



# 29<sup>th</sup> Annual Piper Jaffray Healthcare Conference

November 29, 2017

# Forward Looking Statements

This presentation and the accompanying oral presentation contain forward-looking statements that are based on our management's current expectations and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including, but not limited to, information concerning our business plans and objectives, potential growth opportunities, product development, regulatory approvals, market potential, efficiencies, competitive position, and industry environment, among other statements.

Forward-looking statements are typically identified by words like "believe," "anticipate," "could," "should," "estimate," "expect," "intend," "plan," "project," "will," "forecast," "budget," "pro forma," and similar terms. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions, future events and other factors including, but not limited to, those related to: our future financial performance, our sales backorders; our expectations regarding the sales and marketing of our products, including our enoxaparin product and our naloxone product; our expectations regarding the integrity of our supply chain for our products, including the risks associated with single-source suppliers; the timing and likelihood of FDA approvals and regulatory actions on our product candidates, the timing for completion of construction at the Company's IMS facility; manufacturing activities and product marketing activities, including utilization of our manufacturing capacity; our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully obtain FDA approvals and commercialize our product candidates; the potential for adverse application of environmental, health and safety and other laws and regulations on our operations; our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as other competitive factors; the potential for our marketed products to be withdrawn due to patient adverse events or deaths, or if we fail to secure FDA approval for products subject to the Prescription Drug Wrap-Up program; our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers; the amount of price concessions or exclusion of suppliers adversely affecting our business; our ability to establish and maintain intellectual property on our products and our ability to successfully defend these in cases of alleged infringement; the implementations of our business strategies for our product candidates and technology; the potential for exposure to product liability claims; our ability to expand internationally; and our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally. Moreover, we operate in highly competitive and rapidly changing environments, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These and other risk factors, which are described in greater detail in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2017, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur as forward-looking statements are inherently susceptible to uncertainty and changes in circumstances as with any projections or forecasts. Moreover, neither we, nor any other person, assume responsibility for the accuracy and completeness of the forward-looking statements. Any forward-looking statements made by us in this presentation speak only as of the date of this presentation, and we undertake no obligation to update any forward-looking statements for any reason after the date of this presentation, except as required by law.

NTD: Additional specifics to be included based on topics to be discussed in presentation

# Company Overview

## Key Highlights

- Headquarters in Rancho Cucamonga, CA
- Founded in 1996
- Over 1,541 employees and 1.6 million square feet of facilities
- Vertically integrated from R&D to clinical trials, manufacturing, marketing and distribution

## Deep Pipeline and Biosimilar Capabilities

- Currently have product candidates that are technically challenging (i.e., technical barriers to entry for competitors)
  - Generic ANDA product candidates
  - Biosimilar product candidates
  - Proprietary product candidates
- Biosimilar capabilities
  - Immunogenicity, characterization of complex molecules, analysis of proteins and peptides

## Commercial Product Portfolio

- Enoxaparin, generic of Lovenox®, with approximately \$59 million in 2016 sales
- 19 other commercial products
  - Indications include: Deep vein thrombosis, adrenocortical insufficiency, narcotic depression, acute opioid overdose, pain management and anesthesia



## Historical Net Revenue



# Fully Integrated Business Model

- Extensive In-House Product Development Capabilities
  - **Product development:** ~277 employees dedicated to R&D
  - **In Vivo**
  - **Clinical research team**
- Fully-Integrated Back-End Manufacturing Capabilities
  - **API**
  - **Starting material**
- Complete Front-End Integration
  - **Marketing**
  - **Distribution**



- Control over quality and compliance throughout the product development and manufacturing cycle

# Portfolio and Pipeline Overview

# Focus on Products With High Technical Barriers

**Products with large markets  
and technical barriers to entry  
with a focus on generic  
injectable and inhalation**

## Barriers to Entry

- Scarcity of API / raw materials require unique synthetic capabilities
- Complex / biochemical molecules needing characterization and immunogenicity studies
- Difficult or complex manufacturing process
- Proprietary drug delivery technologies
- Biosimilars and new chemical entities with significant potential markets
- Improve formulations of existing drugs
- Relationships with GPOs and retailers

# Commercial Product: Enoxaparin Highlights Amphastar's Strengths

## Overview

- Complex molecule with high barriers to generic entry
  - Only 3 enoxaparin generics ever approved by FDA
- Demonstrates ability to manufacture and commercialize difficult to manufacture products:
  - Cutting-edge characterization technology
  - Immunogenicity studies
  - Paragraph IV and other patent litigation
- Vertical integration reduces cost structure and improves quality control
  - Manufacture API at IMS
  - R&D development, scale up, bioequivalence study, manufacturing, marketing and distribution (non-retail)
  - ANP pending FDA qualification as provider of semi-purified heparin

