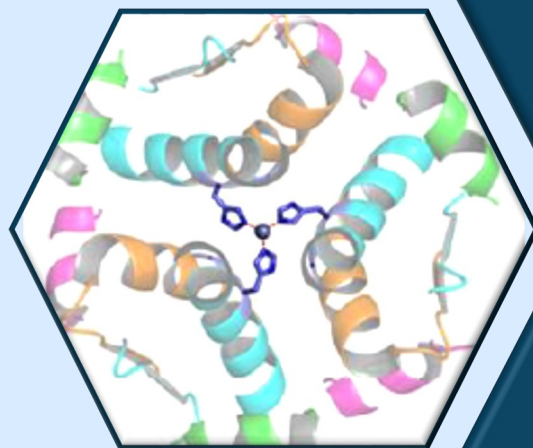




**AMPHASTAR**  
PHARMACEUTICALS



Injectables



Proprietary

Biosimilars

Inhalation

Complex  
Generic

Jefferies London  
Healthcare Conference  
November 2021

# 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 referenced that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance, backlog, sales and marketing of our products, market size and growth, product development, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to our pipeline of product candidates, our share buyback program and other future events, such as the impact of the COVID-19 pandemic including its variants 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 facts but rather are based on Amphastar's historical performance and our current expectations, estimates, and projections regarding our 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 our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 15, 2021. 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 including its variants, 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 our 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 presentation speak only as of the date of the presentation. Amphastar undertakes no obligation to revise or update information or any forward-looking statements in this presentation to reflect events or circumstances in the future, even if new information becomes available or if subsequent events cause our 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.

# Company Framework

# 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

**Product Development**

**API / Key  
Components  
Manufacturing**

**US Based Finished  
Product  
Manufacturing**

**Marketing**

**Distribution**

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

# Focus on Products With High Technical Barriers

## Products with:

- Large markets
- High technical barriers to entry

## Focused on:

- Complex Generics
- Biosimilar
- Interchangeable
- Proprietary

## 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
- Delivery technologies: Injectable, MDI, IN, and sustained release
- Particle engineering from nm to  $\mu\text{m}$
- Innovative formulations
- Large molecule product development
- Difficult or complex manufacturing processes



