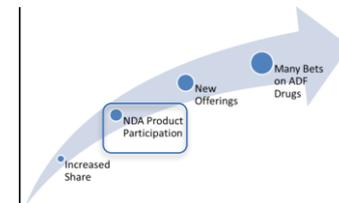
Growth in share supported by contracts with key finished dose providers\*

- Completed qualifications (oxymorphone)
- Customer qualifications that are in-progress (hydromorphone)
- Capitalizing on key brand to generic switches (Oxycontin)



\* Existing contracts are not a guarantee of future business

# Customer NDA Product Launches Where Noramco Supplies API



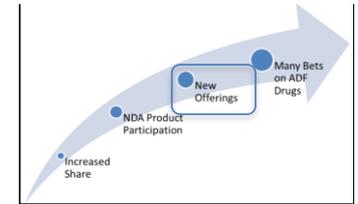
Noramco API	Methylnaltrexone	Buprenorphine HCl	Naltrexone HCl	Oxycodone NME
<b>Company</b>	Confidential	Confidential (two)	Confidential	Confidential
<b>Product</b>	Relistor	Sub-Q NDA Formulations	Contrave®	NKTR-181 Peg-Oxy
<b>Indication</b>	Opioid-Induced Constipation (OIC)	Opioid Addiction	Obesity	NME: Pegylated Oxycodone
<b>Status</b>	Submitted NDA June 23, 2015	Commercial and Ph II NDA	Partnering to resolve formulation issues	Enrolling Ph III complete by YE 2012
<b>Expected Noramco Commercial Approval</b>	1H 2017	Confidential Commercial, and 2016 to 2018	Commercial, Noramco potential in 2017/18	1H 2018
<b>Notes</b>	Long-term supply agreement for supply of >75% of Methylnaltrexone. Supplying 1.8tons in next 18 months	Several NDA and NDA, 505(b)2 opportunities not listed	FDA agreed in Oct to a faster path to resubmitting NDA; enrolling in last clinical ahead of schedule	Noramco selected as second source, development agreement drafted. Post approval submission

← Higher Probability

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# New Offering (Pipeline) from Noramco



Noramco API	Cannabinoid Family	Amphetamines	Fentanyl
<b>Company</b>	Confidential	Confidential	Confidential
<b>Product</b>	Epidiolex® and Sativex® and their generics	Generics of Adderall®, Dexedrine®	Generics of Duragesic®, Actiq®
<b>Indication</b>	CNS, Seizure, Pain	ADHD	Pain
<b>Status</b>	Clinical material using Noramco IP. Purchase Order in hand	Q1 2016 Filing Launch 2017/2018	Filing submitted Feb 2015, assessing customer interest with samples
<b>Market Comment</b>	<i>Confidential</i> Estimate 10 to 50 tons	Current US Market ~26 tons, growing at 11%	US Market ~1,200kg

# Working With Innovators Assures Noramco Participates In ADF\* Launches



Product	Active	ADF Means	Noramco	Status
<i>Confidential</i>	Oxycodone	Antagonist (NIC)	100%	Commercial
	Morphine	Antagonist (NTX)	100%	Commercial
	Hydromorphone	Mechanical	100%	Commercial
	Tapentadol	Mechanical	100%	Commercial
	Oxymorphone	Mechanical	80%	Commercial
	Oxycodone	Antagonist (NTX)	100%	Commercial
	Oxycodone	Mechanical	10%	Commercial
	Oxycodone	Mechanical	Mallinckrodt	Commercial
	Hydrocodone	Mechanical	100%	Commercial
	Hydrocodone	Antagonist (NTX)	100%	Development
	Oxycodone	Mechanical	100%	Development
	NME: Peg-OXY	Biochemical	In Progress	Development
	NME: Prodrug	Enzymatic	In Progress	Development
	Codeine	Mechanical	100%	Filed
	Hydromorphone	Antagonist (NLX)	100%	Filed
	Oxycodone	Mechanical	100%	Filed
	Oxycodone	Antagonist (NLX)	10%	Filed
	Morphine	Mechanical	90%	Filed

- Noramco is the sole supplier to the vast majority of commercial and ADF formulations
- Included in filings because we could meet requirements nobody else could (or would)

\*ADF= Abuse Deterrent Drug Formulations



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# Creating A Sustainable Competitive Advantage And Achieving The Lowest Cost



## Cost Drivers of API

Narcotic Raw Material Cost

Volume (Economy of Scale)

Complexity (#Steps)

Conversion Efficiency

Ultra High Purity (ppm)

## Value Creation by:

Agricultural R&D

Chemical R&D

# Creating A Sustainable Competitive Advantage And Achieving The Lowest Cost



All are important but....

## Cost Drivers of API

**Narcotic Raw Material Cost**

Volume (Economy of Scale)

Complexity (#Steps)

**Conversion Efficiency**

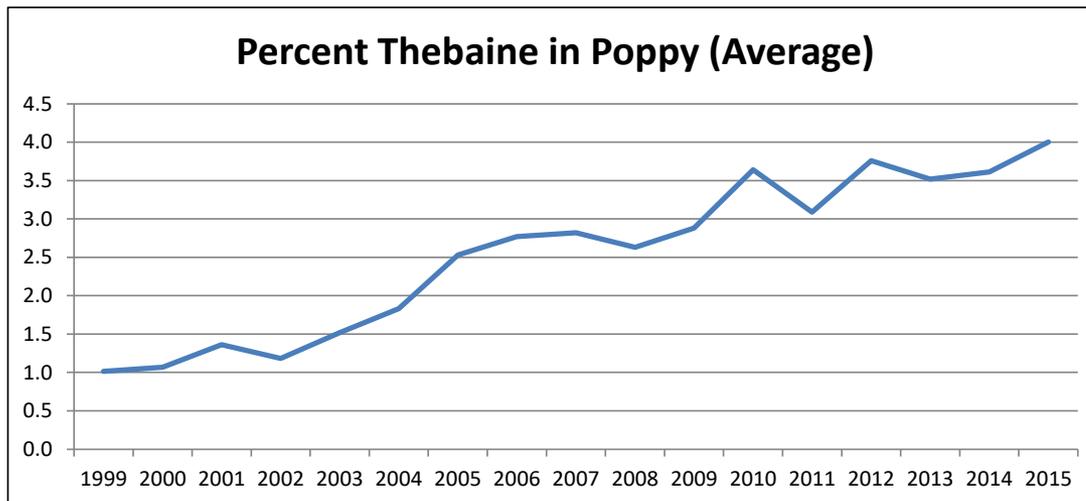
Ultra High Purity (ppm)

