

## **Forward Looking Statements**

This presentation and the accompanying oral presentation contain forward-looking statements, of Amphastar Pharmaceuticals, Inc. ("Amphastar", "we". "our" and 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 above that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance and business trends, our future growth, sales and marketing of our products, market size and expansion, product portfolio, 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, the timing and results of clinical trials, including, with respect to our newly acquired product, the acquisition of BAQSIMI®, the prospective benefits of the acquisition of BAQSIMI®, and other future events, including potential contingent consideration amounts and terms related to the acquisition of BAQSIMI®, the anticipated benefits of BAQSIMI® to our product portfolio, our ability to increase our revenues, Amphastar's commitment to strategically maximizing the commercial potential of BAQSIMI®, and other future events. 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," "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 but not limited to those described in Amphastar's filings with the Securities and Exchange Commission ("SEC"), including in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 1, 2023, our Quarterly Report on Form 10-Q for the guarter ended June 30, 2023, filed with the SEC on August 9, 2023. In particular, there can be no guarantee that the acquisition of BAQSIMI® will be beneficial to our business, that any event, change or other circumstance could cause the results of the acquisition of BAQSIMI® to differ from Amphastar's expectation, that all or any of the contingent consideration will be payable on the terms described herein or at all, or that Amphastar can reliably predict the impact of the acquisition of BAQSIMI® on its financial results or financial guidance. You can locate these reports through our website at http://ir.amphastar.com and on the SEC's website at 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.

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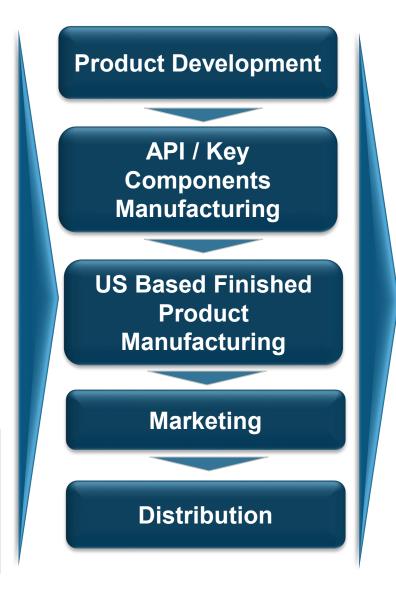






## **Fully Integrated Business Model**

- 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



## **Focus on Products With High Technical Barriers**

#### **Products with:**

- Large markets
- High technical barriers to entry

#### Focused on:

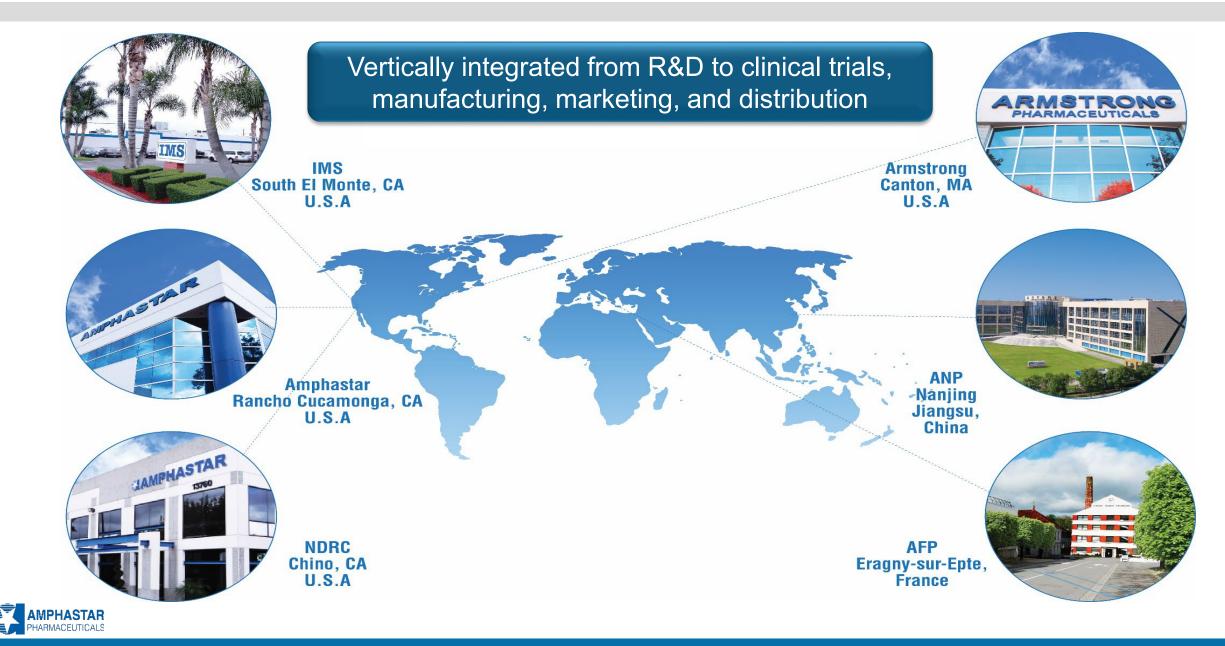
- Complex Generics
- Biosimilar
- Interchangeable
- Proprietary

