



**Amphastar**

Jefferies London Healthcare Conference  
November 21, 2019

# 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, 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drug delivery technologies, as well as other competitive factors; the potential for our marketed products to be withdrawn due to patient adverse events or deaths, or if we fail to secure FDA approval for products subject to the Prescription Drug Wrap-Up program; our expectations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, 2019, 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: Amphastar Facilities

Vertically integrated from R&D to clinical trials,  
manufacturing, marketing and distribution



IMS  
South El Monte, CA  
U.S.A



Armstrong  
Canton, MA  
U.S.A



Amphastar  
Rancho Cucamonga, CA  
U.S.A



ANP  
Nanjing  
Jiangsu,  
China



NDRC  
Chino, CA  
U.S.A



AFP  
Eragny-sur-Epte,  
France



# Company Overview: Commercial Product Portfolio

- Diverse core of over 20 commercial products
- Injectable and MDI products; including complex, combination products
- Indications include: deep vein thrombosis, asthma, opioid overdose, pain management, anesthesia
  - Enoxaparin
  - Lidocaine Injection and Jelly
  - Vitamin K1
  - Naloxone
  - Primatene<sup>®</sup> Mist
  - Medroxyprogesterone
  - Epinephrine
  - Cortrosyn<sup>®</sup>
- Consistent revenues and cash flow



