



2021 Wells Fargo Virtual Healthcare Conference  
September 9, 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.



# 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

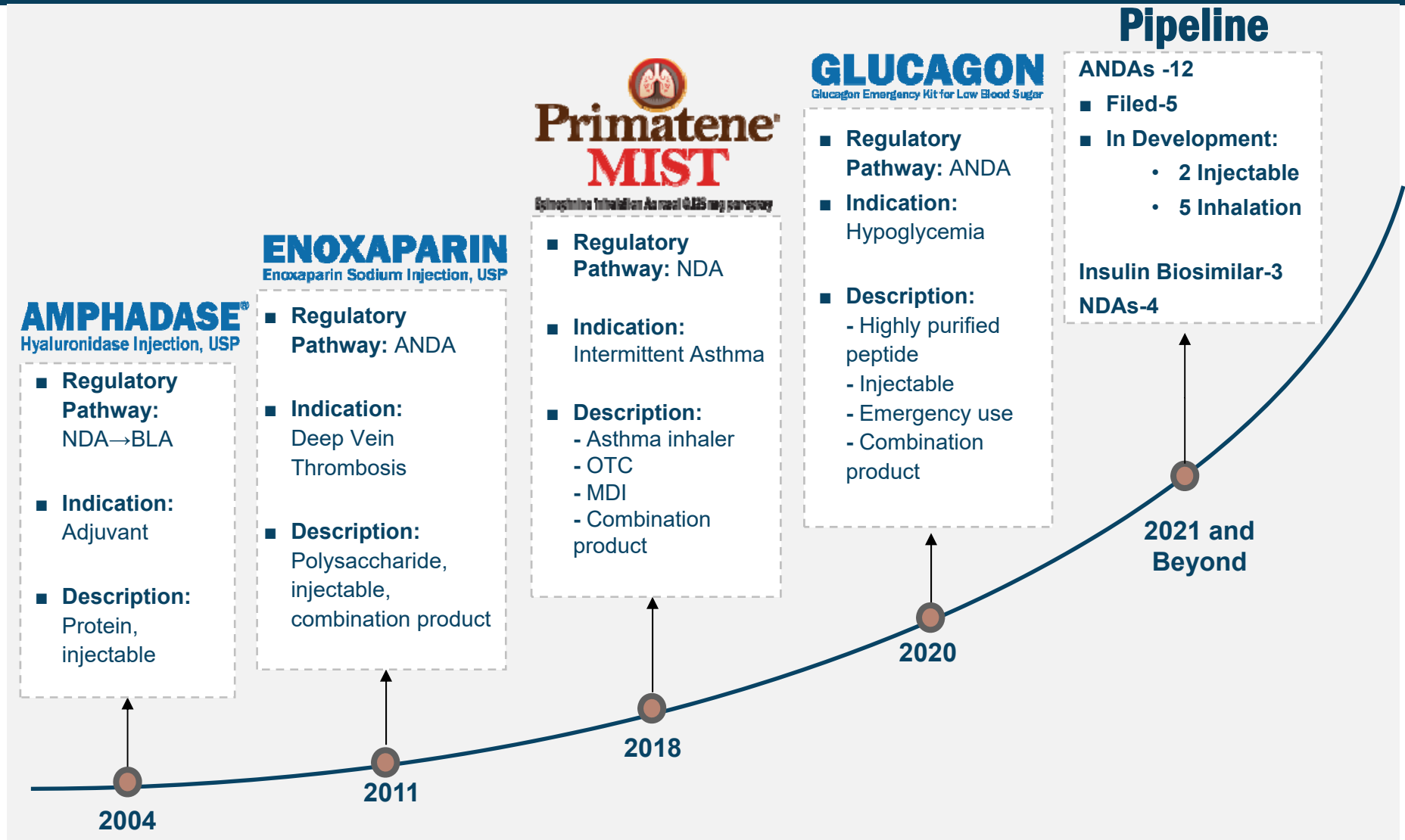
### Focused on:

- Injectables
- Inhalation
- Biosimilar
- Interchangeable

### 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, IN, and sustained release
- Particle engineering from nm to  $\mu\text{m}$
- Innovative formulations