#### **High Technical Barriers to Entry**

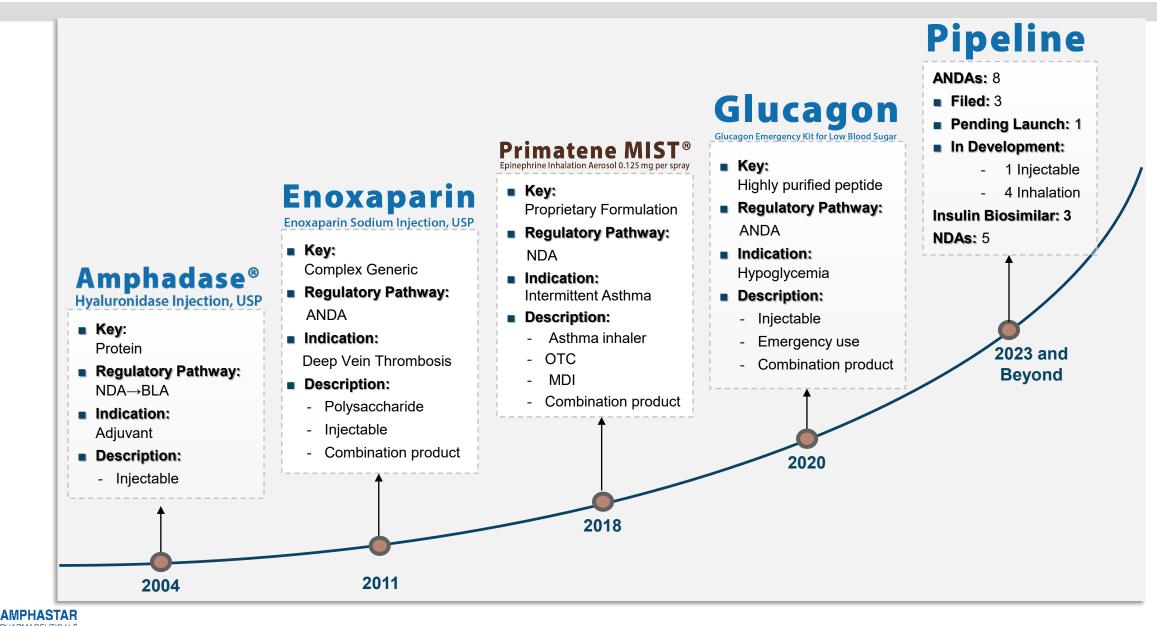
- Scarcity of API requires unique synthetic or rDNA capabilities
- Characterization for complex molecules
- Immunogenicity studies for proteins and complex molecules
- Delivery technologies: Injectable, MDI, IN, and sustained release
- Particle engineering from nm to µm
- Innovative formulations
- Large molecule product development
- Difficult or complex manufacturing processes



## **Amphastar Facilities**



## **Milestones of Pipeline Development**



# **Commercial Product Portfolio**

- Diverse core of over 20 commercial products
- Injectable, intranasal 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
  - BAQSIMI®
  - Glucagon
  - Vitamin K1
  - Naloxone

- Primatene MIST<sup>®</sup>
- Epinephrine PFS & MDV
- Cortrosyn<sup>®</sup>
- Enoxaparin

