



# J.P. Morgan 37<sup>th</sup> Annual Healthcare Conference

**AMRX**  

---

**LISTED**  

---

**NYSE**



**Rob Stewart**  
President and CEO

January 8, 2019

# Safe Harbor Statement

## Safe Harbor Statement

Certain statements contained herein, regarding matters that are not historical facts, may be forward-looking statements (as defined in the Private Securities Litigation Reform Act of 1995). Such forward-looking statements include statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, including, among other things, future operating results and financial performance, product development and launches, integration strategies and resulting cost reduction, market position and business strategy. Words such as "may," "will," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "assume," "continue," and similar words are intended to identify estimates and forward-looking statements.

The reader is cautioned not to rely on these forward-looking statements. These forward-looking statements are based on current expectations of future events. If the underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Amneal Pharmaceuticals, Inc. (the "Company"). Such risks and uncertainties include, but are not limited to: the impact of global economic conditions; our ability to integrate the operations of Amneal Pharmaceuticals LLC and Impax Laboratories, LLC pursuant to the business combination completed on May 4, 2018, and our ability to realize the anticipated synergies and other benefits of the combination; our ability to successfully develop and commercialize new products; our ability to obtain exclusive marketing rights for our products and to introduce products on a timely basis; the competition we face in the pharmaceutical industry from brand and generic drug product companies, and the impact of that competition on our ability to set prices; our ability to manage our growth; the illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products; market perceptions of us and the safety and quality of our products; our dependence on the sales of a limited number of products for a substantial portion of our total revenues; our ability to develop, license or acquire and introduce new products on a timely basis; the ability of our approved products to achieve expected levels of market acceptance; the risk that we may discontinue the manufacture and distribution of certain existing products; the impact of manufacturing or quality control problems; the risk of product liability and other claims against us by consumers and other third parties; risks related to changes in the regulatory environment, including United States federal and state laws related to healthcare fraud abuse and health information privacy and security and changes in such laws; changes to FDA product approval requirements; risks related to federal regulation of arrangements between manufacturers of branded and generic products; the impact of healthcare reform and changes in coverage and reimbursement levels by governmental authorities and other third-party payers; our dependence on a few locations that produce a majority of our products; relationships with our major customers; the continuing trend of consolidation of certain customer groups; our reliance on certain licenses to proprietary technologies from time to time; our dependence on third party suppliers and distributors for raw materials for our products and certain finished goods; the time necessary to develop generic and branded drug products; our dependence on third parties for testing required for regulatory approval of our products; our dependence on third party agreements for a portion of our product offerings; our ability to make acquisitions of or investments in complementary businesses and products on advantageous terms; regulatory oversight related to our international operations; our increased exposure to tax liabilities due to our international operations and the impact of recent U.S. tax legislation; payments required by our Tax Receivable Agreement; our involvement in various legal proceedings, including those brought by third parties alleging infringement of their intellectual property rights; legal, regulatory and legislative efforts by our brand competitors to deter competition from our generic alternatives; the significant amount of resources we expend on research and development; our substantial amount of indebtedness and our ability to generate sufficient cash to service our indebtedness in the future, and the impact of interest rate fluctuations on such indebtedness; risks inherent in conducting clinical trials; our reporting and payment obligations under the Medicaid rebate program and other government purchase and rebate programs; quarterly fluctuations in our operating results; adjustments to our reserves based on price adjustments and sales allowances; investigations and litigation concerning the calculation of average wholesale prices; the high concentration of ownership of our Class A Common Stock and the fact that we are controlled by a group of stockholders. A further list and descriptions of these risks, uncertainties and other factors can be found in the Company's most recently filed Quarterly Report on Form 10-Q and in the Company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.amneal.com](http://www.amneal.com) or on request from the Company.

Forward-looking statements included herein speak only as of the date hereof and we undertake no obligation to revise or update such statements to reflect the occurrence of events or circumstances after the date hereof.