## Value Creation by:

Agricultural R&D

Chemical R&D

# The Value of Agricultural Research



- Narcotic raw material is the single biggest contributor to API costs
- Tasmanian Alkaloids has increased the alkaloid content by 300% over the last 15 years
- INCB data validate that these increases are unparalleled in the industry



## Current Ag R&D Objectives

- Increased yield (alkaloids per ha)
- Reduced processing costs (reduce crop: straw ratio, capsule characteristics)
- Increased crop production efficiency to reduce the gap between average and maximum crop yields
- Risk management of raw material supply (new production regions e.g. Victoria)

## Tasmanian Alkaloids R&D - Three Areas of Work



- Plant Breeding and Improvement
  - On-going core activity that has delivered results
  
- Agronomy
  - Translating Agricultural R&D to the field
  - Leveraging Field Staff
  
- Biotechnology
  - Transformational innovation area

# Plant Improvement – In Tasmania



## Description

Ongoing conventional plant breeding program to improve the alkaloid content and productivity

## Objective

Release new varieties with 5% increase per year relative to previous year

## Desired Outcomes

Increased Thebaine and Codeine yields per ha

Improved growth characteristics (*e.g.*, constant height, dwarf varieties, etc)

Production of thebaine and codeine lines with differential herbicide resistance (decreased field and factory production costs)

Development of seedless or sterile varieties (increased straw/crop ratio)

# Agronomic Research



## Description

Increase poppy plant production efficiency and alkaloid yield production through optimisation of crop husbandry (*i.e.*, R&D translated to the real world with field staff)

## Objectives

Introduction of new technologies to increase crop production efficiency and decrease field and processing costs

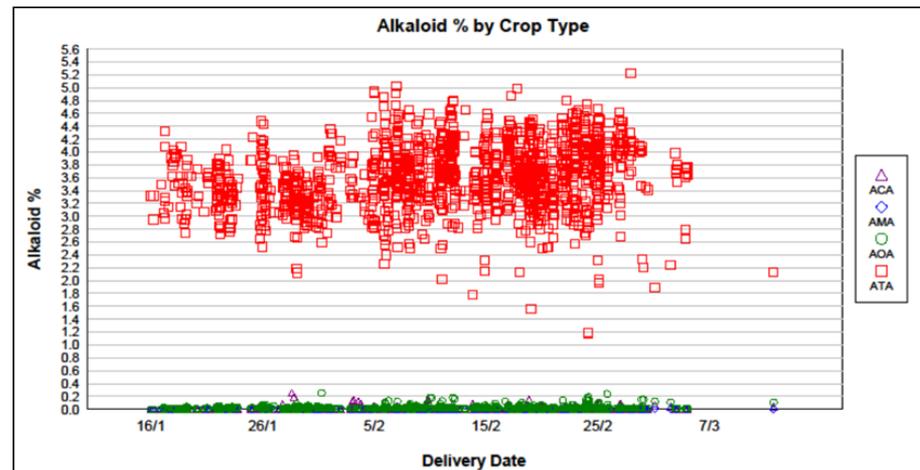
## Desired Outcomes

Reduction in gap between average and best yields →

Increase yields per ha

Increase disease resistance

Improve growth characteristics



# Biotechnology – In Tasmania



## Description

Develop poppy polyploids for commercial crop production using targeted mutagenesis and gene regulation

## Objectives

Increase efficiency of alkaloid production

## Desired Outcomes

Increase Thebaine and Codeine alkaloid content from current level by 20% in the near term and 50%+ long-term

Development of seedless or sterile commercial varieties

Provide new parent material for conventional breeding

# Creating A Sustainable Competitive Advantage And Achieving The Lowest Cost



All are important but....

## Cost Drivers of API

- Narcotic Raw Material Cost
- Volume (Economy of Scale)
- Complexity (#Steps)
- Conversion Efficiency
- Ultra High Purity (ppm)

## Value Creation by:

- Agricultural R&D
- Chemical R&D



# Chemical and Analytical R&D Summary



- Tasmanian, Australia
  - Extraction improvements and development on all poppy varieties
  - Extraction support and process troubleshooting (including external API's)
- Athens, Georgia and Wilmington, Delaware
  - Customer support and specialized customer samples
  - Plant support for Noramco manufactured API's and US external intermediates
  - Development and improvements of new and existing API's + reference standards
- Schaffhausen, Switzerland
  - Development and improvement of API and intermediate processes
  - Production Support of all externally manufactured API's
- Global Functions Located Across Sites:
  - Regulatory Affairs and Technical Services



## Summary of Key Chemical R&D Contributions

Developed and **commercialized 10+ APIs** in 6 years

### **Cost of goods improvements** for core products

(oxycodone, hydrocodone, codeine, morphine, Nals, and Bup)

- 2015 is a transition year for customers to new Oxycodone and Codeine processes
- Full-year benefit to COGS in 2016 for >75% of Oxycodone volume and >50% of Codeine

Fully filed **dual-sourced Nal-family** via thebaine or oripavine

R&D has adapted our products **to secure business**

- Inclusion in ADF forms by low level impurity control
- New filed particle sizes for sophisticated ER formulations