# 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



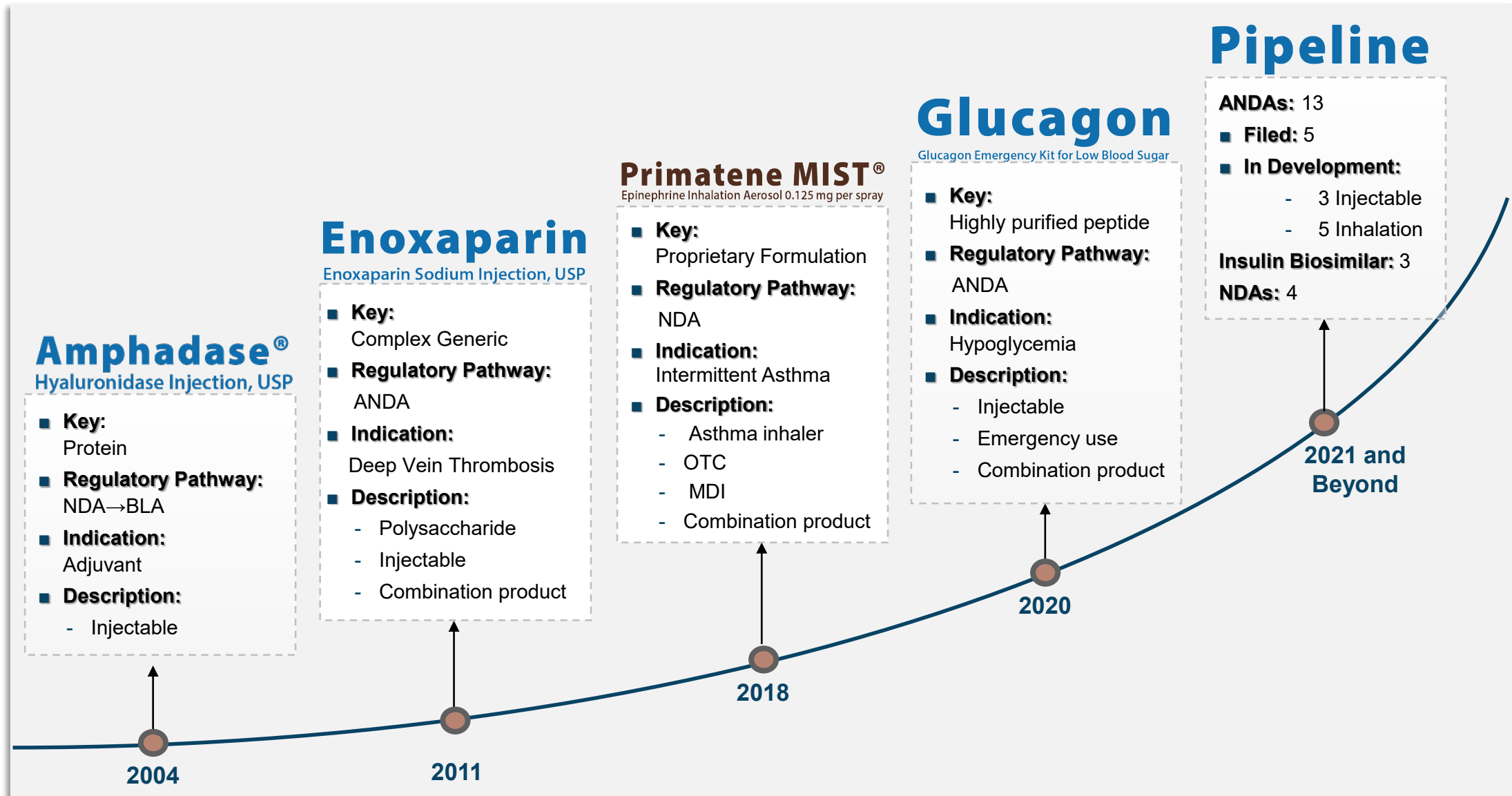
**NDRC**  
Chino, CA  
U.S.A



**AFP**  
Eragny-sur-Epte,  
France



# Milestones of Pipeline Development



# Commercial Product Portfolio

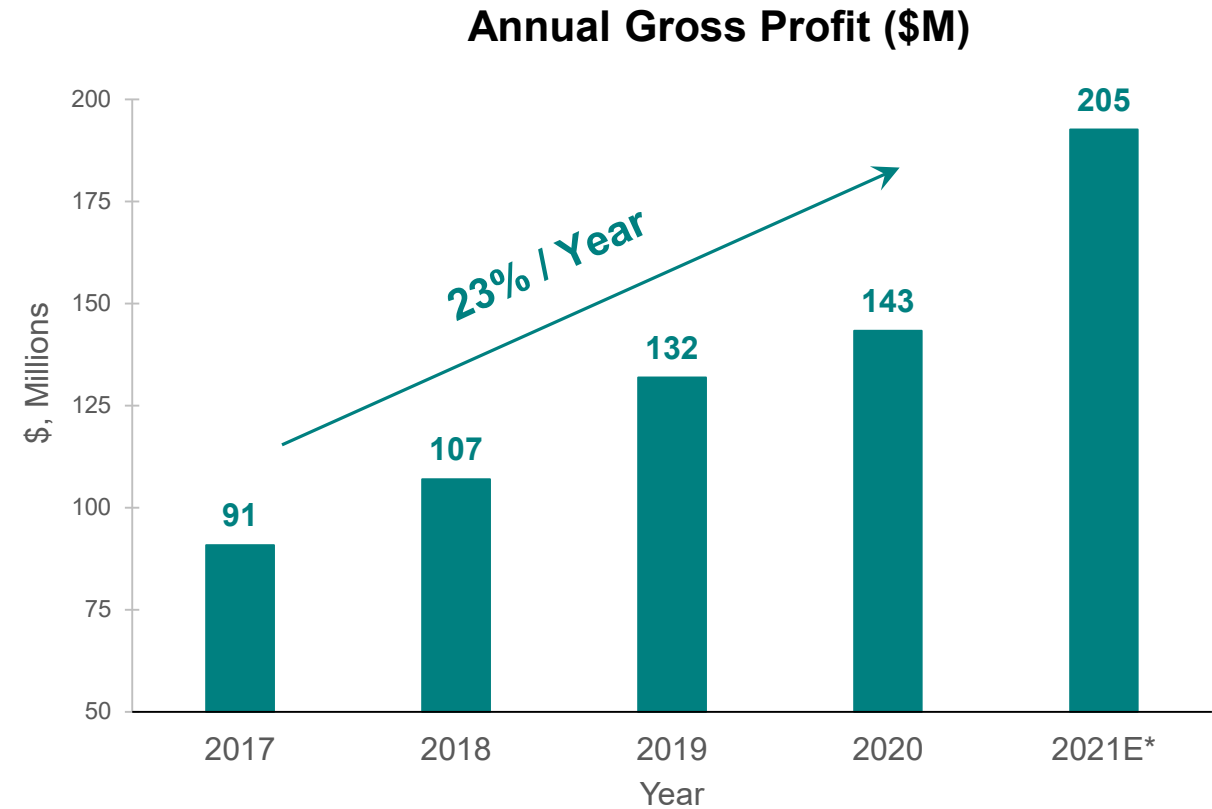
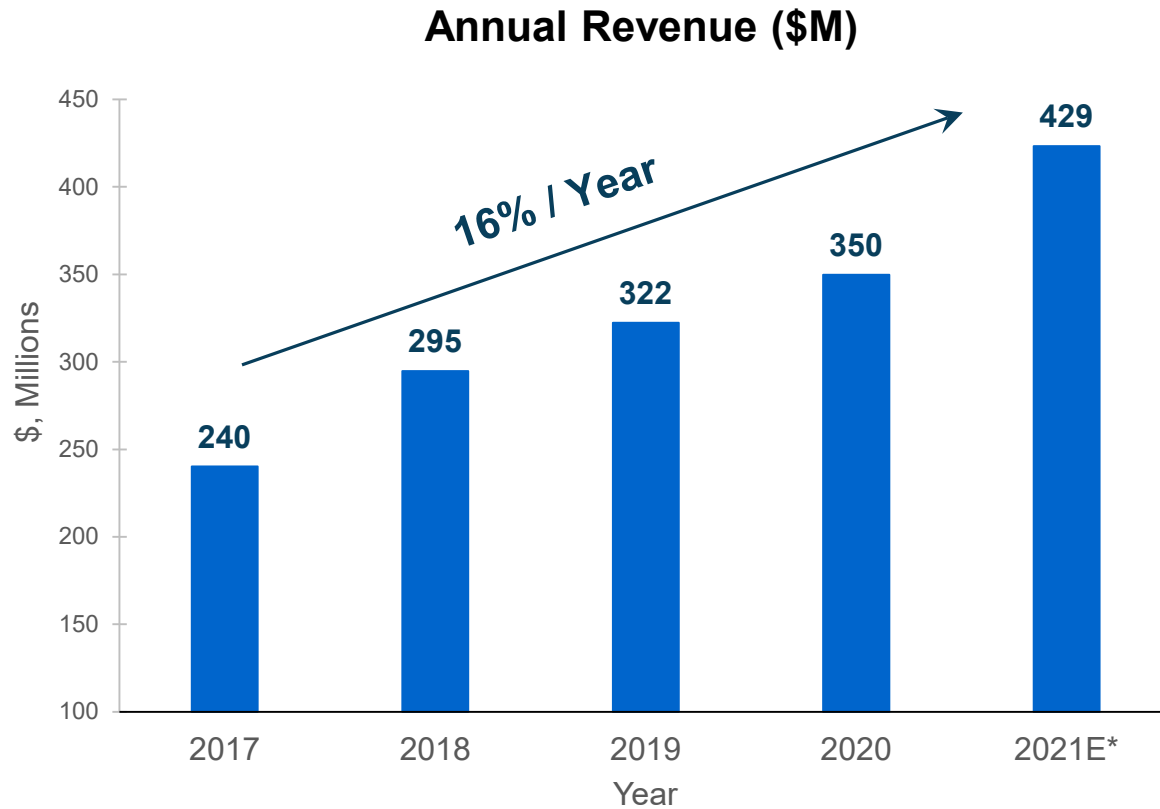
- Diverse core of over 20 commercial products
- Injectable and MDI products; including complex, combination products
- Consistent revenue and cash flow
- Indications include: deep vein thrombosis, asthma, opioid overdose, pain management, anesthesia, and hypoglycemia
  - Enoxaparin
  - Glucagon
  - Lidocaine Injection and Jelly
  - Vitamin K1
  - Naloxone
  - Primatene MIST®
  - Medroxyprogesterone
  - Epinephrine PFS & MDV
  - Cortrosyn®





