



**AMPHASTAR**  
PHARMACEUTICALS

Raymond James Virtual 2020 Human  
Healthcare Innovation Conference  
June 18, 2020

# 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.

All statements in this presentation that are not historical are forward-looking statements, including, among other things, statements relating to the Company's expectations regarding future financial performance, backlog, sales and marketing of its products, market size and growth, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to its pipeline of product candidates, its share buyback program and other future events, such as the impact of the COVID-19 pandemic and related responses of business and governments to the pandemic on our operations and personnel, and on commercial activity and demand across our business operations and results of operations. These statements are not historical facts but rather are based on Amphastar's historical performance and its current expectations, estimates, and projections regarding Amphastar's business, operations and other similar or related factors. Words such as "may," "might," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expect," "intend," "plan," "project," "believe," "estimate," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Amphastar's control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Amphastar's filings with the Securities and Exchange Commission, including in the Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 16, 2020. In particular, the extent of COVID-19's impact on our business will depend on several factors, including the severity, duration and extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time. You can locate these reports through the Company's website at <http://ir.amphastar.com> and on the SEC's website at [www.sec.gov](http://www.sec.gov). The forward-looking statements in this release speak only as of the date of the release. Amphastar undertakes no obligation to revise or update information in this press release or the conference call referenced above to reflect events or circumstances in the future, even if new information becomes available or if subsequent events cause Amphastar's expectations to change.

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.



# 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

# 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



## 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

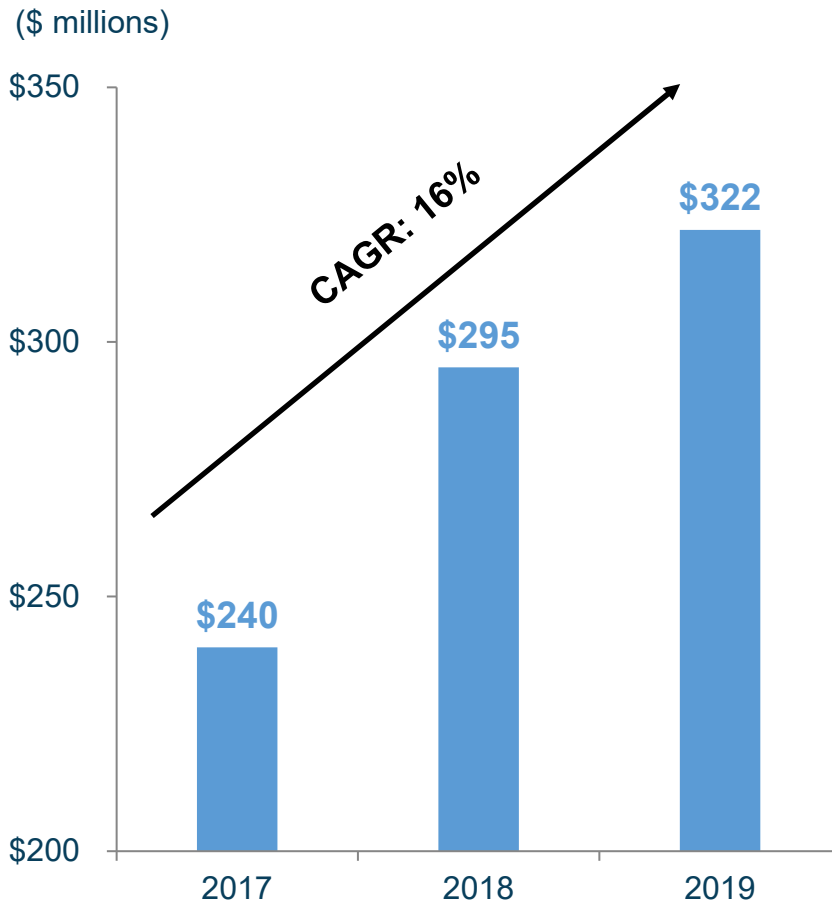
# Company Overview: Commercial Product Portfolio