# Milestones of Pipeline Development



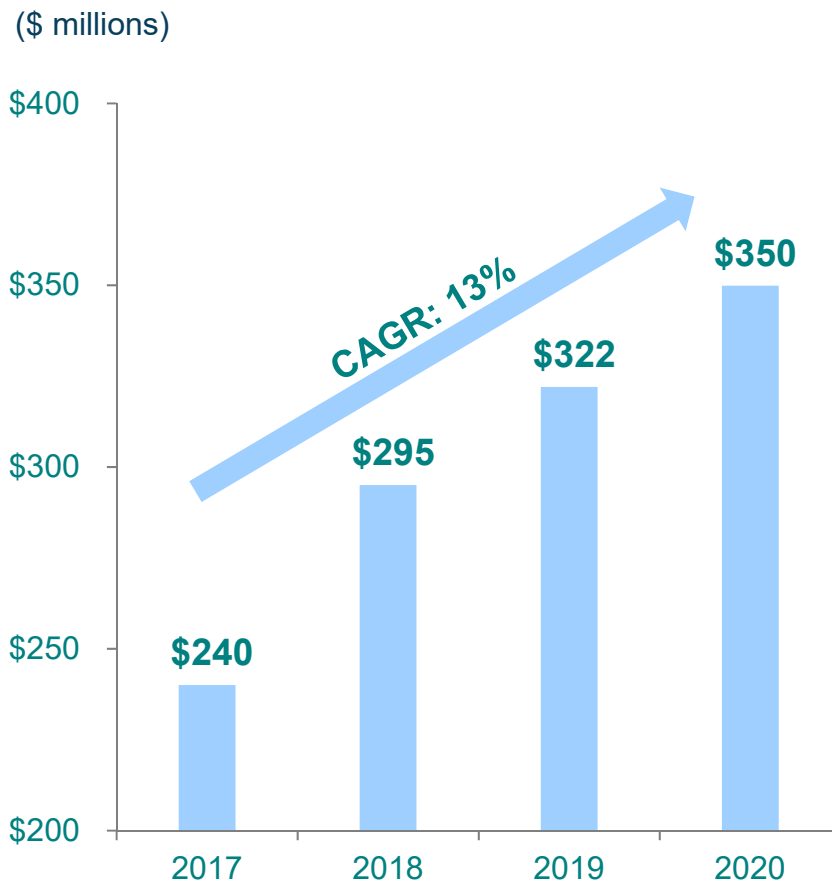
# Company Overview: Commercial Product Portfolio

- 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, and hypoglycemia
  - Enoxaparin
  - Glucagon
  - Lidocaine Injection and Jelly
  - Vitamin K1
  - Naloxone
  - Primatene MIST®
  - Medroxyprogesterone
  - Epinephrine
  - Cortrosyn®
- Consistent revenues and cash flow