# Sales and Marketing

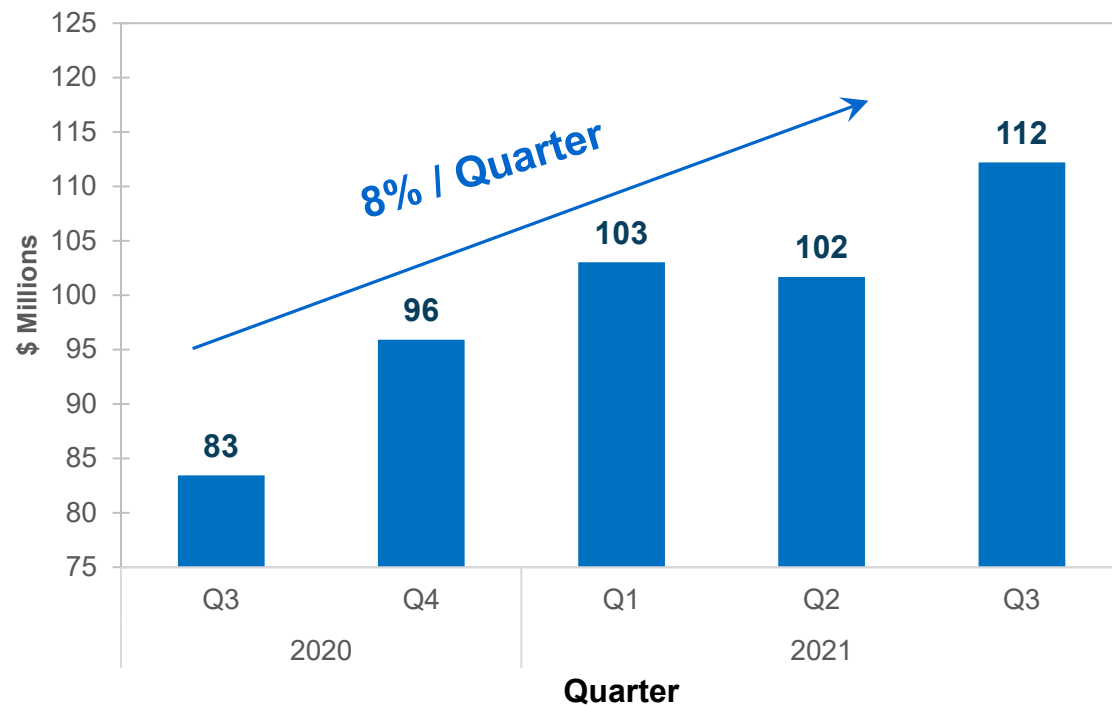
# Sales and Gross Profit Trend



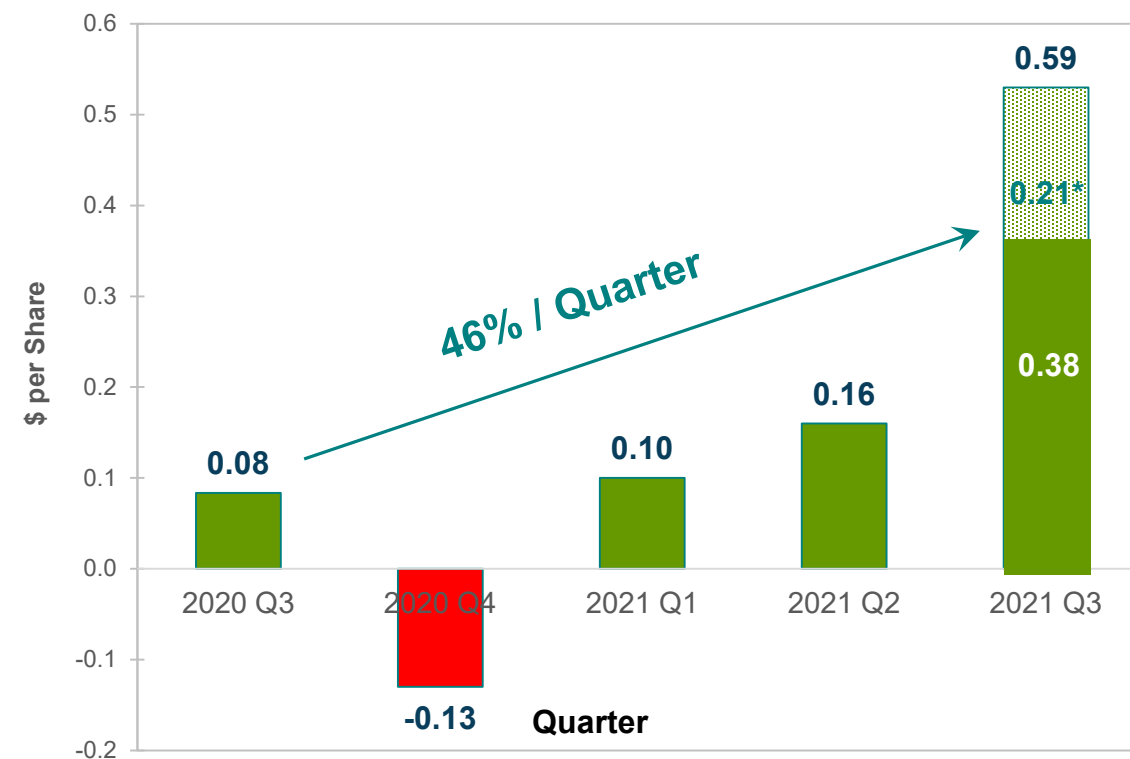
\* Based on consensus estimates

# Recent Quarter Trend: Sales & Net Profit

## Recent Quarterly Revenue (\$M)



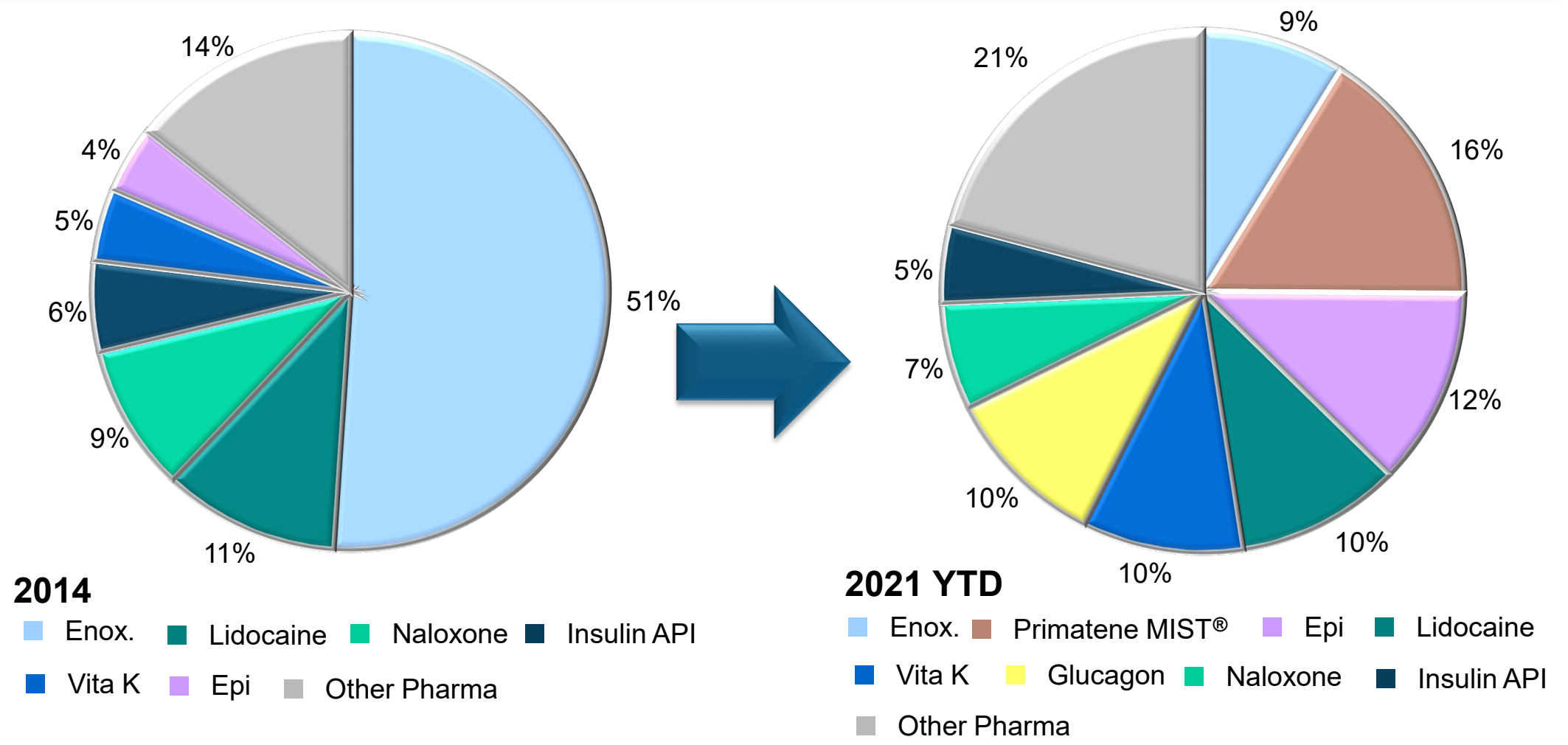
## Recent Quarterly: EPS (\$)



\*One time event; excluded from the calculation of the quarterly growth rate.