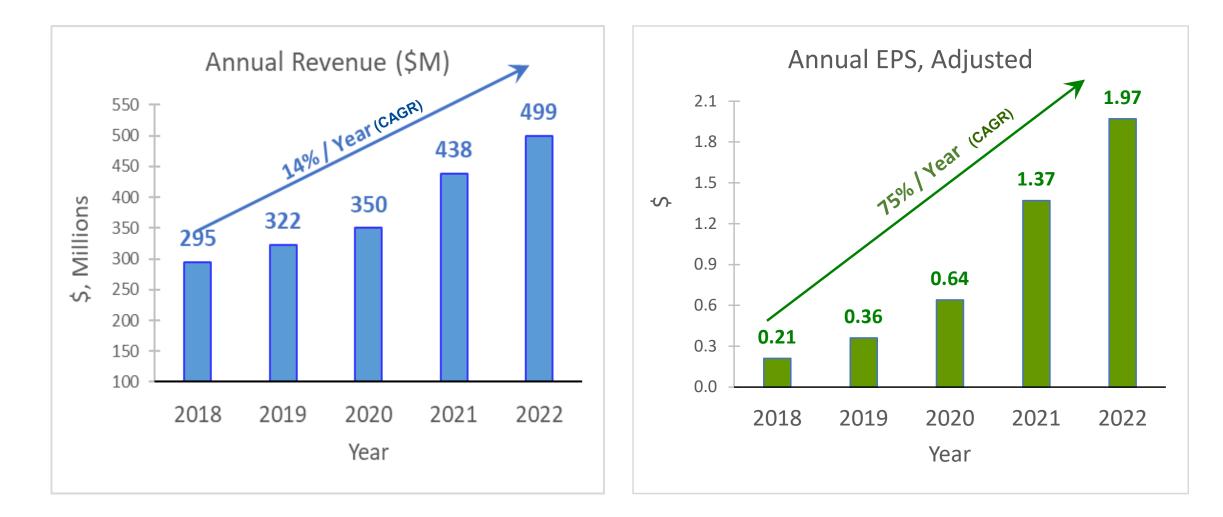
- Lidocaine Injection and Jelly
- Regadenoson
- Ganirelix
- Vasopressin