## Schaffhausen Business and Technical Operations



### World Wide Narcotics Franchise Schaffhausen:

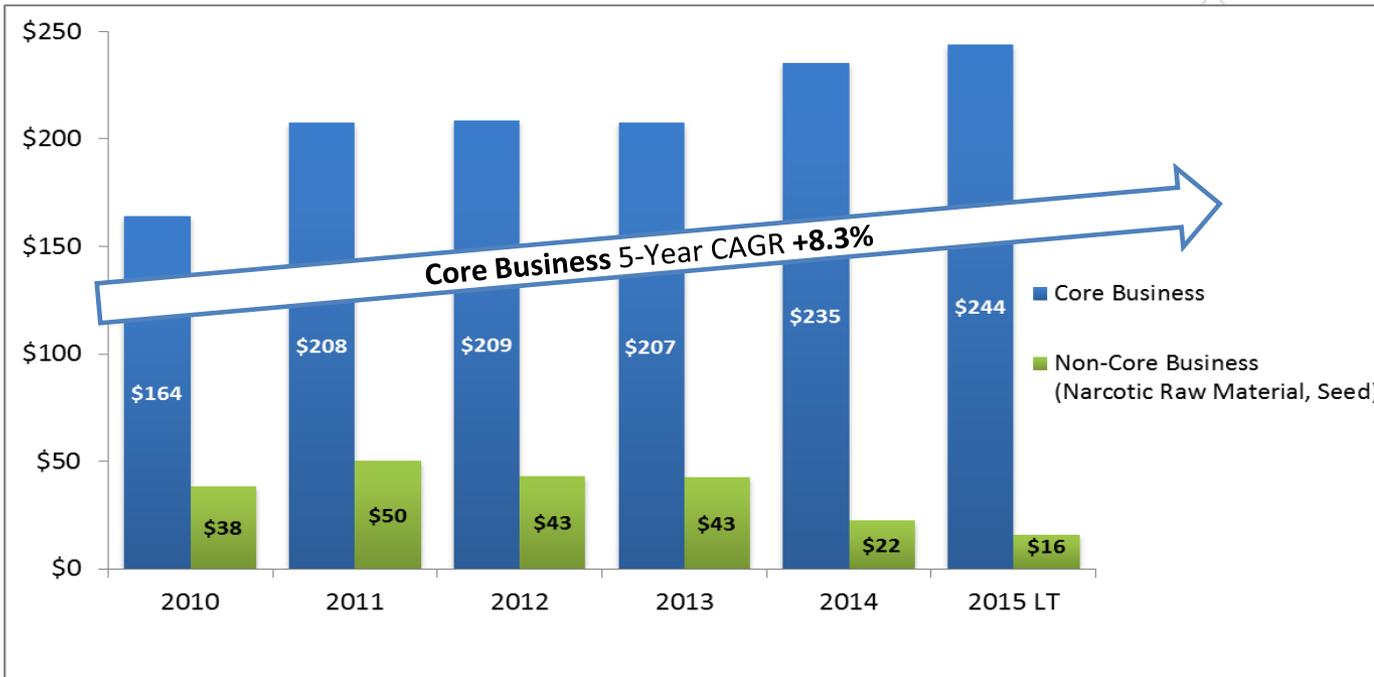
- Manages virtual OUS Supply Chain with products representing 50% of NF product portfolio, approx 15 SKUs
- Owns and maintains IP of the Naltrexone family APIs including regulatory filings
- Profits from Swiss tax benefits
- Very experienced and productive R&D center for WWNF
- Developing a commercial process for the new API Cannabidiol
- Overall HC of 30 (8 within JSC)



## Agenda

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# 2010 – 2015 Noramco Sales (\$MM, Unaudited)



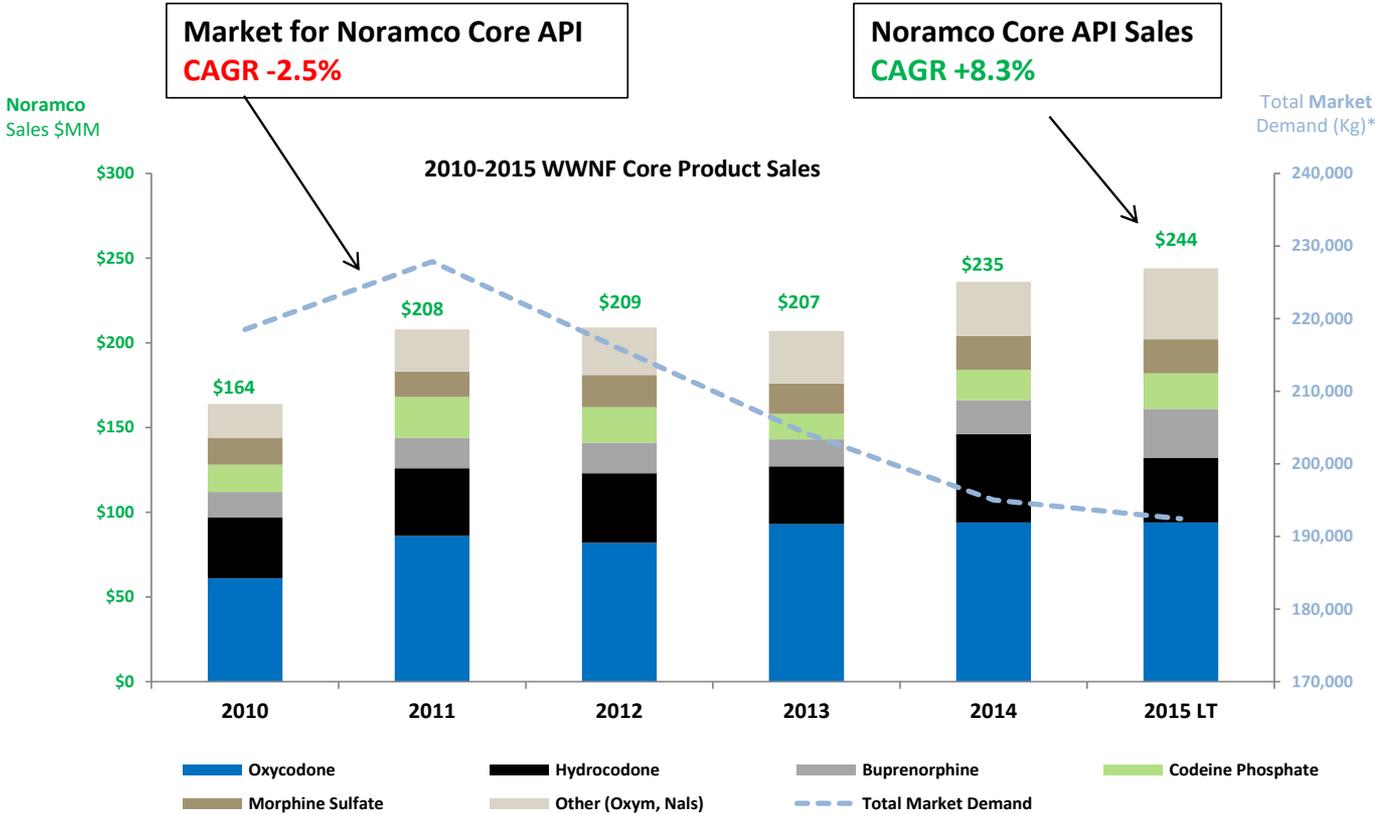
Core % Growth	+26.5%	+0.5%	(0.7%)	+13.6%	+3.6%
Total % Growth	+27.5%	(2.4%)	(0.8%)	+3.2%	+0.8%