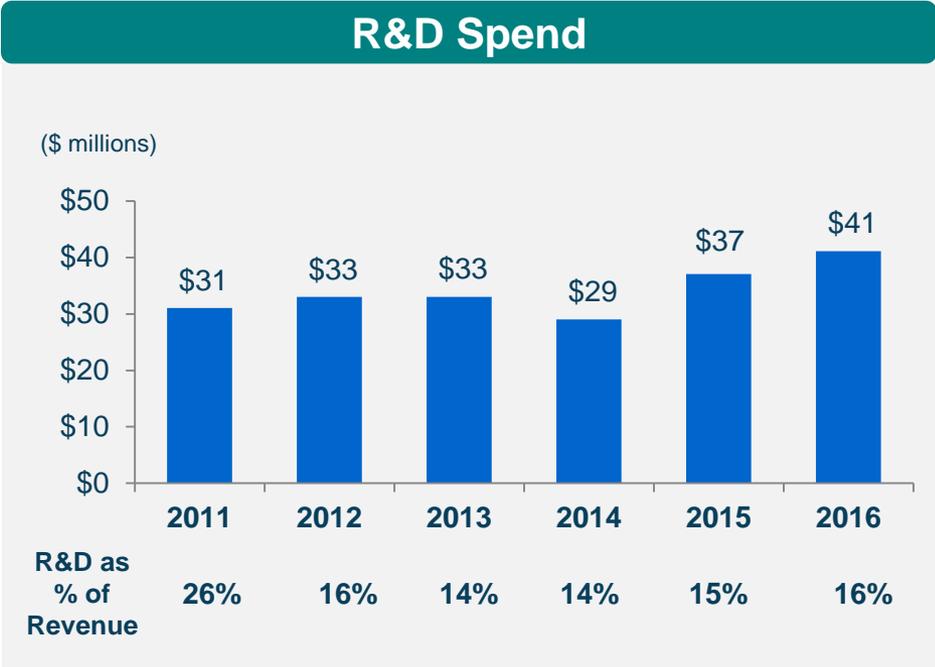
## Manufacturing Process

- 1 ■ ANP heparin filed
- 2 ■ IMS converts heparin to enoxaparin API
- 3 ■ Amphastar compounds, fills, packages and ships enoxaparin



# Focused on Research and Development Investment

- Strategic focus to make substantial R&D investments to expand our product portfolio and grow our business
- Leveraging technical capabilities and/or identify and develop high-margin opportunities
- We believe our emphasis and investment in R&D differentiates us from our competitors as our focus is on the long-term growth of our company
- We have 277 employees dedicated to R&D



# Generic Pipeline - ANDA

Pipeline						
16 Product Candidates						
Delivery Technology	Therapeutic Area	Characterization	Immunogenicity	Particle-Engineering	Sustained-Release	Peptide and Protein Technology
Injectable	Endocrinology	✓	✓		✓	✓
Injectable	Hematology	✓				
Injectable	Reproductive System	✓			✓	
Injectable	Other	✓				
Inhalation	Respiratory	✓		✓		

- Pipeline reflects strategy of developing products with technical barriers
  - Limited competition
  - Tend to have higher margins
- Five filed ANDAs with IMS\* sales of over \$0.8 Billion
- Five Injectable ANDAs in development targeting products with IMS Sales of over \$1.0 Billion
- Six Inhalation ANDAs in development targeting products with IMS Sales of over \$10 Billion



# Generic Pipeline – Biosimilar

Pipeline						
<u>3 Product Candidates</u>						
Delivery Technology	Therapeutic Area	Characterization	Immunogenicity	Particle-Engineering	Sustained-Release	Peptide and Protein Technology
Injectable	Endocrinology	✓	✓			✓

- Pipeline reflects strategy of developing products with technical barriers
  - Limited competition
  - Tend to have higher margins
- Injectable Biosimilars in development targeting products with IMS Sales of over \$15 Billion
- Utilize insulin from our AFP facility