# **Sales and Marketing**

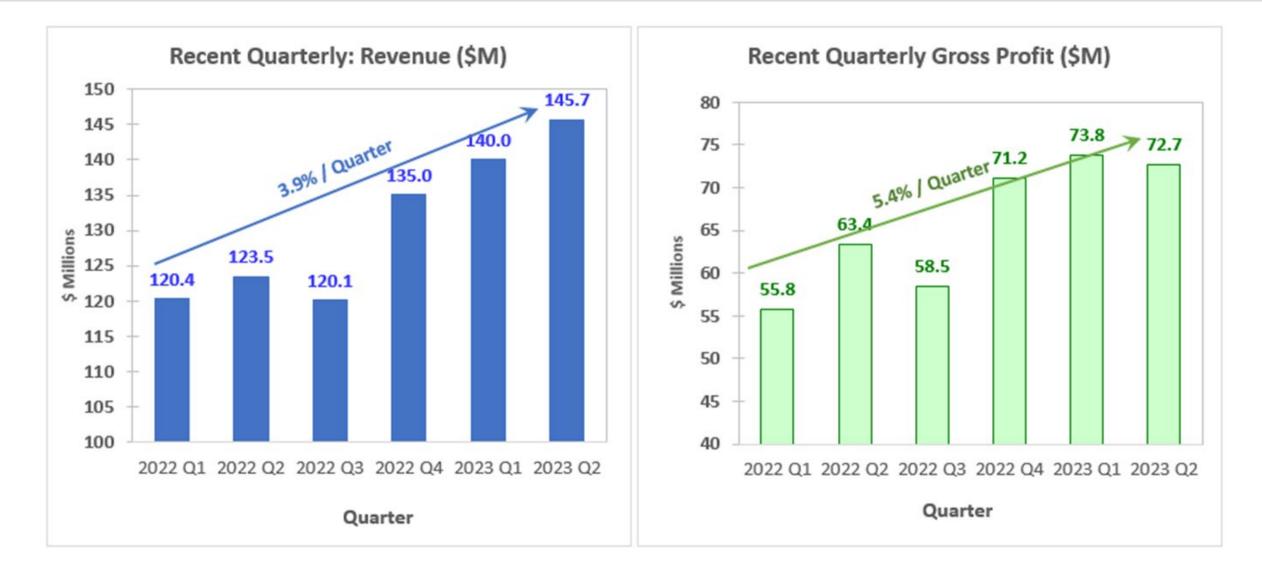


## Sales and EPS Trend



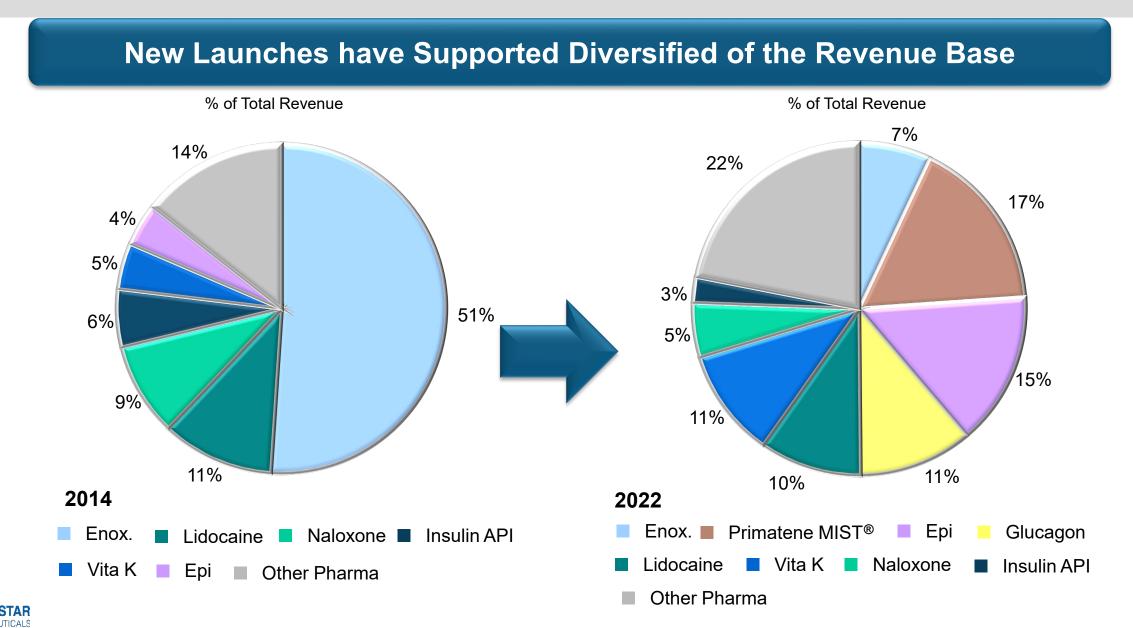


## **Recent Quarter Trend: Sales & Gross Profit**





## **Existing Products Provide Strong Base**

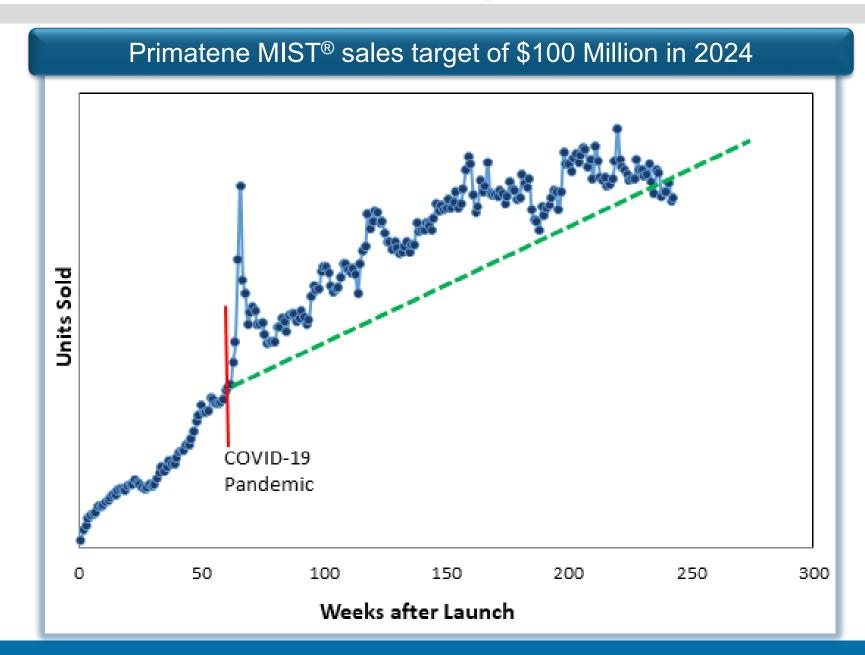


# Primatene MIST<sup>®</sup> - 17% of 2022 Revenues

- Primatene MIST<sup>®</sup>, a proprietary and patent-protected over-thecounter epinephrine inhalation product
- The only FDA approved asthma inhaler available OTC, launched Dec 2018
- Multiple scientific articles were published in support of Primatene MIST<sup>®</sup>
- Intensive cardiovascular studies >40,000 data points
- US Adult asthma patients: 20 million per CDC\*
- 17% of Amphastar sales in 2022



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





# **BAQSIMI®** Acquisition



## **BAQSIMI®** Transaction

	Overview
Product:	<ul> <li>Amphastar entered into a definitive agreement with Eli Lilly and Company to acquire BAQSIMI<sup>®</sup> (glucagon) nasal powder (the "Transaction")</li> </ul>
Terms:	<ul> <li>Cash payments: <ul> <li>\$500 million in cash at closing</li> <li>\$125 million in cash at 12 months after closing</li> </ul> </li> <li>Contingent cash payments: <ul> <li>Up to \$450 million in for the product sales-based milestones during the first five years after closing (measured for each successive 12 month period starting on first of the month following closing) <ul> <li>One \$100 million payment if the annual net sales reach \$175 million</li> <li>Up to two \$100 million payments for each year the annual net sales reach \$200 million</li> <li>One \$150 million payment if the total net sales in the first 5 years following closing reach \$950 million</li> </ul> </li> </ul></li></ul>