- Core Business sales continues to grow due to increase in market share
- Total Noramco sales 5-year CAGR of **+5.1%** (Core Business is +8.3%)

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# Noramco Core API sales have increased in a declining market (Unaudited)



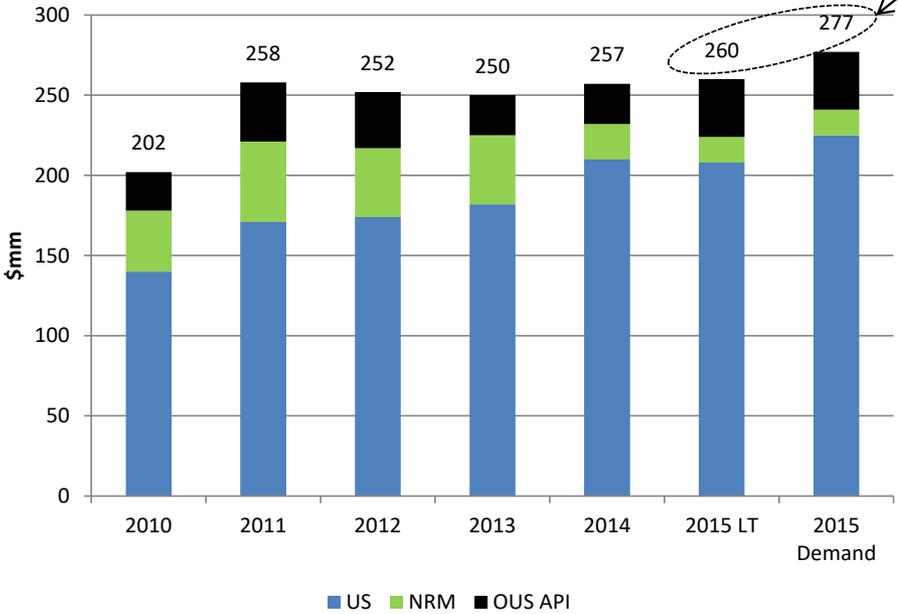
\* Total Market Volume includes IMS sales actuals through June 2015 in markets accounting for >92% of Noramco Sales

# WW Narcotics: Supply Chain Impacts to 2015 Sales



## WWNF 5 Year Sales (Unaudited)

2015 Supply Chain Impacts



**Customer Demand Exceeds Supply by \$17mm**

Supply issues example:  
 25% of Oxycodone produced this year has been reprocessed  
 Impact: 2015 US Sales would be 6 to 10% higher without Supply Issues

# 2010 – 2015 Noramco Financial Metrics (\$MM, Unaudited)



	2010	2011	2012	2013	2014	2015 LT
<b>Revenue</b>	<b>\$ 202</b>	<b>\$ 258</b>	<b>\$ 252</b>	<b>\$ 250</b>	<b>\$ 258</b>	<b>\$ 260</b>
Cost of Products Sold	(138)	(172)	(176)	(180)	(180)	(188)
<b>Gross Profit</b>	<b>\$ 64</b>	<b>\$ 86</b>	<b>\$ 76</b>	<b>\$ 69</b>	<b>\$ 78</b>	<b>\$ 71</b>
<i>GP %</i>	32%	33%	30%	28%	30%	28%
SG&A	12	11	14	17	15	14
R&D	11	9	11	12	14	14
<b>Total Operating Expense</b>	<b>\$ 23</b>	<b>\$ 20</b>	<b>\$ 25</b>	<b>\$ 29</b>	<b>\$ 29</b>	<b>\$ 28</b>
<i>Expense % to Sales</i>	11%	8%	10%	12%	11%	11%
Other Expense/(Income)	1	1	2	(2)	(1)	(1)
<b>Operating Income</b>	<b>\$ 40</b>	<b>\$ 65</b>	<b>\$ 49</b>	<b>\$ 42</b>	<b>\$ 50</b>	<b>\$ 45</b>
<i>Operating Margin %</i>	20%	25%	19%	17%	19%	17%
Depreciation	19	18	16	15	16	16
Amortization	-	-	-	-	-	-
<b>EBITDA</b>	<b>\$ 59</b>	<b>\$ 83</b>	<b>\$ 65</b>	<b>\$ 58</b>	<b>\$ 66</b>	<b>\$ 61</b>
<i>% to Sales</i>	29%	32%	26%	23%	25%	23%
<b>Financial Metrics</b>						
Cash Flow	\$ 28	\$ 21	\$ (2)	\$ (14)	\$ 2	\$ 20
Inventory	\$ 120	\$ 122	\$ 154	\$ 203	\$ 223	\$ 229
Capital Spend	\$ 15	\$ 21	\$ 20	\$ 25	\$ 23	\$ 19

Note: The 2013 and 2014 financial information above excludes inventory reserves of \$19MM and \$11MM, respectively, where that inventory is expected to be sold through in 2016 or beyond.