# Existing Products Provide Strong Base

## Diversified Revenue



# Primatene MIST®

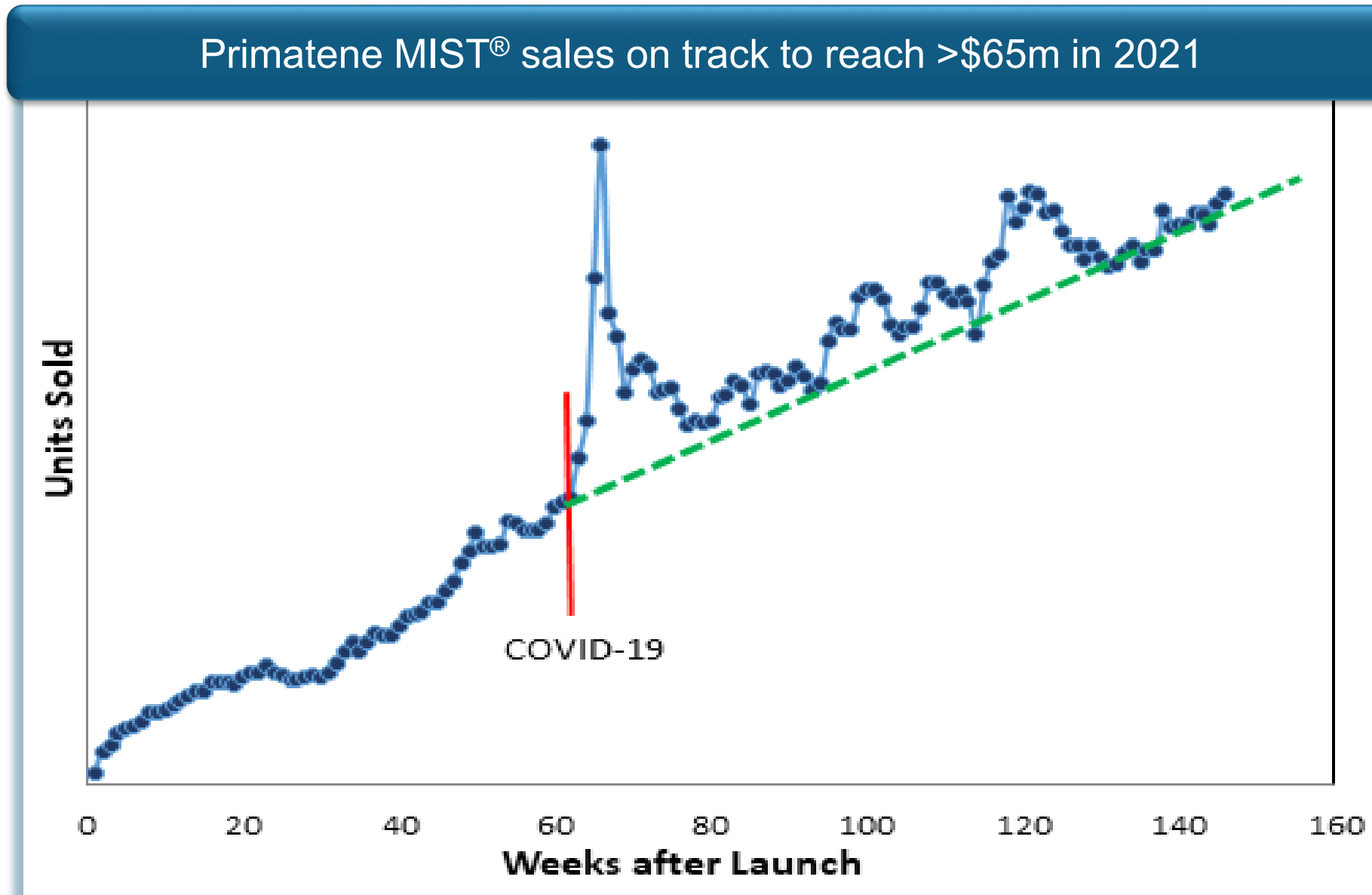
- Primatene MIST®, a proprietary and patent-protected over-the-counter epinephrine inhalation product
- The only FDA approved asthma inhaler available OTC, launched Dec 2018
- Multiple scientific articles were published in support of Primatene MIST®
- Intensive cardiovascular studies >40,000 data points
- US Adult asthma patients: 20 million per CDC\*