- 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

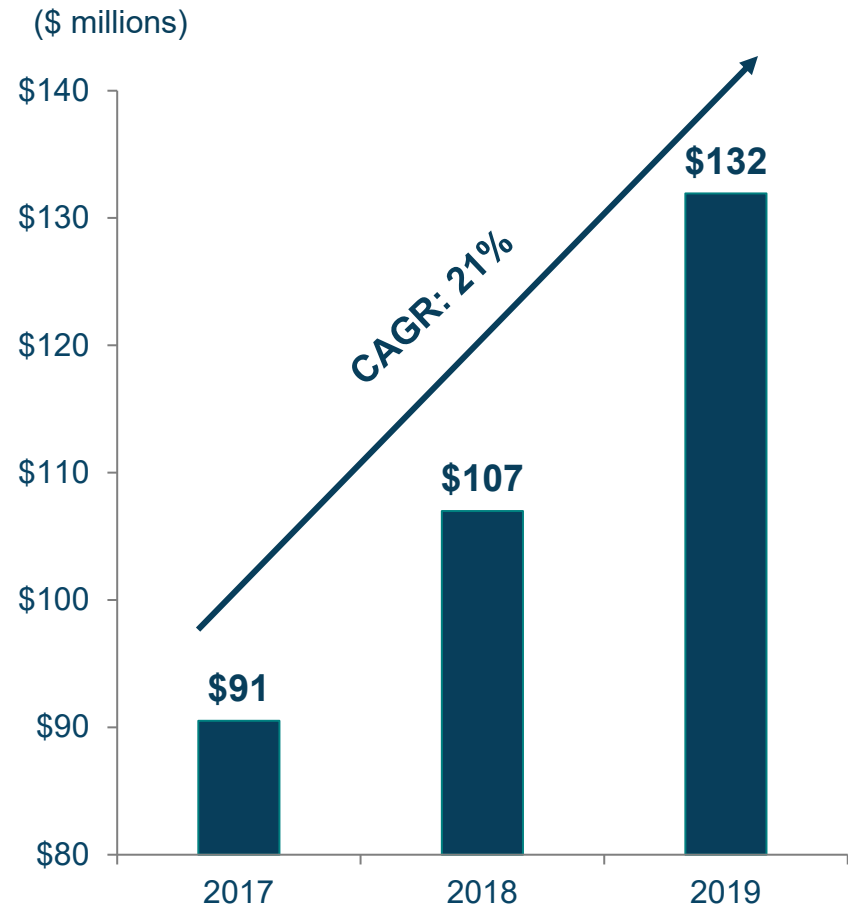


# Company Overview: Sales and Gross Profit Trend

## Historical Net Revenue



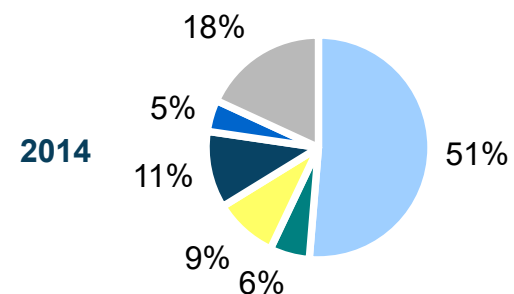
## Historical Gross Profit



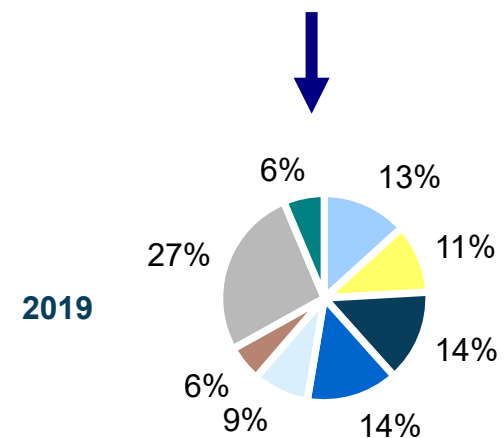
## Existing Products Provide Strong Base

Products	Net Revenue (\$ Millions)	
	2018	2019
Naloxone	\$37	\$35
Lidocaine	\$43	\$46
Vitamin K1	\$42	\$46
Enoxaparin	\$53	\$43
Medroxyprogesterone (MPA)	\$24	\$28
Primatene® Mist	\$4	\$18
Other Pharma Products	\$68	\$86
Insulin API	\$24	\$20
<b>Total</b>	<b>\$295</b>	<b>\$322</b>