Assumption of milestone payments:	Amphastar will assume Lilly's obligation of sales-based milestone payments to a 3 <sup>rd</sup> party, up to \$125 million if net sales of covered products (including BAQSIMI) hit certain sales milestones at \$350 million and above in a 12 month period

#### **BAQSIMI®** Strategic Rationale: A Transformative Transaction for Amphastar



#### **BAQSIMI®** Patient Impact

## **Glucagon is underutilized:**

The American Diabetes Association (ADA) recommends that patients at increased risk for Level 2 hypoglycemia be prescribed glucagon<sup>1</sup>

#### Amphastar will focus on BAQSIMI<sup>®</sup> to better serve patients

Approximately 7 million people are treated with insulin and only about 0.7 million (~10%)<sup>2</sup> of these patients currently utilize glucagon

# BAQSIMI<sup>®</sup> is currently a category leader for ease in patient use:

**Simple nasal administration:** Currently the only non-injection glucagon approved by the FDA, passively absorbed in the nose, provide lower barrier for administration than injection

Ready-to-use with no reconstitution or priming required

#### **Portability for Consumers:**

Smaller product size than other glucagon products, and wider temperature storage range than other glucagon injection product.

<sup>1</sup>American Diabetes Association. *Standards of Medical Care in Diabetes—2020. Diabetes Care*. 2020;43(suppl 1):S1-S212. <sup>2</sup>Estimates based on IQVIA Annual TRx volume in 2022.

### **BAQSIMI®** Overview

- BAQSIMI<sup>®</sup> is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia-in patients with diabetes ages 4 years and above
- Simple nasal administration: no inhalation required
- Single, fixed 3mg dose