# Primatene MIST<sup>®</sup> Sales Trend: In-Store Weekly Sales in UNITS

Primatene MIST<sup>®</sup> sales on track to reach >\$65m in 2021

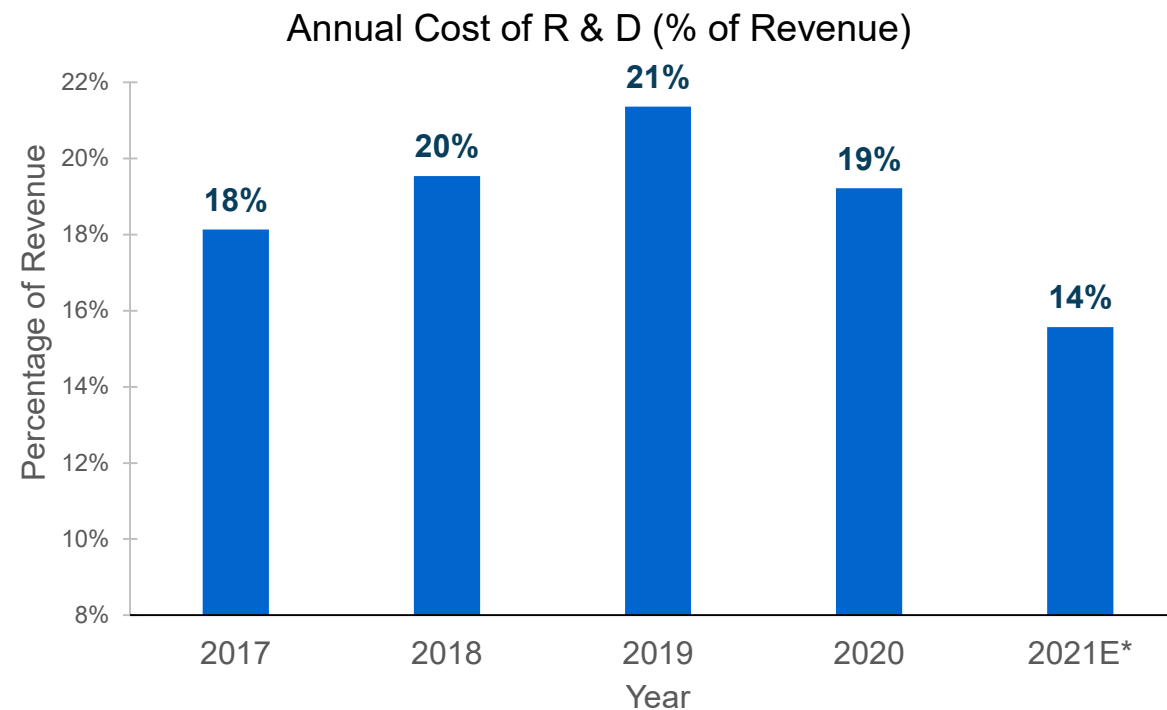


# R&D and Pipeline

# Focused on R&D Investment

- Strategic focus to make substantial R&D investments to expand our product portfolio
- Diverse pipeline development with flexibility and scalability for sourcing API, starting material, and research under our vertically – integrated platform
- Emphasis and investment in R&D differentiates us from our competitors as our focus is on the long-term growth of our company
- Fully covered R&D team from early stage to clinical trial and from laboratory to scale-up

**Self-funded R&D investment of approximately \$280 million in the recent 5 years**



# Amphastar Nanjing Pharmaceuticals (ANP) Overview

- Established to provide APIs and starting materials to Amphastar
- Current portfolio of APIs and starting materials
  - 4 FDA approvals for Amphastar's NDAs/ANDAs
  - 17 DMFs on file with the FDA for Amphastar's pipeline candidates
  - Several additional DMFs in development



# Pipeline – ANDAs with Technical Barriers

## Generic Pipeline, 13 Candidates with Technical Barriers

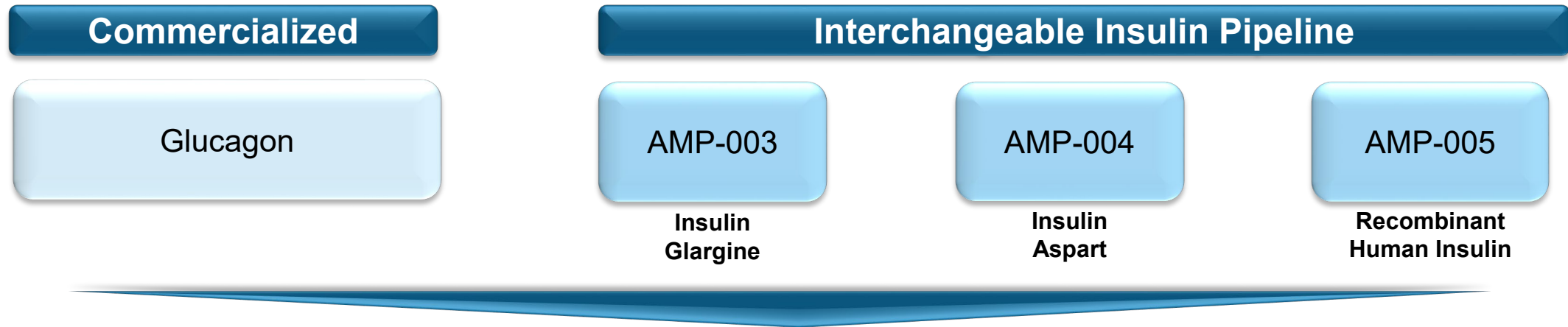
- **Technical platforms to be used:**

Characterization of complex molecules, immunogenicity, peptide and protein product development and production, particle engineering, sustained-release and novel formulation

ANDA Type	Product Code	Current Stage	*IQVIA Sales
Injectable	AMP-002	Filed; GDUFA date Q1 2022	+\$300 Million
	AMP-006	Filed; GDUFA date Q1 2022	+\$50 Million
	AMP-009 (Regadenoson)	Filed; P-IV	+\$600 Million
	AMP-013 (Vasopressin)	Filed; P-IV	+\$800 Million
	AMP-015 (Teriparatide)	Filed; GDUFA date Q2 2022	+\$650 Million
	AMP-018	Development	+\$6.5 Billion
	AMP-020	Development	
	AMP-021	Development	
Inhalation	AMP-007	Stability/clinical trials	+\$8 Billion
	AMP-008	To be filed Q4 2021	
	AMP-016	Stability/clinical trials	
	AMP-017	Stability/clinical trials	
	AMP-022	Development	