# Proprietary Pipeline

## Pipeline

### 6 Proprietary Product Candidates

Candidates	Indication	Delivery	Status	Characterization	Immunogenicity	Particle-Engineering	Sustained-Release	Peptide and Protein Technology
Primatene® Mist HFA	Asthma	MDI	Received CRL Dec. 2016			✓		
Albuterol DPI	Asthma	DPI	Phase II B			✓		
Naloxone Intranasal	Critical Care	Nasal	Received CRL Feb. 2017					

- 3 Proprietary products are in early stage development

# Disclosed Pipeline: Primatene<sup>®</sup> Mist

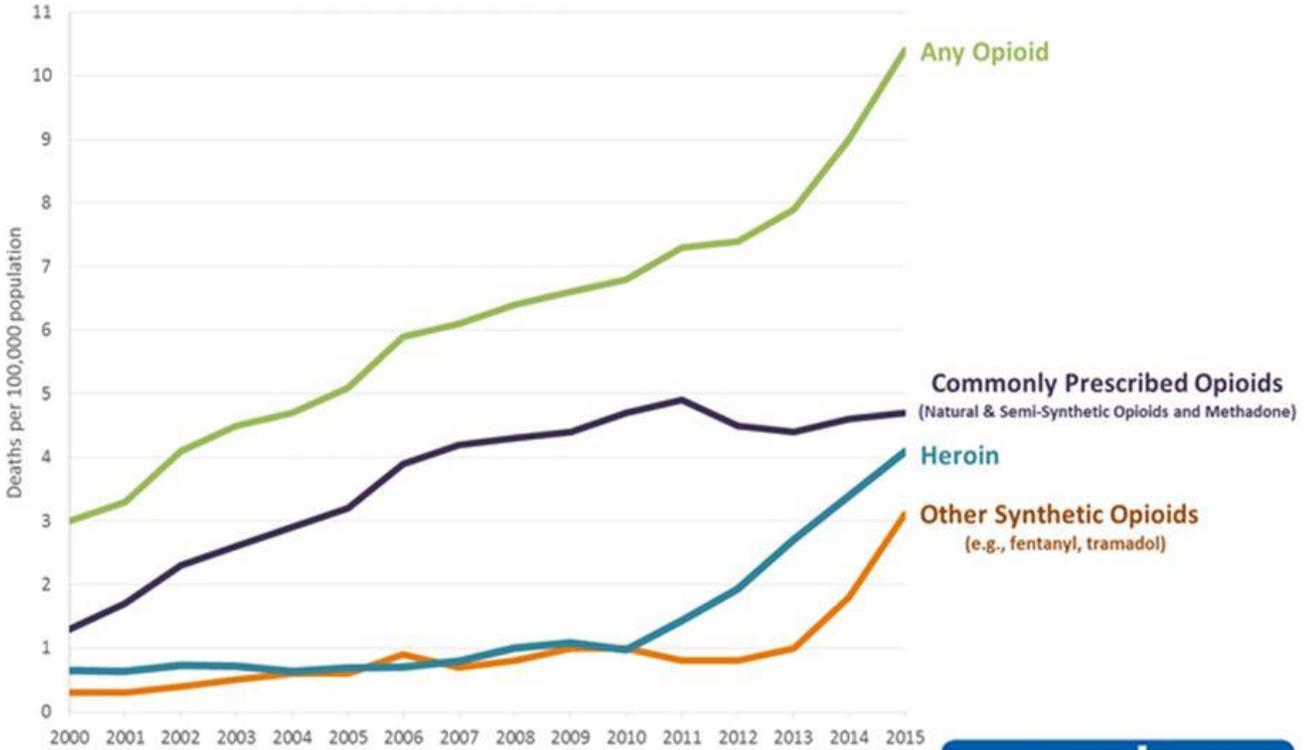
## Overview

- Primatene<sup>®</sup> Mist, a proprietary and patent protected over-the-counter epinephrine inhalation product candidate, is intended for the temporary relief of mild symptoms of intermittent asthma
- Acquired the trade name, Primatene<sup>®</sup>, in 2008
- Company reformulated Primatene<sup>®</sup> Mist using HFA as a propellant and submitted an NDA in 2013
- In February 2014, the FDA's advisory committee voted that data supported efficacy, but that safety had not been established for OTC use
- Received complete response letter (CRL) from the FDA in May 2014, which asked for additional data, label revisions and follow-up studies to support consumers' ability to correctly use the product in the OTC setting
- The Company conducted label comprehension studies and behavioral studies
- The Company resubmitted its application in June 2016 and received a CRL in December 2016
- The Company submitted the protocol, for what it believes is the final human factor study, to the FDA



# Naloxone Opportunity

### Overdose Deaths Involving Opioids, United States, 2000-2015



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. <https://wonder.cdc.gov/>.