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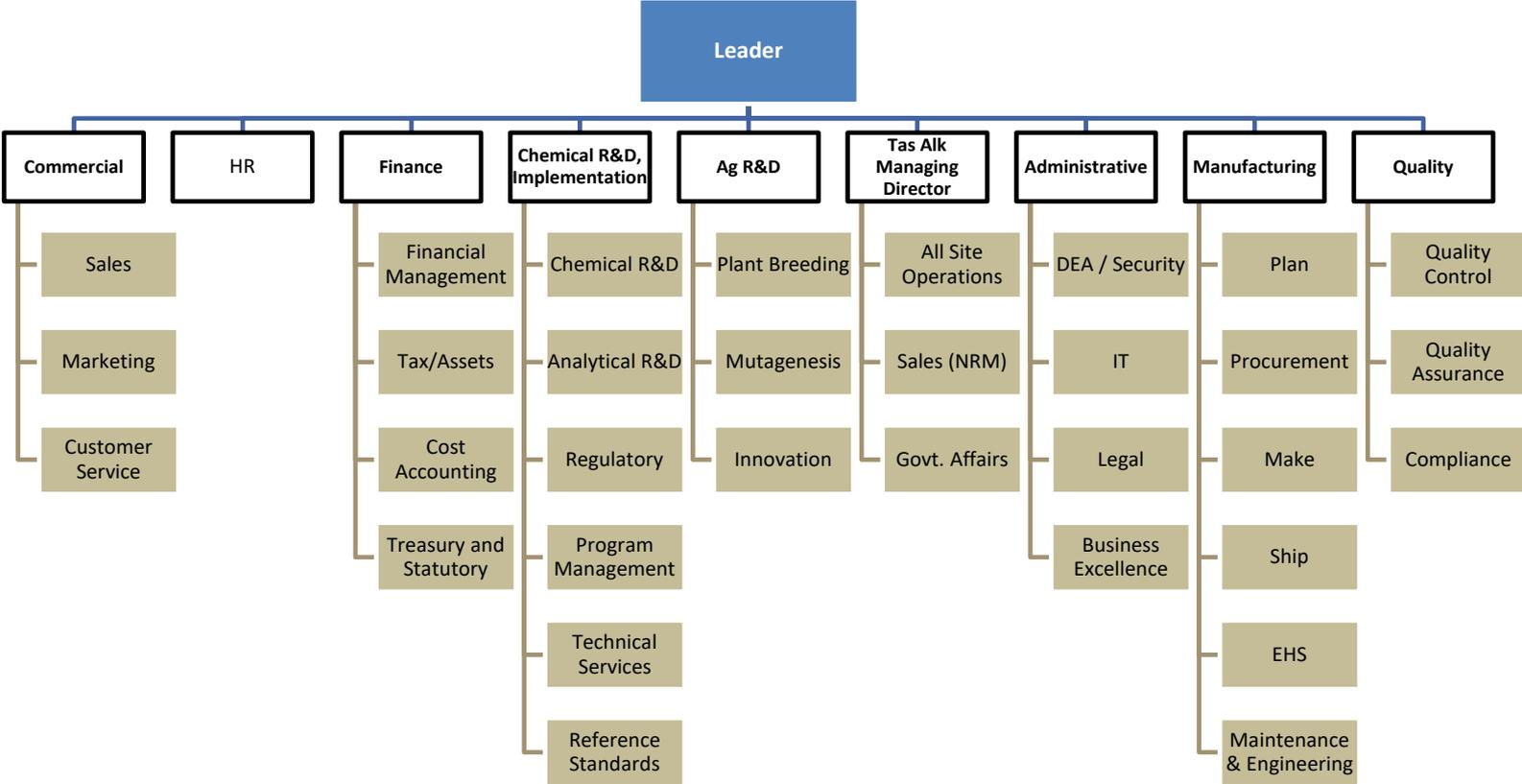
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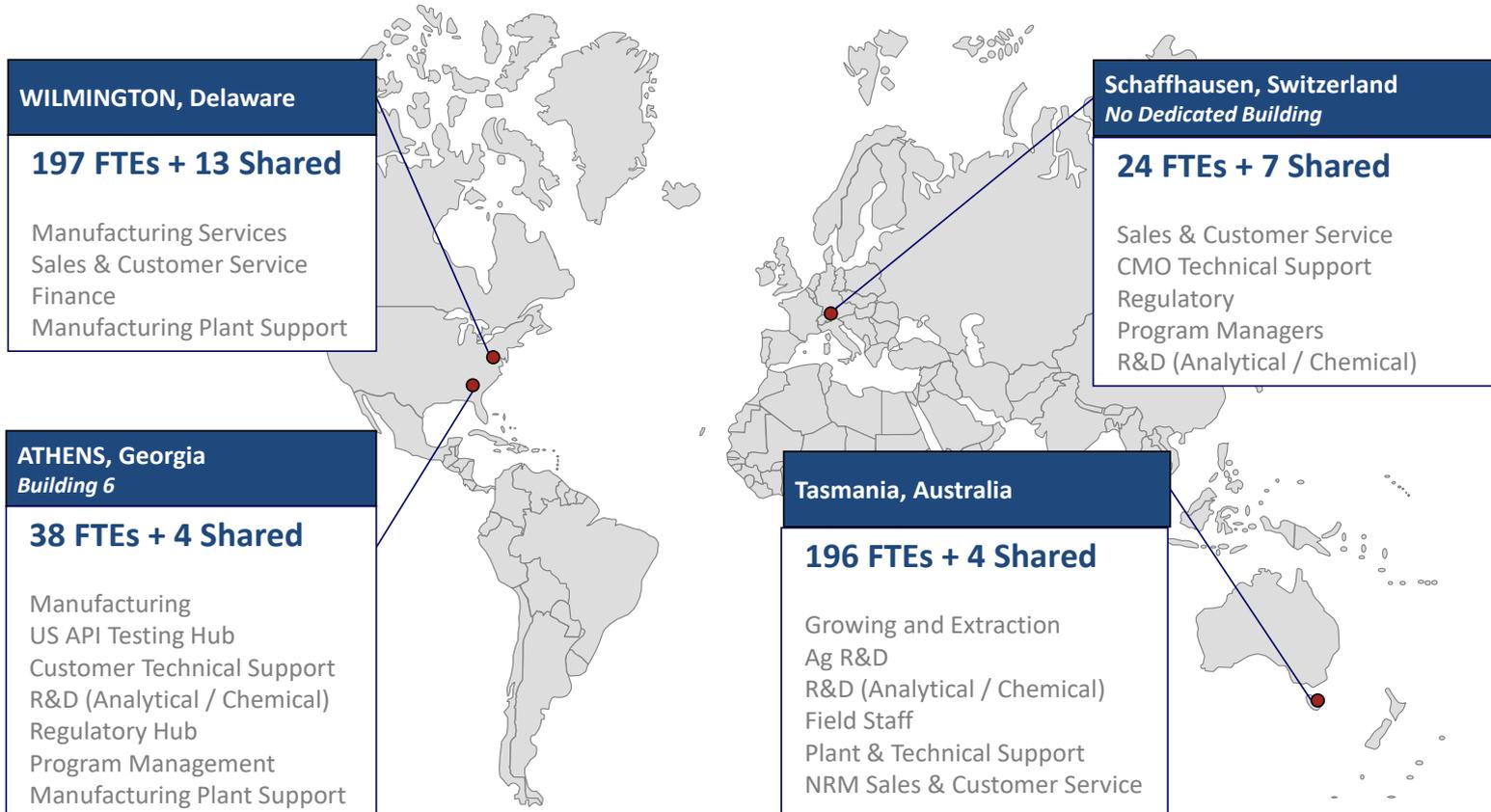
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# Noramco Organization