# Diabetes Portfolio



- **First and only FDA approved generic Glucagon**
- **Covers the full spectrum of the insulin from rapid to long acting**
- **First IND has been filed**
  - *Clinical program is progressing and on track to file as planned*
- **\$13 Billion in IQVIA sales as of June 2021, ~130 millions of units of both pens and vials**

## Amphastar Factors in Achieving Interchangeability:

- **Demonstrated technological platform to achieve high-purity**
  - *Proven with Hyaluronidase, Enoxaparin and Glucagon approvals*
- **Company's sophisticated characterization technology and achievements of highly – purified peptides (with rDNA origin)**
- **API platform is sourced in-house**
  - *Amphastar France and Amphastar Nanjing*

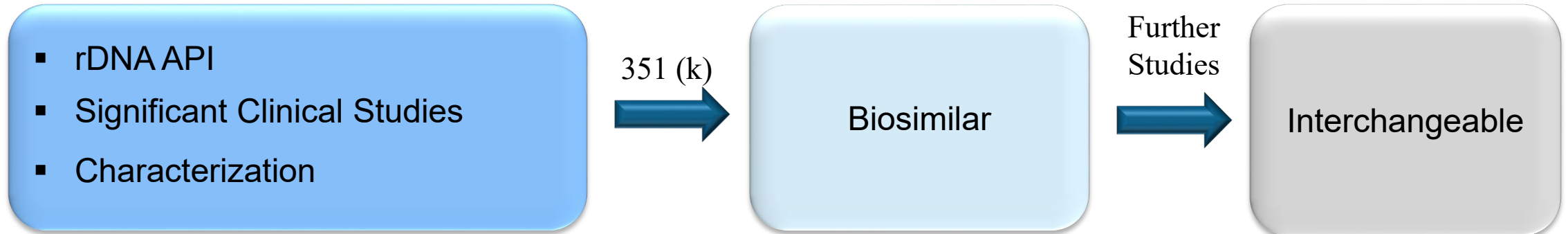
## Favorable FDA Regulatory Pathways / Guidance:

- **FDA Guidance making comparative clinical immunogenicity unnecessary if extended characterization and highly-purified API are both achieved**
  - *Reduces number of clinical trials necessary*
  - *Lowers total cost and time of the clinical program*

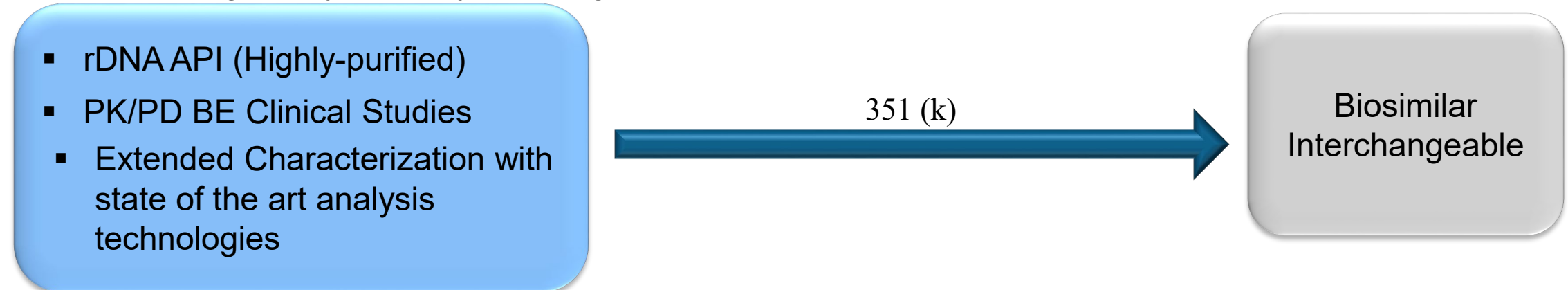
# Current Regulatory Pathways for Interchangeable Biosimilar Insulin