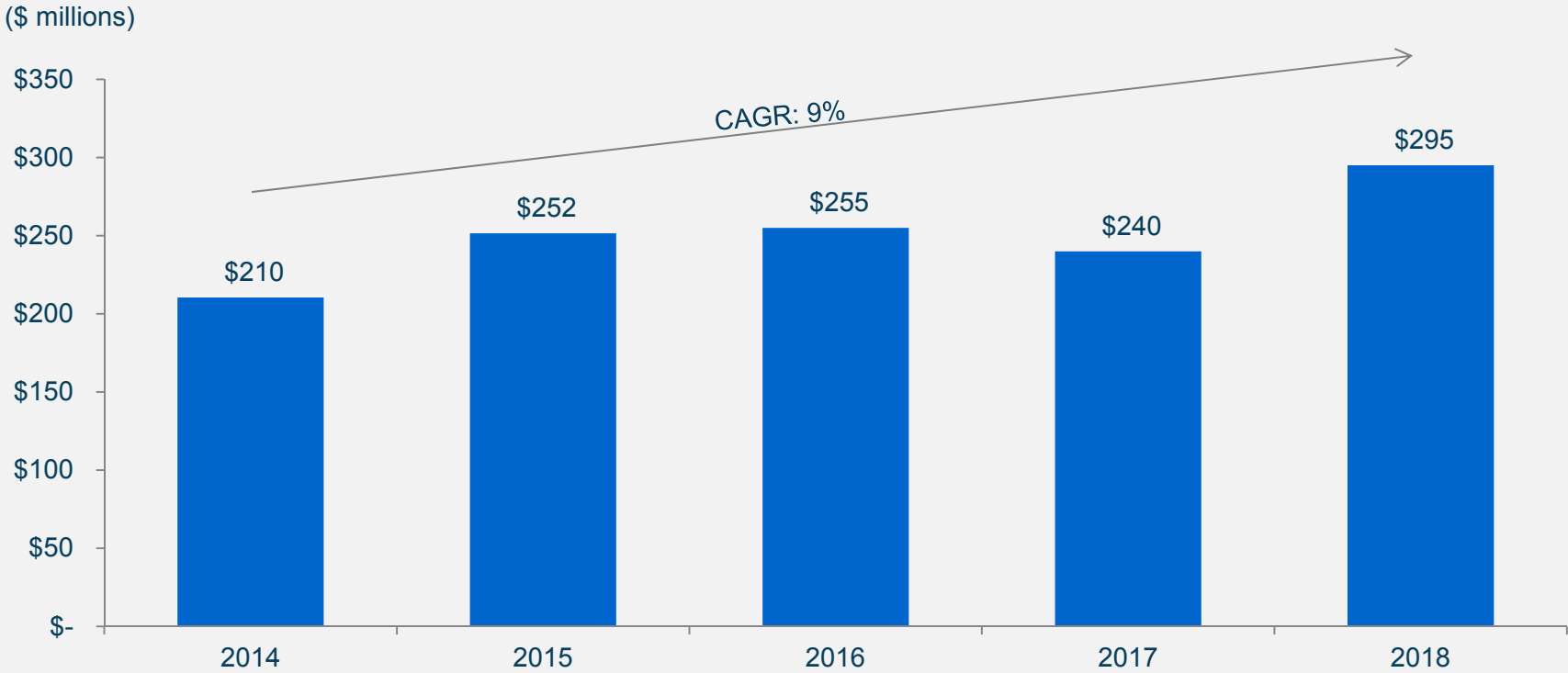
## Company Overview: Capabilities

### 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

# Company Overview: Sales Trend

## Historical Net Revenue



## Focus on Products With High Technical Barriers

### Products with:

- Large markets
- High technical barriers to entry

### Focused on:

- Generic injectables
- Inhalation
- Biosimilars

### High Technical Barriers to Entry

- Scarcity of API requires unique synthetic or rDNA capabilities
- Characterization for complex molecules
- Immunogenicity studies for proteins and complex molecules
- Difficult or complex manufacturing processes
- Proprietary delivery technologies: PFS, MDI, DPI, IN and sustained release
- Particle engineering from nm to  $\mu\text{m}$
- Innovative formulations

# Fully Integrated Business Model

- Extensive in-house product development capabilities
  - Strong product development
  - State-of-the-art instruments
  - Animal studies
  - Clinical research team

- Fully integrated back end manufacturing capabilities
  - API and starting materials
  - Key components

- Complete front end integration
  - Marketing
  - Distribution



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



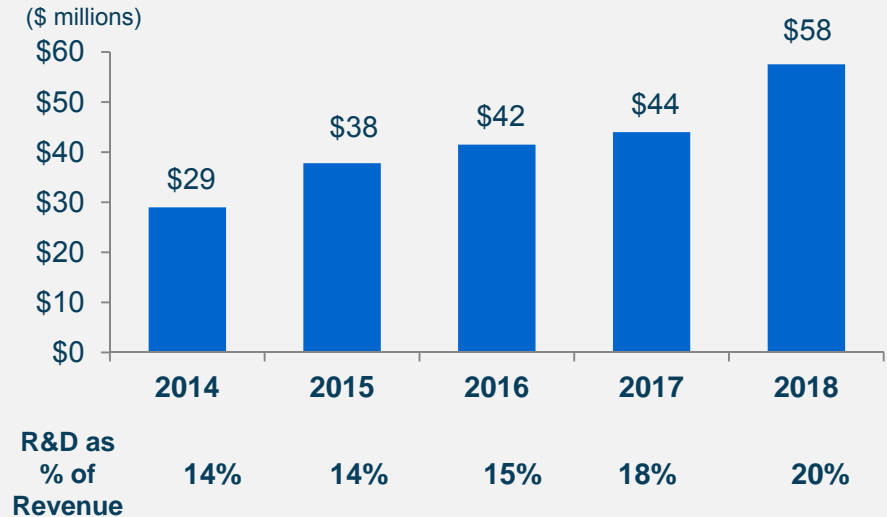
## Amphastar Nanjing Pharmaceuticals (ANP)

- Acquired Nanjing Puyan Pharmaceutical Technology in 2009 for \$0.7 mm; renamed Amphastar Nanjing Pharmaceuticals
- Established to provide APIs and starting materials to Amphastar
- Current portfolio of APIs and starting materials
  - 4 approvals including hyaluronidase and heparin starting materials and APIs for nitroprusside and isoproterenol
  - 14 DMFs
  - 4 additional DMFs in development
- Sale of 42% of business for \$57 mm in 2018
- Proceeds are being used to fund expansion into finished product manufacturing
- ANP plans to begin selling APIs to third parties outside of the U.S.

# 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 over 300 employees dedicated to R&D

## R&D Spend



# Generic Pipeline - ANDA

## Pipeline

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

- Pipeline reflects strategy of developing products with technical barriers
  - Limited competition
  - Higher margins

- **Five filed ANDAs with IQVIA\* sales of approximately \$1.1 Billion**
- Five Injectable ANDAs in development targeting products with IQVIA Sales of approximately \$4 Billion
- Six Inhalation ANDAs in development targeting products with IQVIA Sales of approximately \$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
  - Higher margins
- Injectable biosimilars in development targeting products with IQVIA sales of approximately \$14 Billion
- Utilize insulin from our AFP and ANP facilities

# Proprietary Pipeline

## Pipeline

### 4 Proprietary Product Candidates

Candidates	Indication	Delivery	Status	Characterization	Immunogenicity	Particle-Engineering	Sustained-Release	Peptide and Protein Technology
Naloxone Intranasal	Critical Care	Nasal	Received CRL Feb 2017					
Project 2	Endocrinology	Inj.	505 (b) (2)	✓				✓
Project 3	Critical Care	Nasal	505 (b) (2)	✓				
Project 4	Other	Inj.	505 (b) (2)	✓	✓			