# Solid Foundation to Deliver Long-Term Sustainable Growth

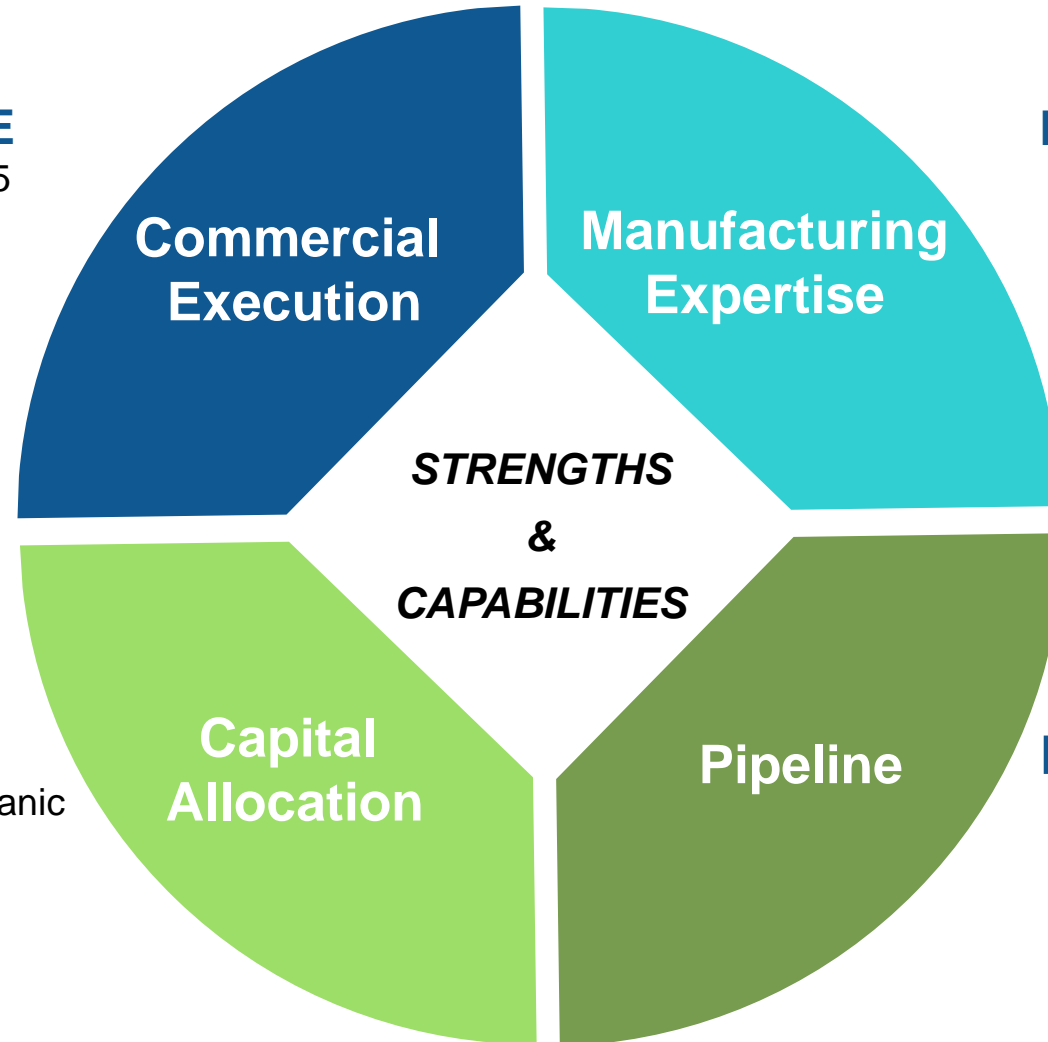
## STRONG TRADE PRESENCE

>200 generic product families – Top 5 U.S. generics company<sup>1</sup>

6 specialty products

## STRONG CASH FLOW

Supports ongoing investments in organic and inorganic growth opportunities



## INTEGRATED SUPPLY CHAIN

9 global manufacturing facilities with R&D located at each facility

## DIVERSIFIED R&D PIPELINE

~220 generic projects

3 biosimilar products

1 specialty product in clinical Phase 3

~\$200MM in annual R&D investment



<sup>1</sup> Per IQVIA Sales Data  
Data as of 12/31/18

# Significant Progress Achieving Key Strategic Milestones in 2018



## OPERATIONAL EXECUTION

Led U.S. generics industry in approvals and launches

62 ANDAs approved + 10 tentative approvals

42 products launched

31 ANDAs submitted

Strong growth from Specialty products Rytary® and Unithroid®



## MERGER INTEGRATION

Amneal + Impax merger completed May 2018

On track to achieve more than \$200 million in cost synergies earlier than planned