# 483 Full Time Equivalents Support the Franchise (455 direct and 28 shared with J&J\*)



\* The 28 shared resources are leveraged with J&J and are required to operate the business.  
2 employees located in UK included within Schaffhausen headcount.  
The shared resources are included with Cost of Goods.

## Human Resources Considerations



- Transfer of 455 FTE to buyer
- Maintain comparable level of compensation for at least two years
- J&J has implemented retention bonuses to key employees to ensure business continuity



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## Deal Process



- After management presentation, process letter for preliminary bid sent to you describing
  - Cash consideration for business
  - Source of financing and need for audited financials
  - Indication of level of review and approval within organization prior to submission of preliminary bid
- Data room access based on preliminary bid
- Submission of final binding bids
- Contract negotiations



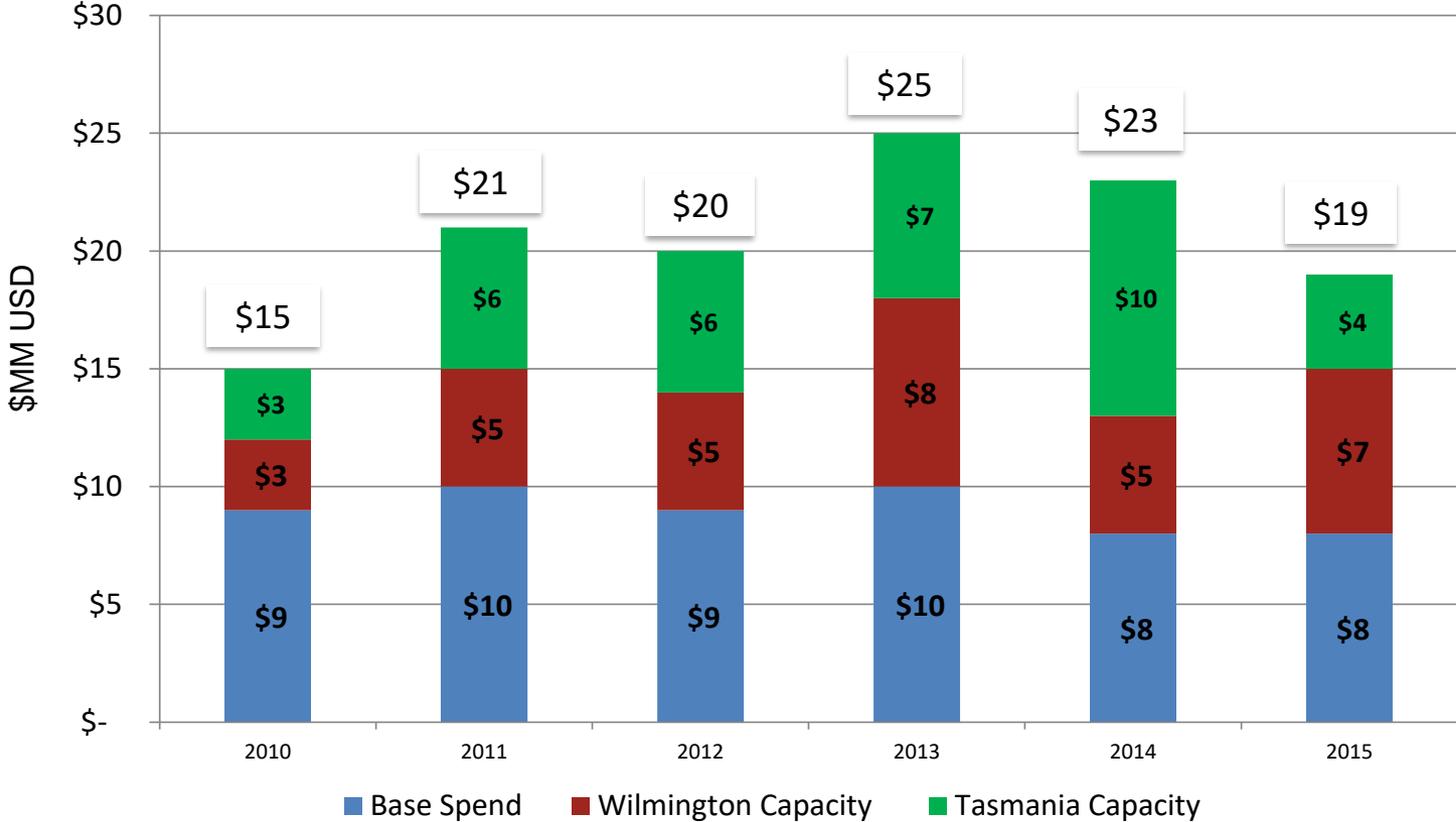
Thank You !