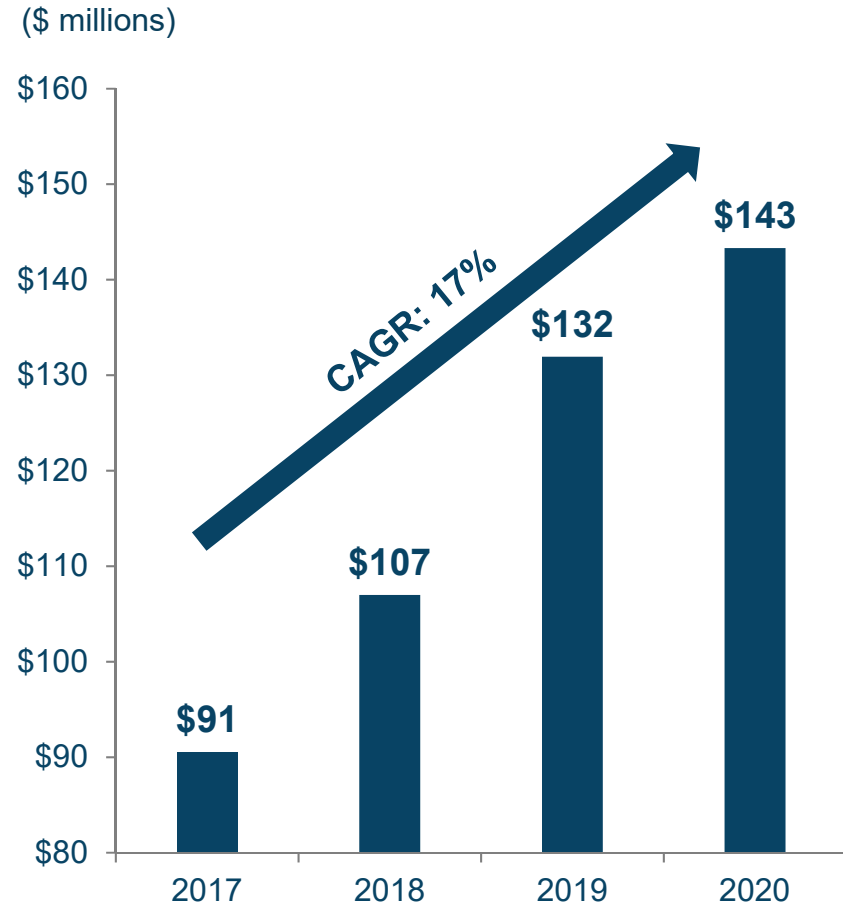


# Company Overview: Sales and Gross Profit Trend

## Historical Net Revenue



## Historical Gross Profit

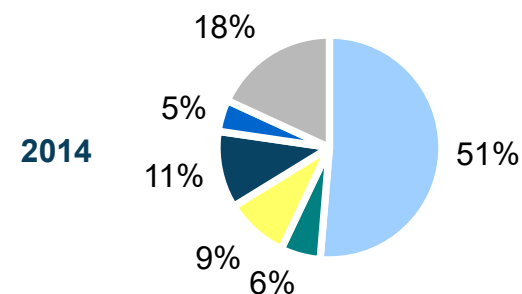




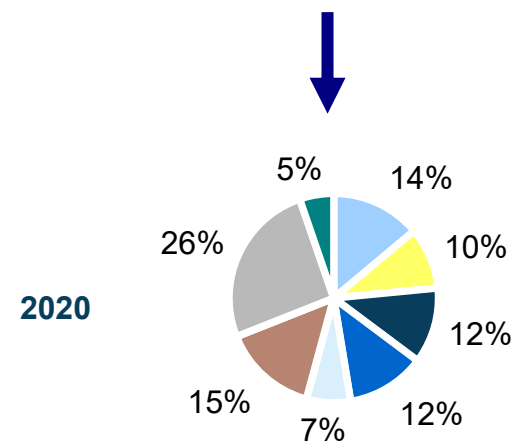
## Existing Products Provide Strong Base

Products	Net Revenue (\$ Millions)	
	2019	2020
Primatene MIST®	\$18	\$52
Enoxaparin	\$43	\$49
Vitamin K1	\$46	\$43
Lidocaine	\$46	\$41
Naloxone	\$35	\$33
Epinephrine	\$14	\$24
Other Pharma Products	\$101	\$90
Insulin API	\$20	\$18
<b>Total</b>	<b>\$322</b>	<b>\$350</b>

## Diversified Revenue



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



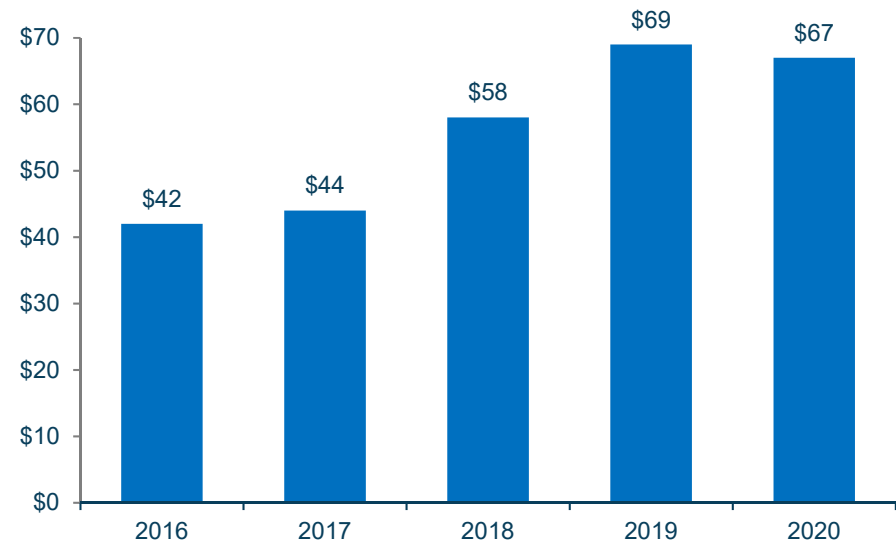
■ Enox. 
 ■ Naloxone 
 ■ Lidocaine 
 ■ Primatene MIST® 
 ■ Vita K 
 ■ Other Pharma 
 ■ Insulin API 
 ■ Epi