Peel



Open

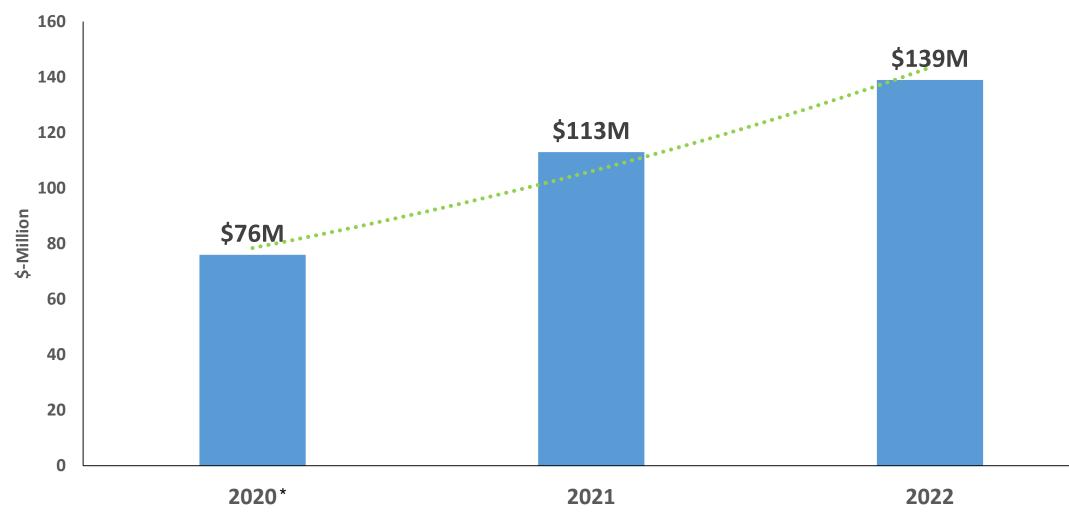


Push

## **Novel Glucagon Product Landscape**

	AMPHASTAR PHARMACEUTICALS	<b>Xeris</b> BIOPHARMA	novo nordisk <sup>®</sup>	
		Guoke HypoPen (glucagon injection)	Arc + sector	
	<b>BAQSIMI<sup>®</sup></b>	Gvoke	Zegalogue	
Route of Administration	Nasal	Injection	Injection	
Shelf Life	24 months	30 months	12 months	
Approved Age Group	4+ years	2+ years	6+ years	
Launch Year	2019	2019	2021	
	BAQSIMI <sup>®</sup> is a category leader in the novel glucagon class			

### **BAQSIMI®** Sales



#### **BAQSIMI® Worldwide Annual Sales**

#### **BAQSIMI®** Forecast

## Sales

- Projected to reach \$145 million to \$155 million annualized in 2023
- Net Economic Benefit (sales minus expenses) will be booked until Amphastar take over distribution from Lilly
- Projected to reach peak of \$225 million to \$250 million
- Adjusted EPS<sup>(1)</sup>
  - Project \$0.12 to \$0.18 incremental adjusted EPS in 2023
  - Project \$2.00 to \$2.50 incremental adjusted EPS at peak
  - (1) Adjusted EPS is a non-GAAP financial measure. Reconciliation to the nearest GAAP measure is unavailable without unreasonable efforts. Refer to the section titled
     "Non-GAAP Financial Measures" for an explanation of non-GAAP financial measures.