Completed all manufacturing at Hayward site in December and completed sales of owned buildings

All actions required to deliver synergies are completed



## CAPITAL DEVELOPMENT

Levothyroxine Partnership with Jerome Stevens and Lannett

Acquisition of Gemini Laboratories

gMakena® partnership with American Regent

Biosimilar Avastin® partnership with mAbxience

# Near-Term Priorities to Build from Position of Strength

OUR  
GOAL

Drive for double-digit  
earnings growth

Continue to drive strong  
operational cash flows



## **Capitalize on Organic Growth**

*Continue to leverage industry leading approvals and on-time launch performance*



## **Drive Operational Excellence**

*Maintain superior customer service and highest level of quality*



## **Improve Earnings Potential**

*Recognize synergy capture from the merger and maintain tight cost control*

# Long-Term Priorities to Drive For Double-Digit Earnings Growth

OUR  
PORTFOLIO  
FOCUS

Generics

Specialty

Biosimilars



## ***Continue to Drive Organic Growth***

*Ongoing investment in Generic and Specialty R&D*



## ***Pursue Creative Business Development***

*Tuck-in acquisitions as well as larger transactions to strengthen key portfolios including acceleration of injectable presence and growing our Specialty franchise*



## ***Explore Additional Commercial Adjacencies***

*Further diversify Amneal's commercial footprint*

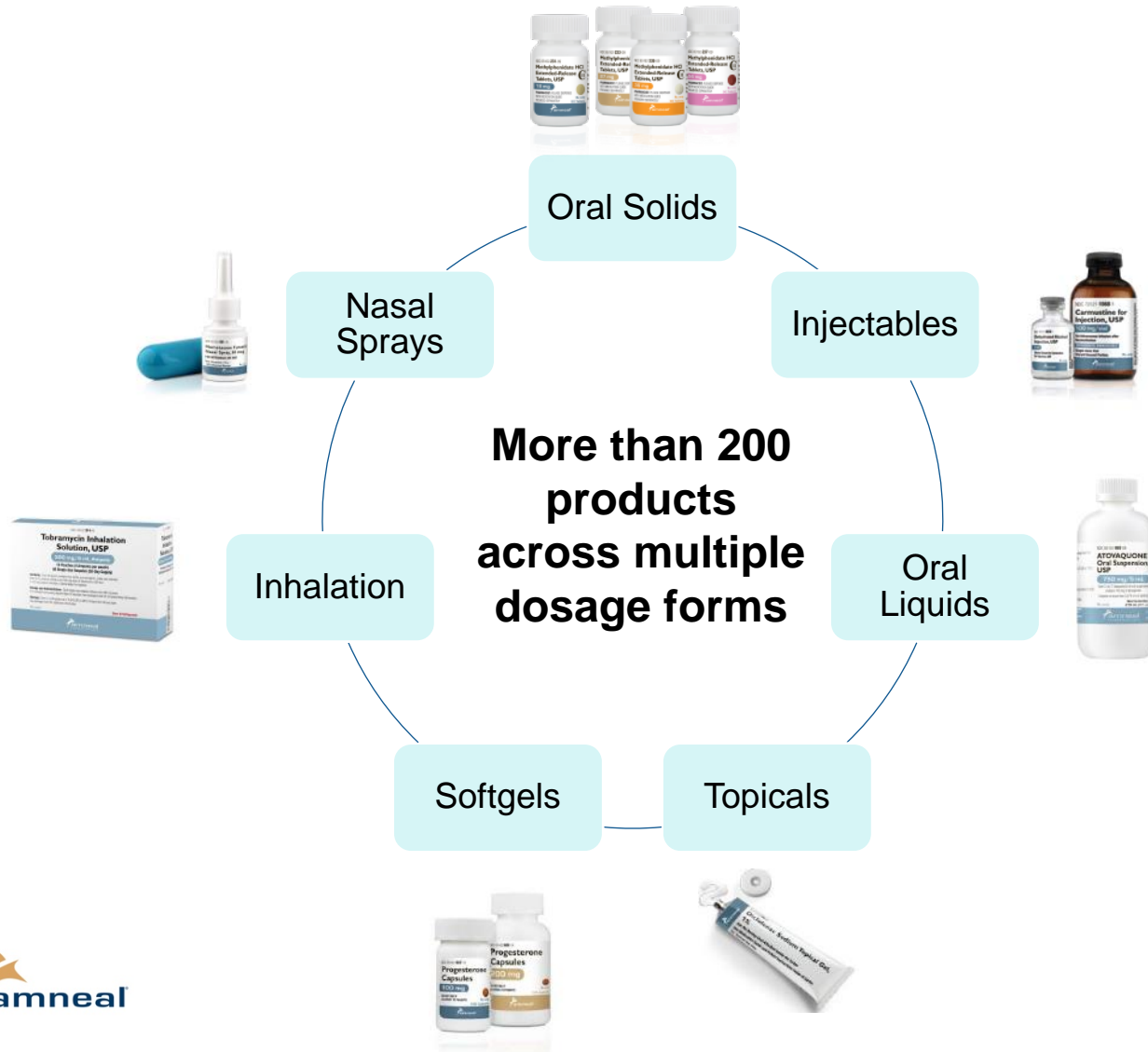


# Generics Business



Delivering  
Quality, Trust  
and Value

# Diversified Generics Commercial Portfolio



## Portfolio Changes in 2018

- 42 products launched