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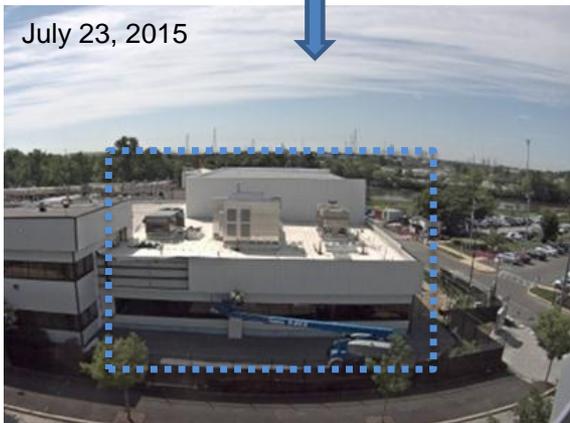
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69

# Noramco 2010 – 2015 Capital Spend



# Increased Capacity Wilmington: \$14 MM Expansion Underway



- Fully approved and in progress
- Warehouse vault and office occupancy Nov 2015
- Milling on-line Q1 2016
  - Doubles the milling capacity of all products (currently a bottleneck)

# Global Regulatory Portfolio



Current Dossiers								
Product	Mfg. Site	USA	Canada	EDQM CEP	Japan	Australia	New Zealand	EU/ROW
Amphetamines (4 DMFs)	WT	*						
Buprenorphine Base	Tas Alk	T	T	T	T			T
	Geel	N	N	N	*	J	J	J
	AT	N						
Buprenorphine HCl	Geel	N		N		N		J
	AT	N	*					
Codeine Phosphate (classic)	Tas Alk			T				T
	WT	N						
Codeine Phosphate (Tasman)	WT	N						
	Aesica			N				N
Dronabinol	Cilag	C						
Fentanyl Base	AT	N	*					
Hydrocodone Bitartrate (nHBT)	AT/WT	N	N					
Hydromorphone HCl	AT	N	N	N		N	N	J
Iron Sucrose	Cilag	C						C
Methylnaltrexone Br	Cilag	C						
Methylphenidate HCl (current)	AT	N	N	J	J	J	J	J
Methylphenidate HCl (one-step)	AT	*	*	*				
Morphine Sulfate	WT	N	N					
Naloxone HCl	Cil/Aesica	C	C	C				Closed
Naltrexone Base	Cil/Aesica	C						*
Naltrexone HCl	Cilag	C		C				C
Oxycodone HCl (nOXY/OXY3)	AT/WT	N	N	N		N	N	N
Oxycodone HCl (OXY3)	Aesica			N				
Oxymorphone Base	WT/AT	N (IND)						
Oxymorphone HCl	WT	N						
Purified Oxycodone Base	WT	N	*					

\*In-process

N=DMFs held by Noramco

J=DMFs held by J&J

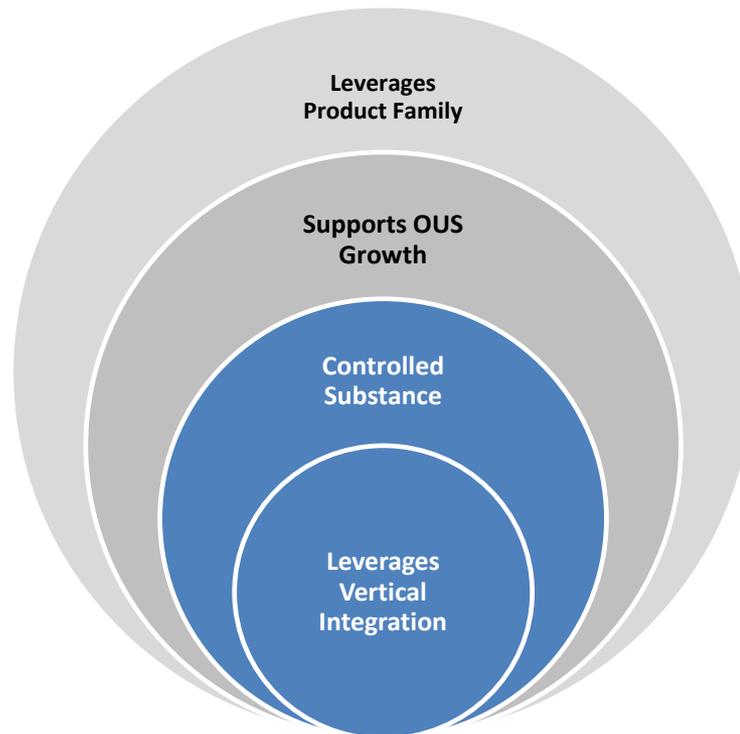
T=DMFs held by TasAlk

C=DMFs held by Cilag

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# Noramco Product Strategy Summary



Leveraging Narcotic Raw Materials from Tasmania

Controlled Substance Agonist or Antagonist

Sustainable Competitive Advantage

# Current Facilities and Offices



	<u>Personnel Supporting Business</u>
• USA	
Wilmington DE Manufacturing Site	174
Leased Office Space Wilmington	21
Athens GA Research and Office Space	56
• Switzerland	
Office and Laboratory Space	30
• Tasmania	
Westbury Manufacturing Site	200
• UK	
2 Home Based Offices	2
	<hr style="width: 100px; margin-left: auto; margin-right: 0;"/> ~483 Total

# Many Investments to Assure Noramco in New Launches



Xartemis / Mallinckrodt  
(LA oxy+APAP ADF)

ELI-200 / Elite  
(SA oxy + NTX ADF)

MoxDuo / QRx Pharma  
(SA oxy+morph)

Oxaydo®/ Egalet  
(SA oxy ADF)

KP-201 / KemPharm  
(Hydrocodone ADF)

KP-511 & 506 /  
KemPharm  
(OXY + HMH ADF)

## Short Acting Opioids



## Long Acting Opioids

Hysingla / Purdue  
(hydrocodone ADF)

Zohydro ER / Pernix  
(hydrocodone ADF)

Eglaet-001 / Egalet  
(morphine ADF)

PF329/Signature  
(Hydrocodone **ADF**)

GRT-6005/6006  
NOP Receptor NMEs

Exalgo / Mallinckrodt  
(HMH ADF)

Embeda / Pfizer  
(morph + NLX ADF)

CEP-33237 / Teva  
(hydrocodone ADF)

NKTR-181/Nektar  
(OXY **ADF**)

Oxycontin / Purdue  
(OXY ADF)

Xtampza® Collegium  
(Oxycodone Base ADF)

Cerovene  
(morphine ADF)