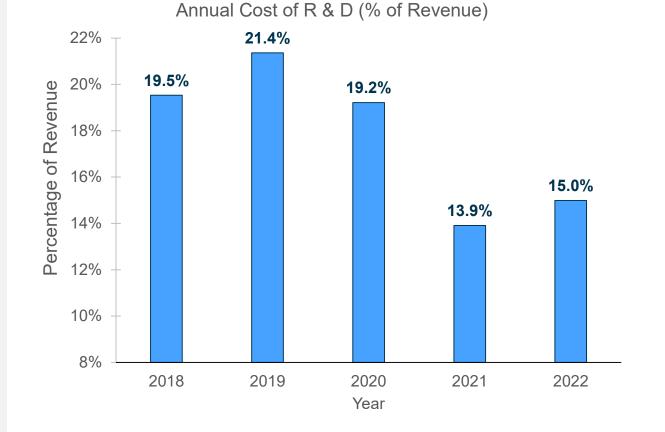
# **R&D** and **Pipeline**



## **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 \$330 million in the recent 5 years





# **Pipeline – ANDAs with Technical Barriers**

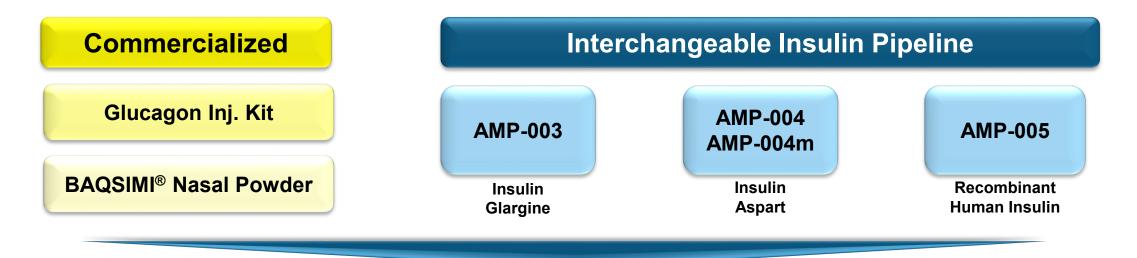
#### Generic Pipeline, 8 Candidates with Technical Barriers

#### 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-009 (Regadenoson)	Approved; Launched April 2023	+\$575 Million
	AMP-002	GDUFA Q2 2023, no FDA Action and no pending requests as of 8/8/23	+\$500 Million
	AMP-015 (Teriparatide)	CRL received and responded; GDUFA Q1 2024	+\$600 Million
	AMP-018	Stability/clinical trials	+\$2.8 Billion
Inhalation	AMP-008	CRL received, response planned Q3 2023	
	AMP-007	Planned Filing Q4 2023	
	AMP-016	Stability/clinical trials	+\$6 Billion
	AMP-017	Stability/clinical trials	
	AMP-022	Development	

## **Diabetes Portfolio**



- BAQSIMI<sup>®</sup>, the first and only FDA approved glucagon nasal powder
- First and only FDA approved generic Glucagon
- Covers the full spectrum of the insulin from rapid to long acting
- AMP-004 BLA planned filing in 2023
- \$11 Billion in IQVIA sales as of June 30, 2023, ~115 million of units of both pens and vials



## **Diabetes Portfolio Cont.**

**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:

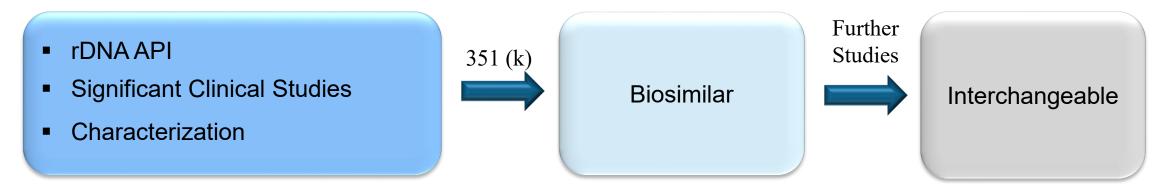
- FDA Guidance making comparative clinical immunogenicity unnecessary if extended characterization and highly-purified API are both achieved
  - Reduces number of clinical trials necessary
  - Lowers total cost and time of the clinical program



# **Current Regulatory Pathways for Interchangeable Biosimilar Insulin**

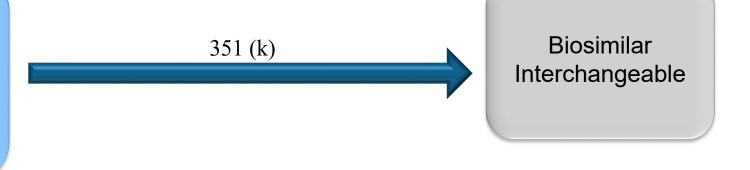
Regulatory Strategy for Insulin Products: Interchangeability