- More than 1/3 of launches were injectable, topical or liquid products including 7 injectable products
- Competition on top products in early 4Q came sooner than expected

## Strategic Priorities

- Targeting up to 50 product launches in 2019
- Portfolio optimization or inability to supply products by some manufacturers could provide upside opportunities
- Ability to consistently supply a broad range of products is becoming a differentiator with customers



# Ongoing Focus on High-Value\* Generic Projects

## Portfolio Selection Focus

- Utilizing in-house capabilities and expertise to continue our focus on more complex dosage forms

## Changing Market Dynamics

- New market dynamics are slowing the uptake of certain generic products
  - Brand rebating tactics
  - Buying group exclusionary formularies
- Nevertheless, over the long-term, we believe the value of our R&D investments will be realized

## PIPELINE

Dosage Form	Submitted Products	% Portfolio	In Development Products	% Portfolio
Oral Solids	67	54%	33	35%
<b>Injectables</b>	<b>19</b>	<b>15%</b>	<b>24</b>	<b>25%</b>
<b>Ophthalmic</b>	<b>6</b>	<b>5%</b>	<b>13</b>	<b>14%</b>
<b>Inhalation</b>	<b>0</b>	<b>0%</b>	<b>7</b>	<b>7%</b>
Topicals	11	9%	7	7%
Transdermals	6	5%	4	4%
Liquids / Suspensions	12	10%	5	5%
Nasal Spray	1	1%	3	3%
Vaginal/Rectal	2	1%	0	0%
<b>Grand Total</b>	<b>124</b>	<b>100%</b>	<b>96</b>	<b>100%</b>



\* High-Value = eFTF, FTF, FTM and other high value opportunities with 0 to 3 competitors  
Data as of 12/31/18

# Investing in Biosimilar Pipeline

Partner	Product	Status
	 	<p>Filed</p> <hr/> <p>Expected to be filed 1H 2019</p>
 <p>From lab to life</p>		<p>Expected to be filed 1H 2020</p>