### Diversified Revenue



■ Enox. 
 ■ Naloxone 
 ■ Lidocaine 
 ■ Vita K 
 ■ Insulin API 
 ■ Other Pharma



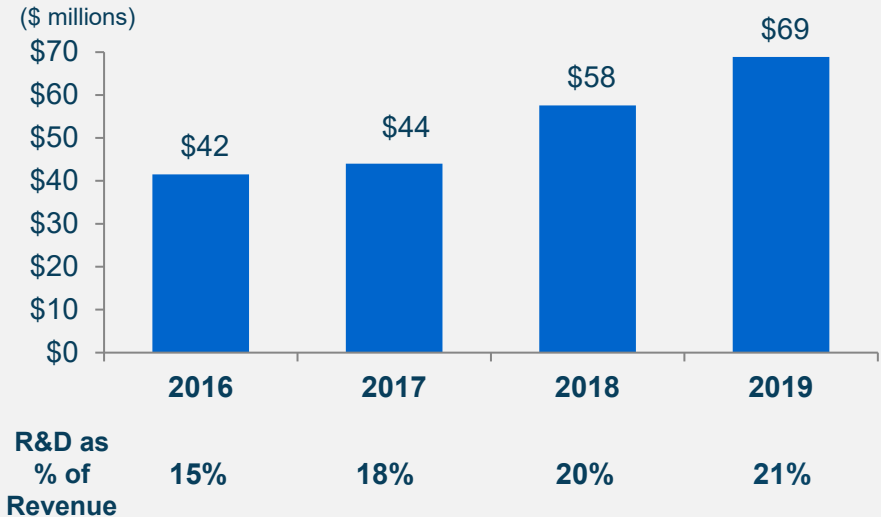
■ Enox. 
 ■ Naloxone 
 ■ Lidocaine 
 ■ Primatene® 
 ■ Vita K 
 ■ Other Pharma 
 ■ Insulin API 
 ■ MPA



# 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

### Technical Capabilities from 14 Product Candidates

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

- **Five filed ANDAs with IQVIA\* sales of approximately \$1.7 Billion**

- Three Injectable ANDAs in development targeting products with IQVIA Sales of approximately \$3 Billion

- Six Inhalation ANDAs in development targeting products with IQVIA Sales of approximately \$9 Billion

- **Filed Pipeline Includes**

- AMP 001 – High technical barrier product with > \$100 mm IQVIA sales and no approved generics
- AMP 002 – High technical barrier product with > \$200 mm IQVIA sales and no approved generics
- Filings for generic Lexiscan® and Vasostriect®



## Generic Pipeline – Biosimilar Insulin

Pipeline						
Technical Capabilities from 3 Product Candidates						
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 \$13 Billion
- Utilize insulin from our AFP and ANP facilities
- Recent draft guidance from FDA
  - Increases possibility of interchangeability
  - Decreases the time and cost of clinical trials



# Proprietary Pipeline

## Pipeline

### Technical Capabilities from 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)	✓	✓			

## Amphastar Nanjing Pharmaceuticals (ANP) Overview

- Acquired Nanjing Puyan Pharmaceutical Technology in 2009 for \$0.7 mm
- Renamed Amphastar Nanjing Pharmaceuticals
- Established to provide APIs and starting materials to Amphastar



# Amphastar Nanjing Pharmaceuticals (ANP) Development

## ■ Current portfolio of APIs and starting materials

- 4 FDA approvals including hyaluronidase and heparin starting materials and APIs for nitroprusside and isoproterenol
- 14 DMFs on file with the FDA
- Several additional DMFs in development

## ■ Sold 42% of ANP ownership for \$57 million in 2018 to fund:

- Manufacturing and Selling API and finished product to the China market



## Primatene<sup>®</sup> Mist History

- Primatene<sup>®</sup> Mist, a proprietary and patent protected over-the-counter epinephrine inhalation product
- The only FDA approved Asthma inhaler available OTC
- Purchased U.S. trademark from Wyeth in 2008
- Intensive cardiovascular studies >40,000 data points
- Special label design for the OTC setting (extensive Human Factors label studies)
- Approved November 2018, launched December 2018



## Primatene® Mist Marketing Update

- 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 and Radio advertising campaign began in July 2019 with national coverage
- Weekly same store sales increased over 250% from the TV advertising launch the first week of July

Available OTC nationwide at:

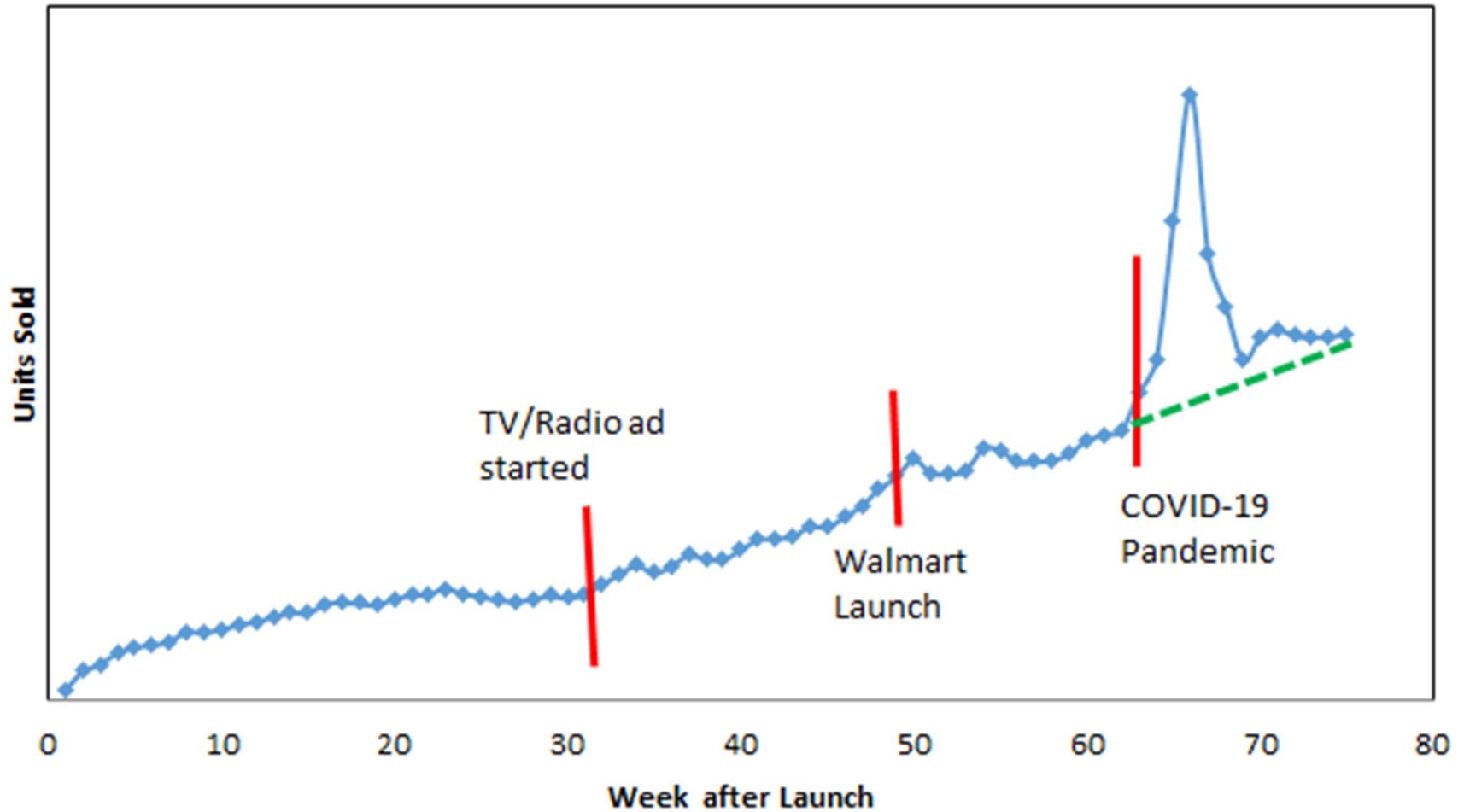


Amphastar \*Amazon, CVS, Walgreens, Walmart, Rite Aid, and Amazon including logos, are trademarks of their respective owners.



# Primatene<sup>®</sup> Mist : In-Store Weekly Sales Trend

## Primatene Mist : In-Store Weekly Sales



## Launch Update

- 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
- Epinephrine multi-dose vials launched May 2020
- IMS UK products launch planned 4Q 2020

## Investment Highlights

- Specialty pharmaceutical company focused on technically-challenging generic and proprietary injectable and inhalation products
- Strong base business with approximately \$322 million in 2019 revenue and approximately \$132 million in 2019 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<sup>®</sup> Mist
- Vertically integrated infrastructure and technical expertise for products with high barriers to market entry
- ANP (Nanjing) development broadens our reach to China market and strengthens our 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