A. FDA regulatory pathway for recently approved product



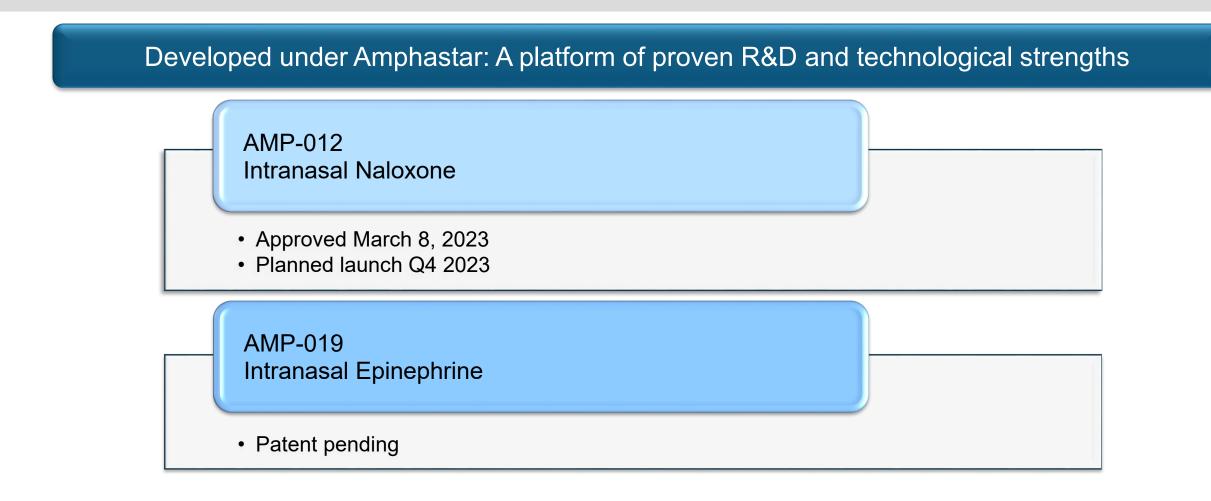
#### B. Amphastar targeted FDA regulatory pathway

- rDNA API (Highly-purified)
- PK/PD BE Clinical Studies
- Extended Characterization with state of the art analysis technologies





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

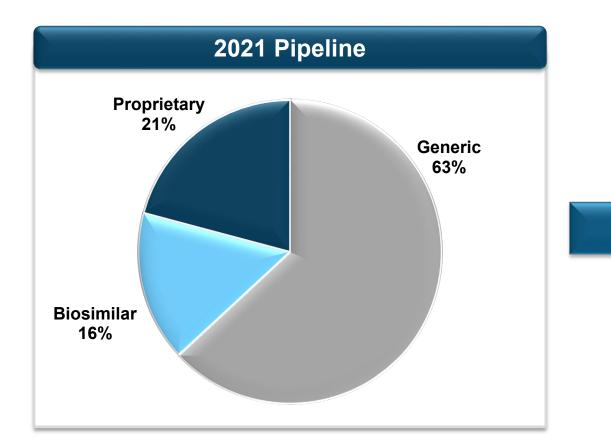


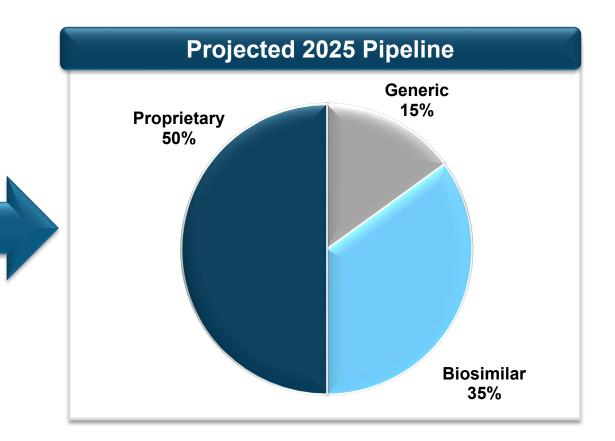
Three early stage products



## **Pipeline Evolution**

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







# **Highlights and Catalysts**



# **Growth Drivers in 2023 and Upcoming Milestones**

# Key Growth Drivers in 2023

- Glucagon Injection Kit
  - Strong sales since launched in Feb. 2021
  - Increased market opportunity
  - Increased capacity approved
- Regadenoson launched April 2023

- BAQSIMI<sup>®</sup> Acquisition
- Primatene MIST<sup>®</sup>
  - Physician sampling program
  - Price increase January 2023

## Key Milestones 2023

## <u>Filings</u>

- AMP-007 planned filing Q4 2023
- AMP-004 planned BLA filing 2023
- AMP-015 (Teriparatide) CRL responded; GDUFA Q1 2024

### **Expected Approvals**

- Intranasal Naloxone approved; planned launch Q4 2023
- AMP-002 CRL responded; GDUFA Q2 2023
- AMP-008 CRL received; response planned Q3 2023