# Specialty Business



Working to  
Meet  
Important  
Medical  
Needs

# Growing Specialty Business to Capture Higher Value Opportunities

## Proprietary marketed products in niche therapeutic areas

- Central nervous system disorders
- Parasitic infections
- Endocrinology

## Established U.S. sales and marketing function

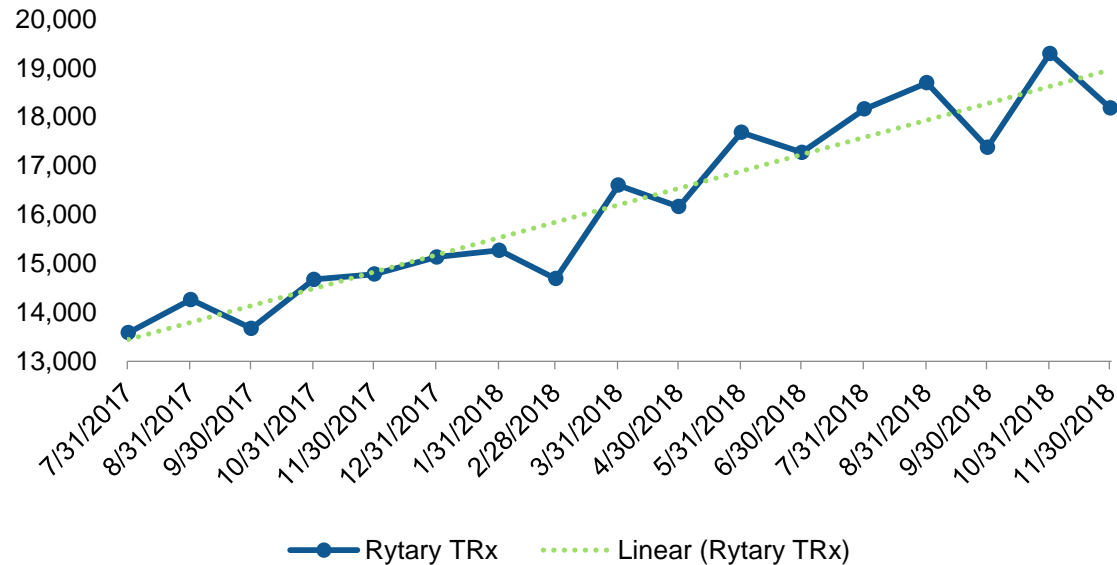
- 145 sales reps and regional managers
- CNS deployment targeting neurologists, movement disorder specialists and other high-prescribing physicians in key markets for Rytary and Zomig
- Endocrinology & Pediatric deployment for Unithroid and Emverm
- Strong managed care and market access



**Committed to Investing in Organic and External Opportunities to Create Long-Term Growth**

# Rytary® – Continued growth in 2018, Positioned Well 2019 and Beyond

Rytary TRx Volume trend



## Positive Performance in 2018

- Currently most successful promoted brand in Parkinson's
- Significant progress in Med D, adding ~ 9mm covered lives
- ~90% claims approval rates