## Regulatory Strategy for Insulin Products: Interchangeability

### A. Recently approved FDA regulatory pathway



### B. Amphastar regulatory pathway with targeted clinical studies



# Pipeline – Proprietary Pipeline, New Drug Applications (NDAs)

Developed under Amphastar: A platform of proven R&D and technological strengths

AMP-012  
Intranasal Naloxone

- Target refiling Q1 2022

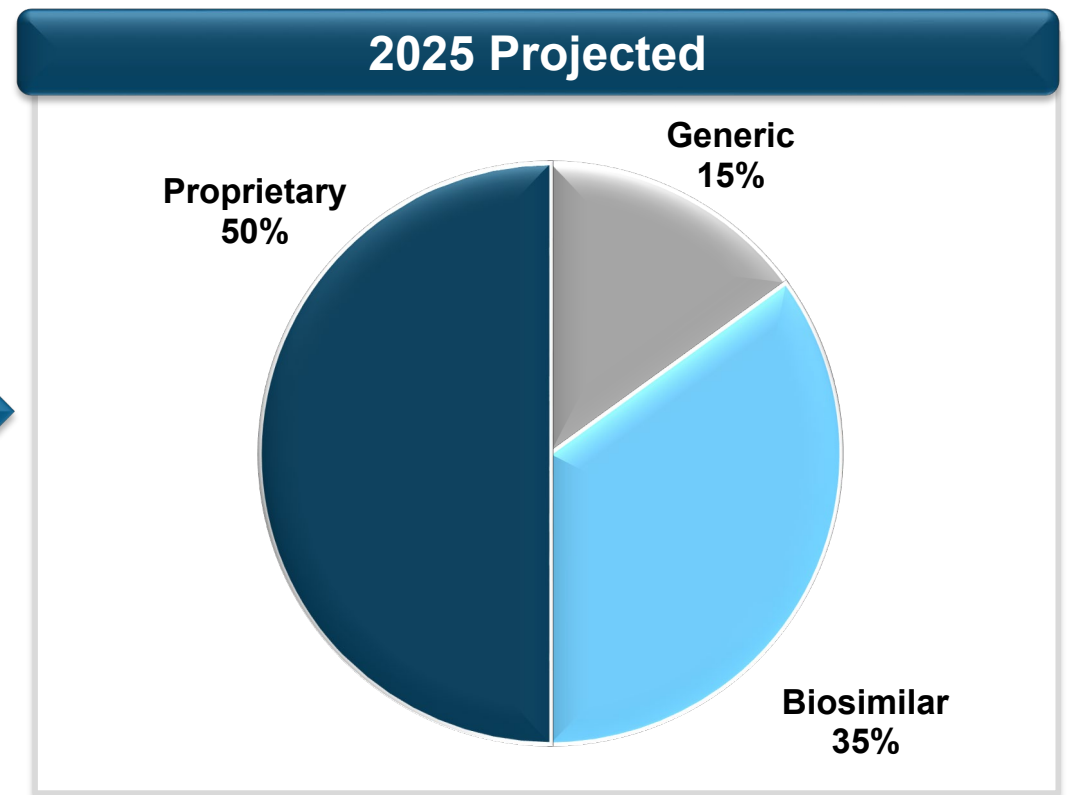
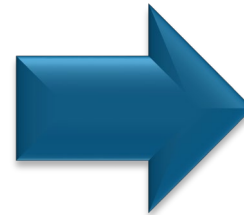
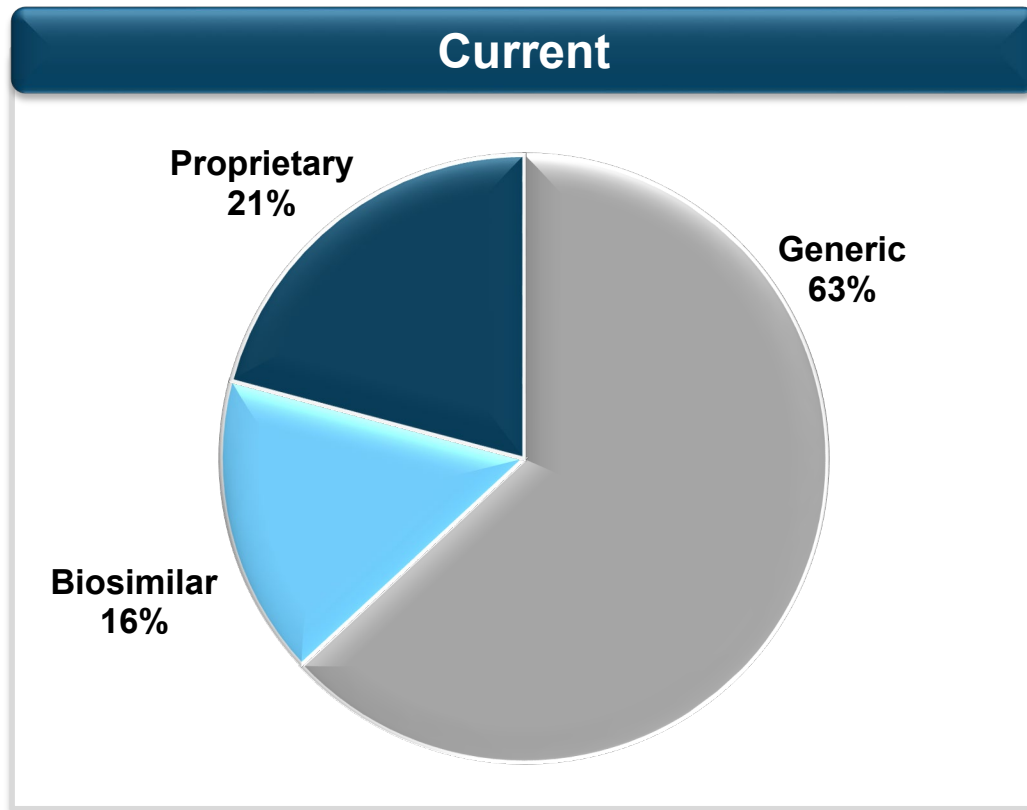
AMP-019  
Intranasal Epinephrine

- Clinical studies progressing well, phase I complete
- Patent Pending

- Two Early stage products

# Pipeline Evolution

Amphastar's pipeline projected to advance with more focus on proprietary and biosimilar products





# Highlights and Catalysts

## Capitalization as of September 30, 2021

(\$ 000s)

Cash, cash equivalents, restricted cash, and short-term investments	\$117,066
Long-term debt, including current portion	\$77,808
Total stockholders' equity	\$430,176
Long-term debt as a percentage of total equity	8.2%

# Growth Drivers in 2021 and Upcoming Milestones

## Key Growth Drivers in 2021

- **Glucagon Injection Kit**
  - *Strong sales since launched in Feb. 2021*
- **Epinephrine multi-dose vials**
  - *Strong year-over-year sales growth*
- **Primatene MIST®**
  - *Nationwide TV, Radio and Digital Advertising driving weekly sales*
  - *Physician sampling program*

## Key Milestones 2021 / 2022

### Filings

- **First Inhalation ANDA filing Q4 2021**
  - *AMP-008*
- **Intranasal Naloxone to be refiled in Q1 2022**

### Expected Approvals

- **AMP-002 GDUFA date Q1 2022**
- **AMP-006 GDUFA date Q1 2022**
- **AMP-015 (Teriparatide) GDUFA date in Q2 2022**
  - *+\$650 million addressable market*