## Focused on R & D 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 350 employees dedicated to R&D

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

(\$ millions)



R&D as % of Revenue	2016	2017	2018	2019	2020
	15%	18%	20%	21%	19%

## 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 NDA/ANDA
  - 17 DMFs on file with the FDA for Amphastar's pipeline candidates
  - Several additional DMFs in development



# Pipeline – ANDA with Technical Barriers

## Generic Pipeline, 12 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
<b>Injectable</b>	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 Q4 2021	+\$650 Million
	AMP-020	Development	+\$2.5 Billion
	AMP-021	Development	

<b>Inhalation</b>	AMP-007	Stability/clinical trials	+\$8 Billion
	AMP-008	To be filed 2H 2021	
	AMP-016	Stability/clinical trials	
	AMP-017	Stability/clinical trials	
	AMP-022	Development	



# Pipeline – Insulin and Proteins, Biologics License Applications (BLAs)

## Insulins and Proteins, Biosimilar and/or Interchangeable

- Three candidates of insulins (“Insulin Program”) and proteins
- Significant US market: IQVIA sales ~\$13 Billion, ~130 millions of units
- Need sophisticated rDNA technology, state-of-the-art analytical technology, and significant investment on development
- Regulatory route: Biological License Application (BLA) 351(k) (Biosimilar) and aim at interchangeable insulin
- Recent FDA guidance

“... if a comparative analytical assessment based on state-of-the-art technology supports a demonstration of “highly similar” for a proposed biosimilar or interchangeable insulin product, there would be little or no residual uncertainty regarding immunogenicity; in such instances, the proposed biosimilar or interchangeable insulin product, like the reference product, would be expected to have minimal or no risk of clinical impact from immunogenicity. **In such instances, a comparative clinical immunogenicity study generally would be unnecessary to support a demonstration of biosimilarity or interchangeability.**” (FDA Guidance, November 2019, Emphasis added.)



## Pipeline – Insulin and Proteins, BLAs

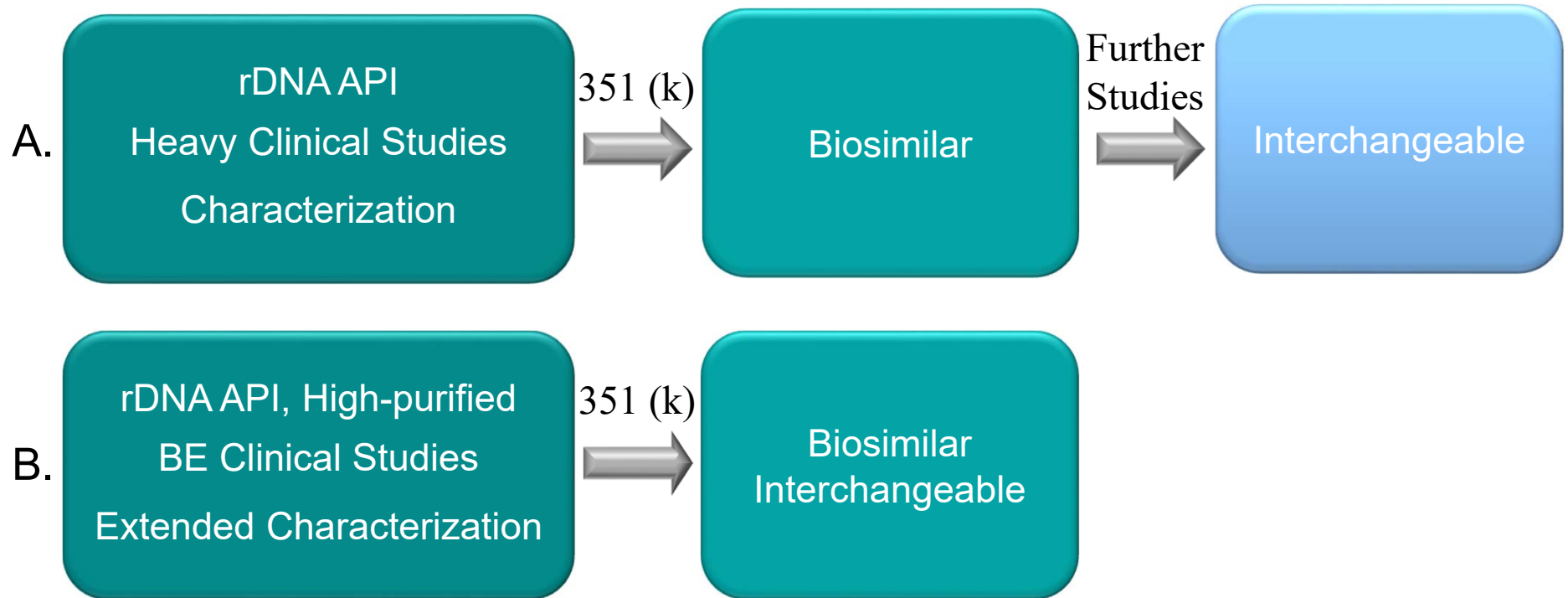
### Insulins and Proteins, Biosimilar and/or Interchangeable