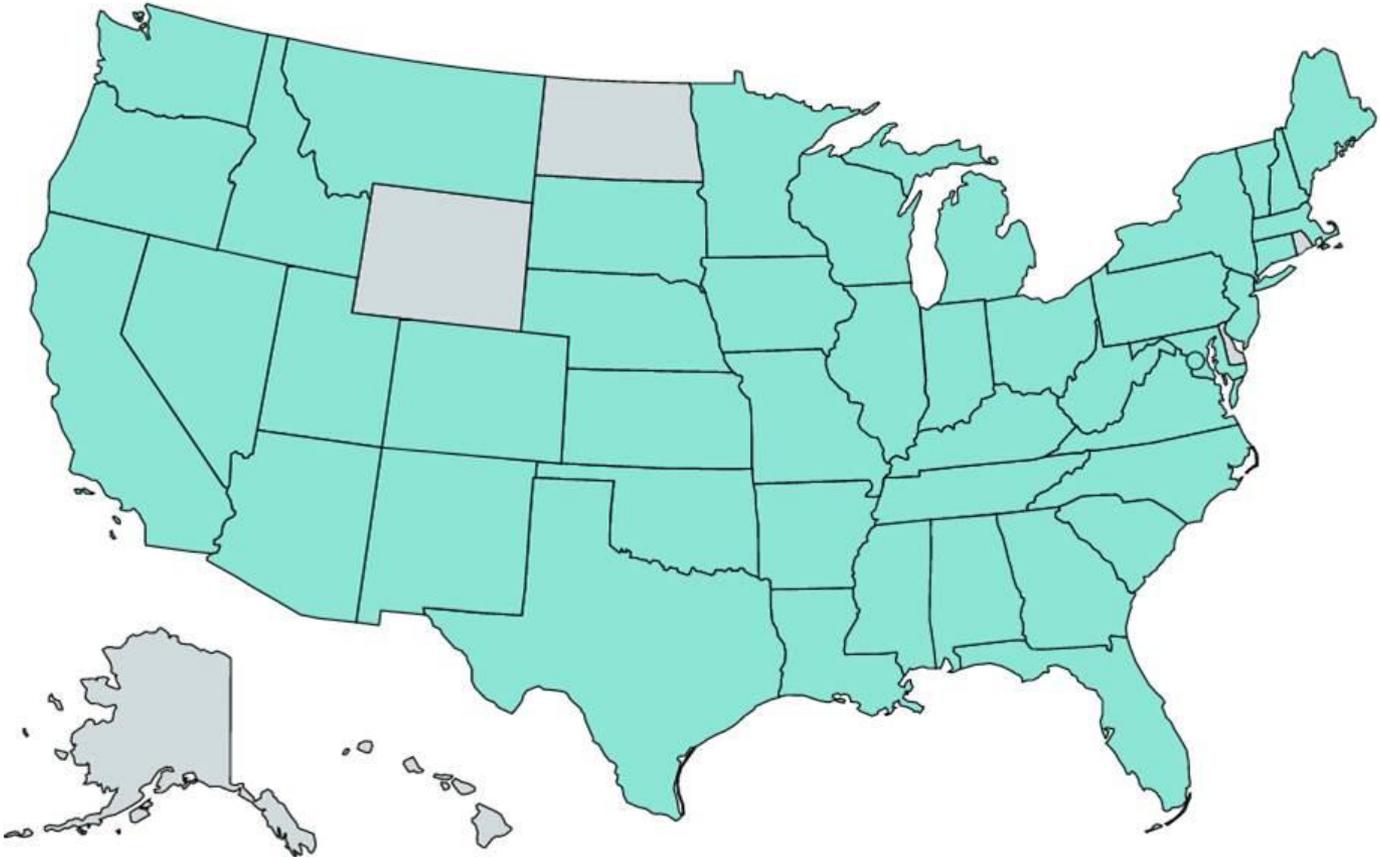


<http://www.cdc.gov/homeandcommunity/recreational-safety/overdose/facts.html>



# Naloxone Opportunity

States with Over-the-Counter Naloxone Access



■ States with OTC naloxone access

# Other Commercial Products

- Diverse core commercial product base of 16 injectable or topical products including Enoxaparin, Cortrosyn® and Lidocaine Jelly
- Key products include:
  - Atropine
  - Epinephrine
  - Ketorolac
  - Lidocaine
  - Lorazepam
  - Morphine
  - Naloxone
  - Procainamide
  - Vitamin K
- Historically, generated consistent revenues and cash flow