Remoxy/Pfizer  
(Oxycodone Base ADF)

Opana / ENDO  
(OMH ADF)

MNK-155 Mallinckrodt  
(Hydrocod+APAP ADF)

Hydrolox ADF / Purdue  
(HMH + NLX ADF)

Oxytrex/PTI  
(OXY + NTX ADF)

XartemisXR / Mallinck.  
(oxy+APAP ADF)

Belbuca / BDSI  
(Bup HCl ADF)

Ascomp ADF / NexGen  
(Codeine + ADF)

Phosphogenics Patch  
(Oxymorphone ADF)

Targiniq / Purdue  
(OXY + NLX ADF)

ALO-02 / Pfizer  
(oxy + naloxone ADF)

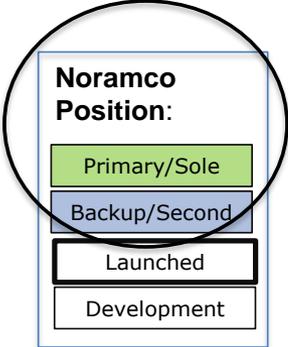
Phosphogenics Patch  
(Oxycodone Base ADF)

ZoHydro / Pernix  
(OXY **non-ADF**)

Collegium 172  
(Oxymorphone Base ADF)

BuTrans / Purdue  
(Bup Base **non-ADF**)

Collegium 195  
(Hydrocodone Base ADF)



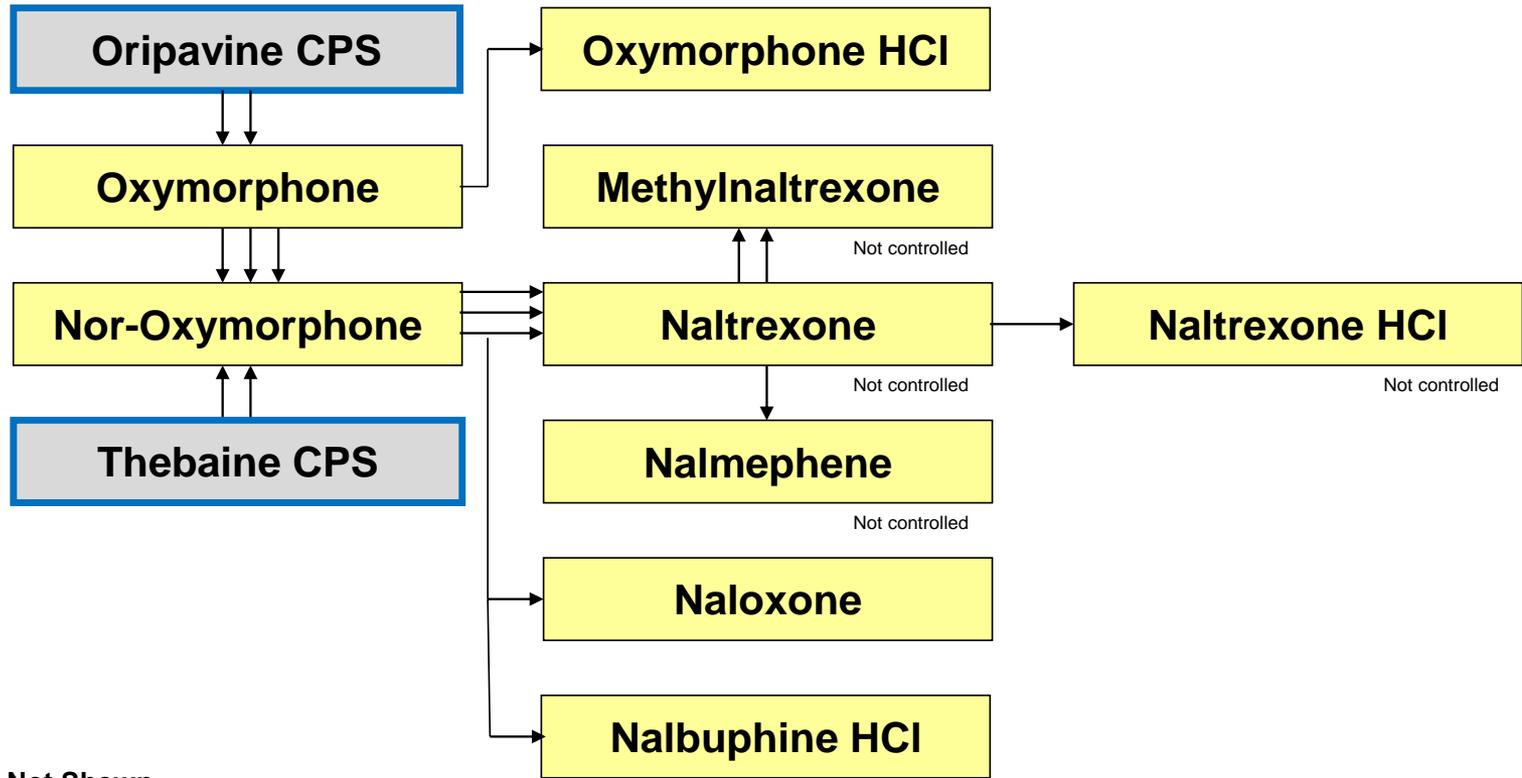
ADF = Abuse Deterrent Formulation

Source: BioMed Tracker, IPD Analytics, company websites & investor relations calls  
Generic estimates based on patent exclusivity expiration date in "FDA Orange Book" or litigation settlements. Noramco Product Management

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# The Nal-Family



**Also Not Shown....**  
 Naltrexol (Orexigen)  
 Naloxol (Nektar)

Naloxanazine (Motac)  
 Nalfurafene (Acologix)

Morphine-6-glucuronide (CENES)  
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# The Value of Chemical R&D



## Oxycodone API

- Conversion efficiency increased by **10%**
- Overall right-first-time in production increased by **5%**
- Plant occupancy reduced by **25%**

Standard costs **reduced by 7%** from 2013 to 2015

## Tasman Codeine API

- Reduced manufacturing steps by **60%**
- Eliminated reliance on Turkey
- Leveraged Tasmanian Alkaloids

Standard costs **reduced by 36%** from 2013 to 2015