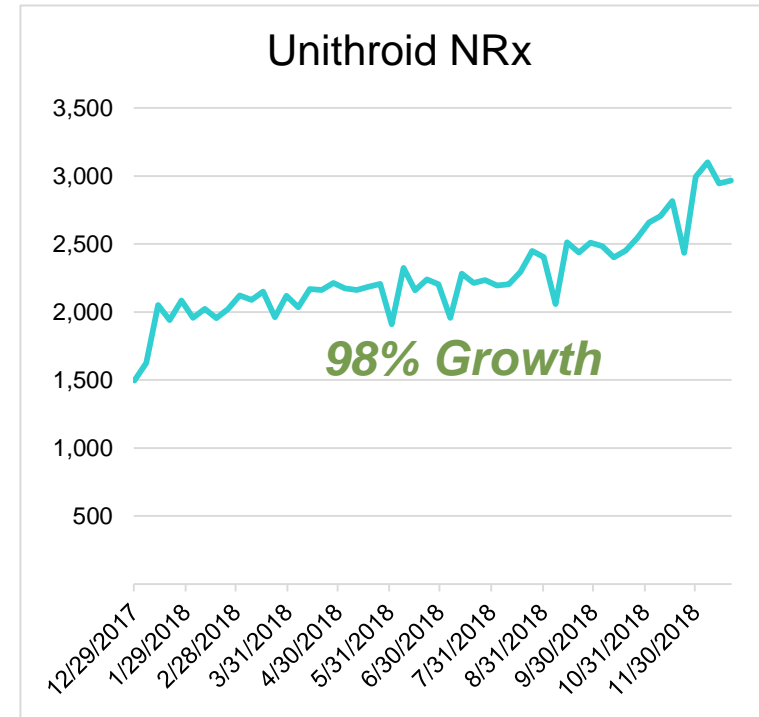
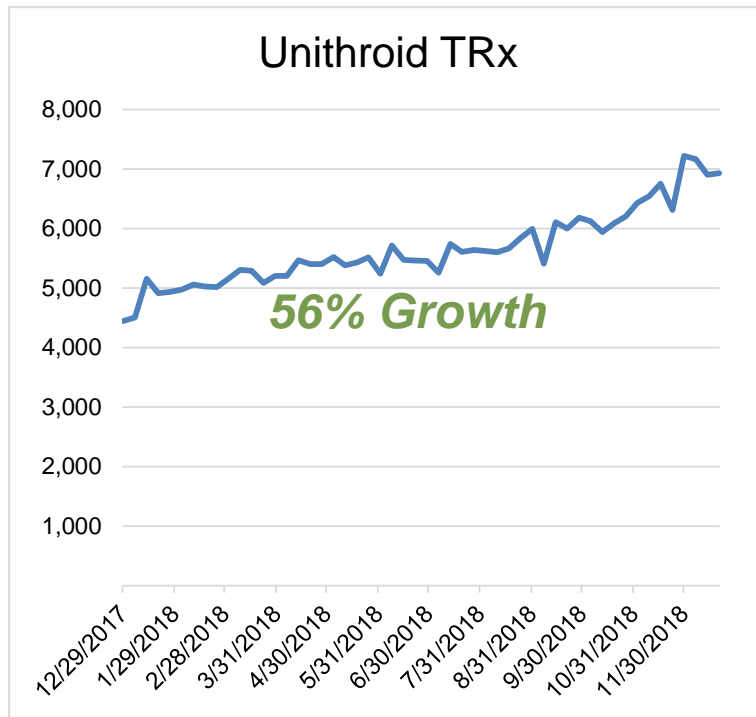
## Action Plan for 2019

- Execute on new positioning, messaging and concepts as part of brand relaunch
- Establish the importance of the Rytary value proposition and better connect with both prescribers and patients
- Increase advocacy/support among key stakeholders to build brand champions
- Continued improvement in Medicare Part D access



# Unithroid® – Strong RX Growth in 2018

- Double-digit growth in TRx and NRx
- **360k+** Annual Total Prescription (TRx) Run Rate
- **154k+** Annual New Prescription (NRx) Run Rate
- Sales force expansion planned in 2019



# IPX203 - Specialty R&D Lead Pipeline Product

- IPX203 is an investigational extended-release capsule formulation of carbidopa-levodopa (CD-LD) for oral administration
- In phase II clinical studies, IPX203 compared to immediate-release (IR) CD-LD demonstrated
  - Significant reduction of “Off” time on the patient PD diary and on the UPDRS Part III
  - Patients on IPX203 had approximately 2.3 hours less “Off” time compared to IR CD-LD in patient PD diary
- Initiated phase III clinical trials in 2018
- Phase III study is being conducted pursuant to special protocol assessment from FDA
- Investigator meeting and first patient enrolled November 2018
- Topline data expected first half 2020
- NDA filing expected in 2021



# Excited About Our Future

## *Focused on Driving for Double-Digit Earnings Growth*



Solid Generic and Specialty business foundation



Large and diverse generic pipeline with high potential



Strong cash flow to support organic and inorganic growth



Ability to deliver creative business development