# Launch Update

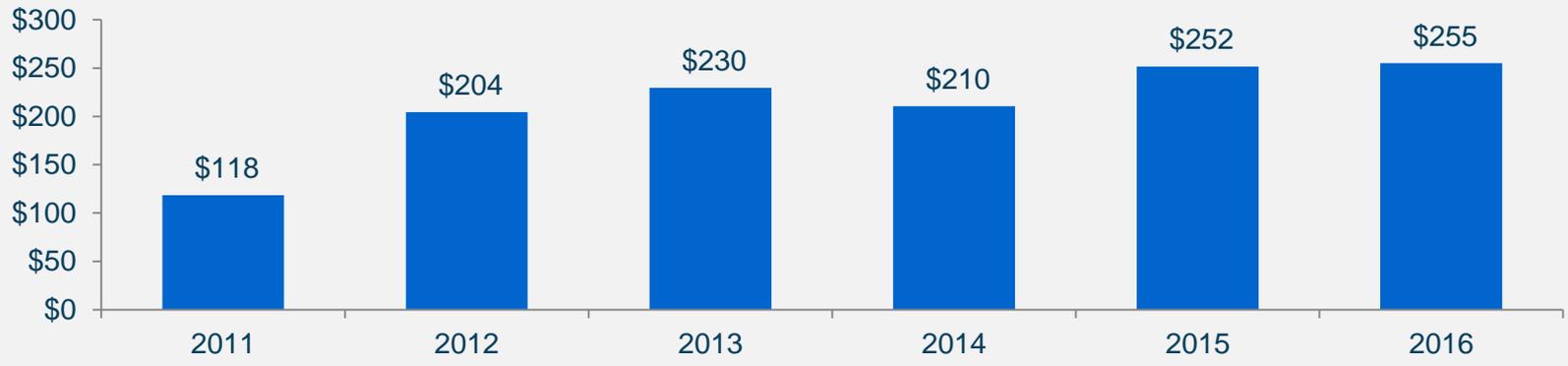
- Ketorolac launched March 2016
- Procainamide launched January 2017
- Neostigmine launch planned November/December 2017
- IMS UK products launch planned 2018

# Financial Overview

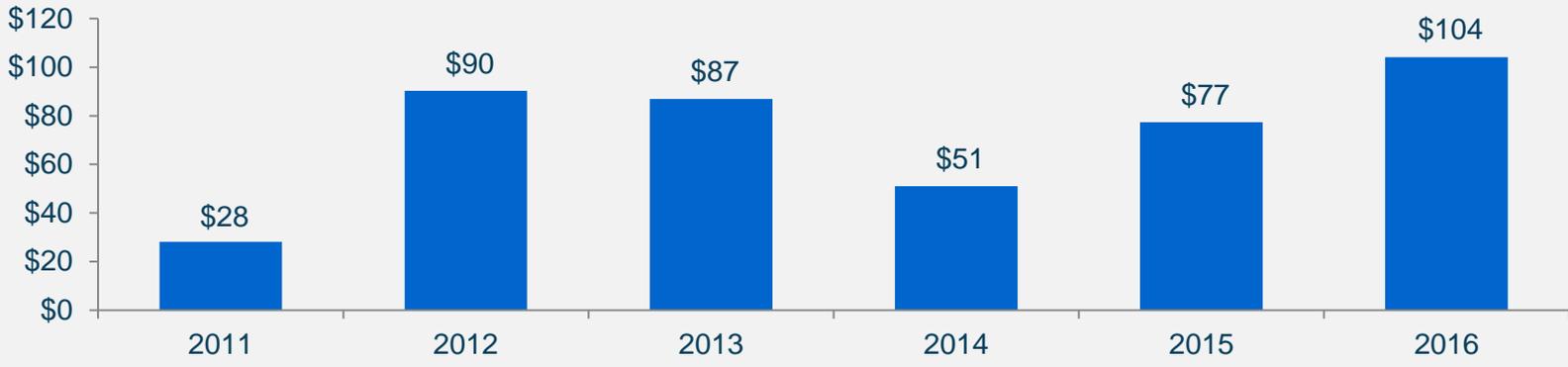
# Historical Financial Performance

(\$ in millions)