# Primatene<sup>®</sup> Mist History

## Overview

- Primatene<sup>®</sup> Mist, a proprietary and patent protected over-the-counter epinephrine inhalation product, is indicated for the temporary relief of mild symptoms of intermittent asthma
- Purchased U.S. trademark from Wyeth in 2008
- Patented HFA formulation
- Intensive cardiovascular studies >40,000 data points
- Special label design for the OTC setting
- Comprehensive OTC label studies
- Approved in November 2018

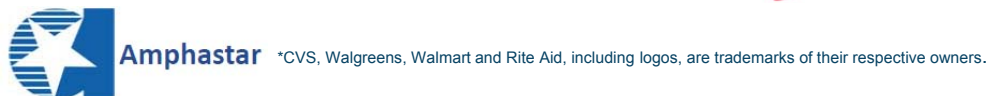


# Primatene® Mist Launch

## Marketing Update

- Launched in December 2018
- Improvements from Primatene® Mist CFC
  - Higher delivery efficiency
  - Dose indicator
  - Aluminum container instead of glass
  - HFA propellant replaces CFC
- Previous peak sales of \$65 million in 2010
- Effective TV advertising campaign began in July 2019
  - Weekly same store sales increased 58% from first week of July to last week of September

Available OTC nationwide at:



## Launch Update

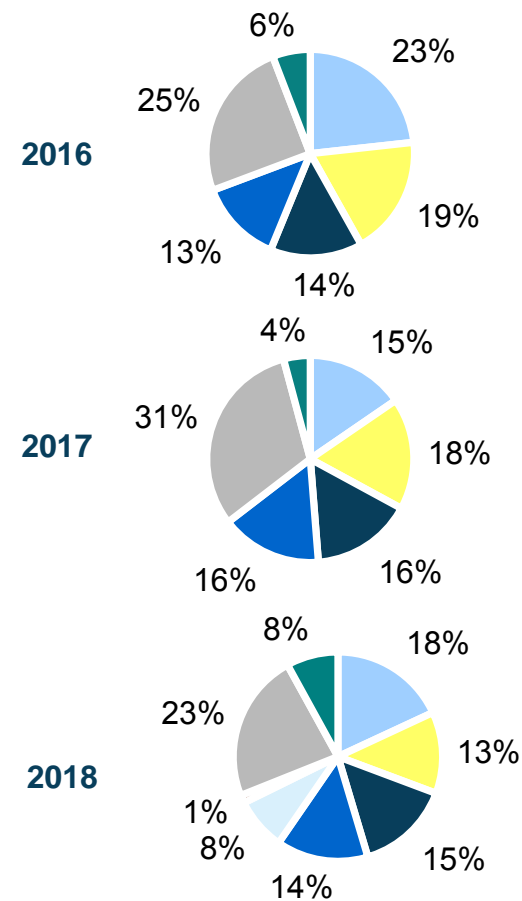
- Neostigmine launched November 2017
- Medroxyprogesterone vials and prefilled syringe launched January/February 2018
- Isoproterenol launched July 2018
- Primatene<sup>®</sup> Mist launched December 2018
- Enoxaparin vials launched November 2019
- IMS UK products launch planned 2020



## Existing Products Provide Strong Base

Products	Net Revenue (\$ Millions)	
	2017	2018
Enoxaparin	\$37	\$53
Lidocaine	\$38	\$43
Vitamin K1	\$38	\$42
Naloxone	\$42	\$37
Medroxyprogesterone (MPA)	\$0	\$24
Primatene® Mist	\$0	\$4
Other Pharma Products	\$75	\$68
Insulin API	\$10	\$24
<b>Total</b>	<b>\$240</b>	<b>\$295</b>

### Percentage of Total Net Revenue



■ Enox.   
 ■ Naloxone   
 ■ Lidocaine   
 ■ Primatene®  
■ Vita K   
 ■ Other Pharma   
 ■ Insulin API   
 ■ MPA

## Investment Highlights

- Specialty pharmaceutical company focused on technically-challenging generic and proprietary injectable and inhalation products
- Strong base business with approximately \$295 million in 2018 revenue and approximately \$107 million in 2018 gross profit
- Robust pipeline of over 20 product candidates in markets with barriers to entry
- Advanced technical capabilities and multiple delivery technologies proven through the successful development and launch of enoxaparin, medroxyprogesterone and Primatene® Mist
- 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