- FDA Guidance established regulatory route by analytical assessment based on state-of-the-art technology supports a demonstration of “highly similar” and heavy clinical study for immunogenicity would be “unnecessary”
- API Manufacturing: rDNA technology, by AFP and ANP
- First INDs for the insulin program have been filed or in the process to file
- The clinical program for an IND in the insulin program is in process
- The cost of clinical program for Insulin products could potentially be significantly reduced



## Pipeline – Insulin and Proteins, BLAs

### Regulatory Strategy for Insulin Products: Interchangeability



We target pathway "B".

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

### Proprietary Pipeline NDA

- The development of innovative proprietary products requires sophisticated technology
- Amphastar's proven R&D, and technical platforms support the development of proprietary pipeline candidates
- Amphastar has expertise in clinical studies to support the NDA development; the NDA 505(b)(2) regulatory route requires clinical studies with a smaller sample size
- Naloxone Intranasal, NDA is pending, planned response to CRL in 2021
- Epinephrine Intranasal, Phase I study completed with successful results
- Two candidates are in the active development phase
- Additional pipeline candidates are in the early stage



## Glucagon for Injection Kit Launch

- The first and only FDA approved generic Glucagon for Injection in 20 years
- FDA determined that our highly-purified synthetic peptide product to be bioequivalent and therapeutically equivalent to Eli Lilly's Glucagon Emergency Kit, which has recombinant DNA (rDNA) origin
- Highlights the Company's sophisticated characterization technology
- Launched in February 2021
- Sales of Eli Lilly's Glucagon Emergency Kit were approximately \$144 million\*



## Primatene MIST<sup>®</sup> History

- Primatene MIST<sup>®</sup>, 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
- Amphastar reformulated Primatene from CFC to HFA
- 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<sup>®</sup> Marketing Update

- Improvements from Primatene MIST<sup>®</sup> CFC
  - Higher delivery efficiency, with improved efficacy at a lower dose
  - Dose indicator
  - Aluminum container instead of glass
  - HFA propellant replaces CFC
- Effective TV and Radio advertising campaign began in July 2019 with national coverage
- Multiple scientific articles were published in support of safe and effective use

Available OTC nationwide at:

**amazon**

**CVS pharmacy**<sup>™</sup>

**Kroger**

**RITE  
AID**

**target**

**Walgreens**

**Walmart**

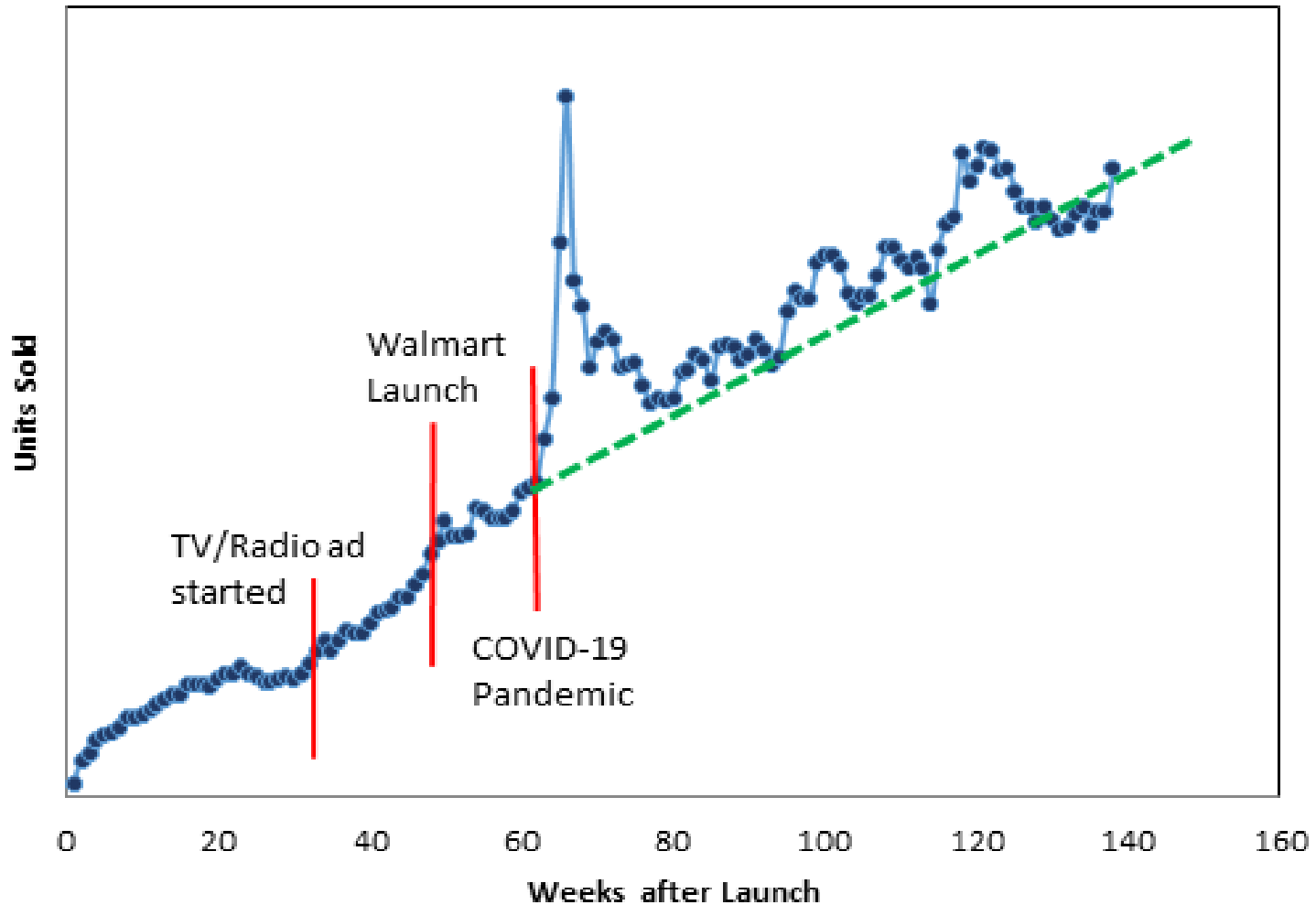


**Amphastar**

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

# Primatene MIST®: Sales Trend

## Primatene Mist®: In-Store Weekly Sales in UNITS



## Growth Drivers in 2021

- Glucagon Injection Kit launched February 2021
- Primatene MIST® indicated for “intermittent asthma”
  - Adult asthma patients: 19.2 million per CDC\*
  - Intermittent adult asthma patients: ~35% (per CDC\*\*), or 6.7 million
- Epinephrine multi-dose vials launched May 2020



## Strong Balance Sheet

### Capitalization as of June 30, 2021

(\$ 000s)

Cash, cash equivalents, restricted cash, and short-term investments	\$138,536
Long-term debt, including current portion	\$38,537
Total stockholders' equity	\$467,223

## Investment Highlights

- Biopharmaceutical company focused on development and manufacturing of technically-challenging BLAs, NDAs, and ANDAs in injectable, inhalable, and intranasal formulations
- Strong base business with approximately \$350 million in 2020 revenue and approximately \$143 million in 2020 gross profit
- Robust pipeline of over 20 product candidates, including the insulin products, in markets with barriers to entry
- Advanced technical capabilities and multiple delivery technologies proven through the successful development and launch of enoxaparin, epinephrine, glucagon, medroxyprogesterone, and Primatene MIST®
- Vertically integrated infrastructure and technical expertise for products with high barriers to market entry
- ANP (Nanjing) development 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