## Historical Net Revenue



## Historical Gross Profit

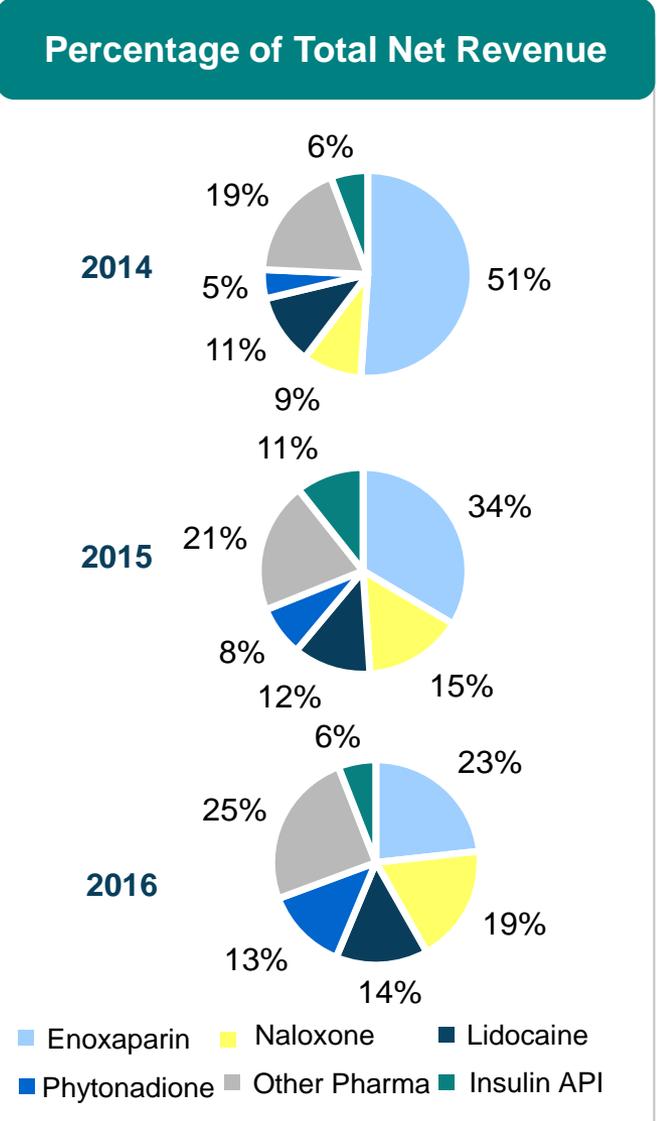


# Historical Financial Statements

(\$ 000s)	Consolidated Statements of Operation			
	Year Ended December 31,			
	2013	2014	2015	2016
<b>Net Revenues</b>	\$ 229,681	\$ 210,461	\$ 251,519	\$ 255,165
Cost of revenues	142,725	159,205	174,172	150,976
<b>Gross profit</b>	86,956	51,256	77,347	104,189
<b>Operating expenses:</b>				
Selling, distribution and marketing	5,349	5,564	5,470	5,466
General and administrative	30,972	34,809	41,504	41,832
Research and development	33,145	28,866	37,271	41,199
<b>Total operating expenses</b>	69,466	69,239	84,245	88,497
<b>Income (loss) from operations</b>	17,490	(17,983)	(6,898)	15,692
<b>Non-operating expenses</b>				
Total non-operating expenses	(263)	(165)	(3,466)	(746)
<b>Income (loss) before income taxes</b>	17,227	(18,148)	(10,364)	14,946
Income tax expense (benefit)	5,365	(7,449)	(7,577)	4,414
<b>Net income (loss)</b>	\$ 11,862	\$ (10,699)	\$ (2,787)	\$ 10,532

# Existing Products Provide Strong Base

Products	Net Revenue (\$ Millions)	
	2015	2016
Enoxaparin	\$85	\$59
Naloxone	\$39	\$48
Lidocaine	\$30	\$37
Phytonadione	\$20	\$33
Other Pharma Products	\$51	\$63
Insulin API	\$27	\$15
<b>Total</b>	<b>\$252</b>	<b>\$255</b>



# Investment Highlights

- Specialty pharmaceutical company focused on technically-challenging generic and proprietary injectable and inhalation products
- Strong base business with approximately \$255 million in 2016 revenue and approximately \$104 million in 2016 gross profit
- Robust pipeline of over 20 product candidates in attractive markets
- Advanced technical capabilities and multiple delivery technologies proven through the successful development and launch of enoxaparin
- Vertically integrated infrastructure and technical expertise for products with high barriers to market entry
- Successful track record of company and product acquisitions
- Experienced management team with deep scientific experience