

Better health.
Within reach.
Every day.

Meet the Management Series – Generics
September 2021

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Agenda and speakers

2:00 –2:05pm	Welcome	Siggi Olafsson
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2:05 –2:25pm	Business overview	Brian Hoffmann
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2:25 –2:35pm	Operations and Quality	Mike Balog
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2:35 –2:45pm	Commercial	Kristy Ronco
<hr/>		
2:45 –2:50pm	Wrap up	Brian Hoffmann
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2:50 –3:30pm	Q&A	All speakers



Siggi Olafsson
CEO



Brian Hoffmann
President

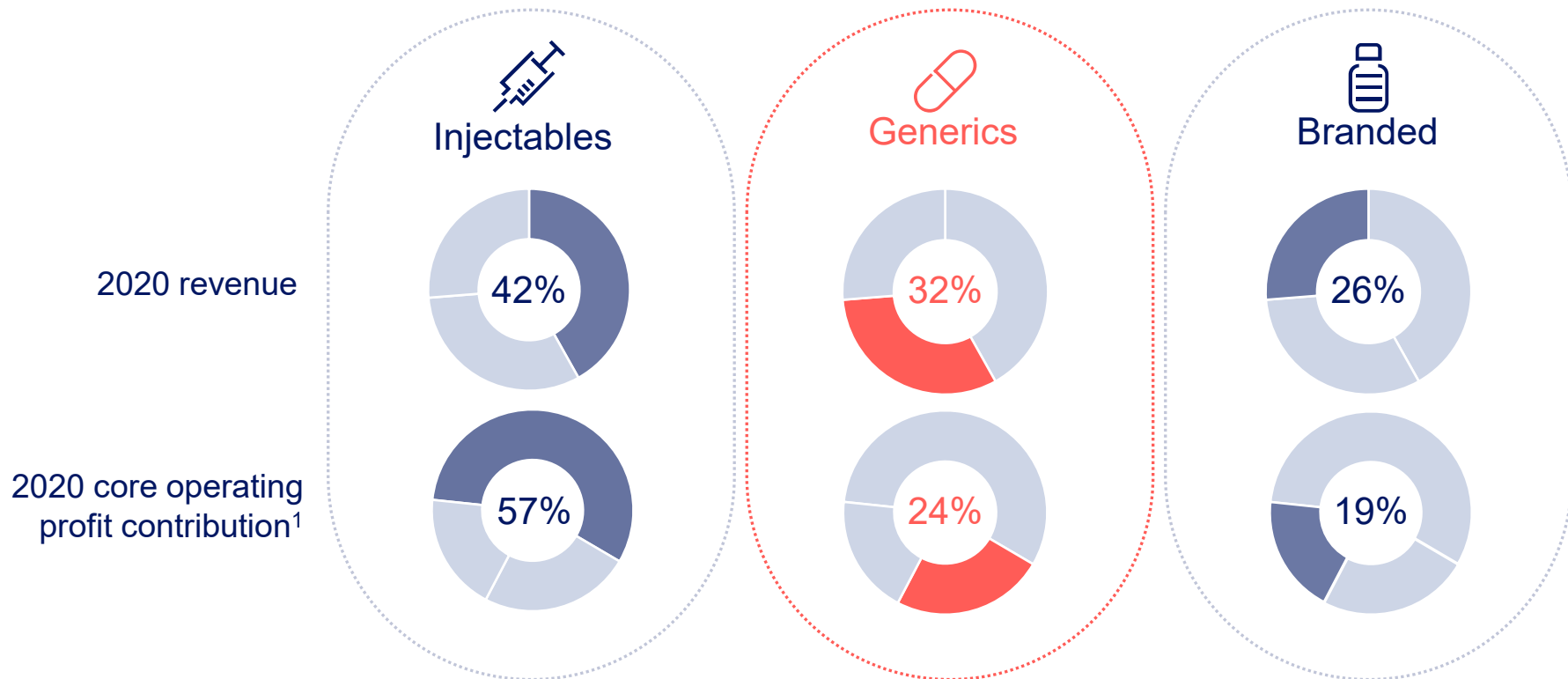


Kristy Ronco
Chief Commercial
Officer



Mike Balog
SVP Operations

Generics – A high value, growing asset



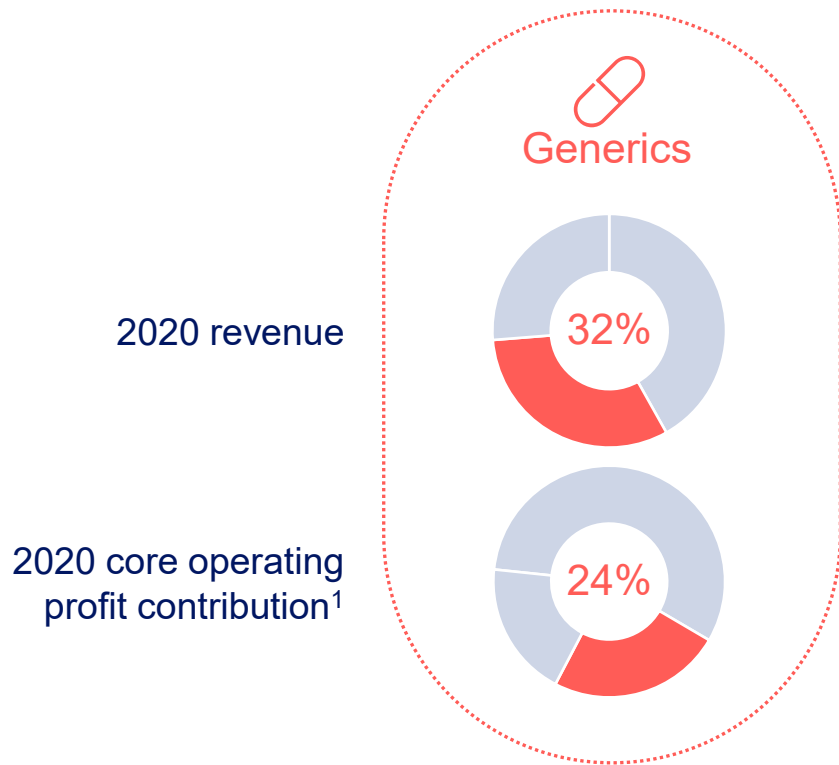
¹ Core operating profit is \$566 million. Before unallocated corporate costs of \$98 million and operating profit from Other business of zero, core operating profit contribution from business segments is \$664 million.

Business overview



Brian Hoffmann
President, Generics

Our Generics business today



Top 10 generic non-injectable manufacturer in the U.S.²



Differentiated generics and specialty brands driving significant value



Customer- and patient-centricity are critical toward achieving our strategic ambitions



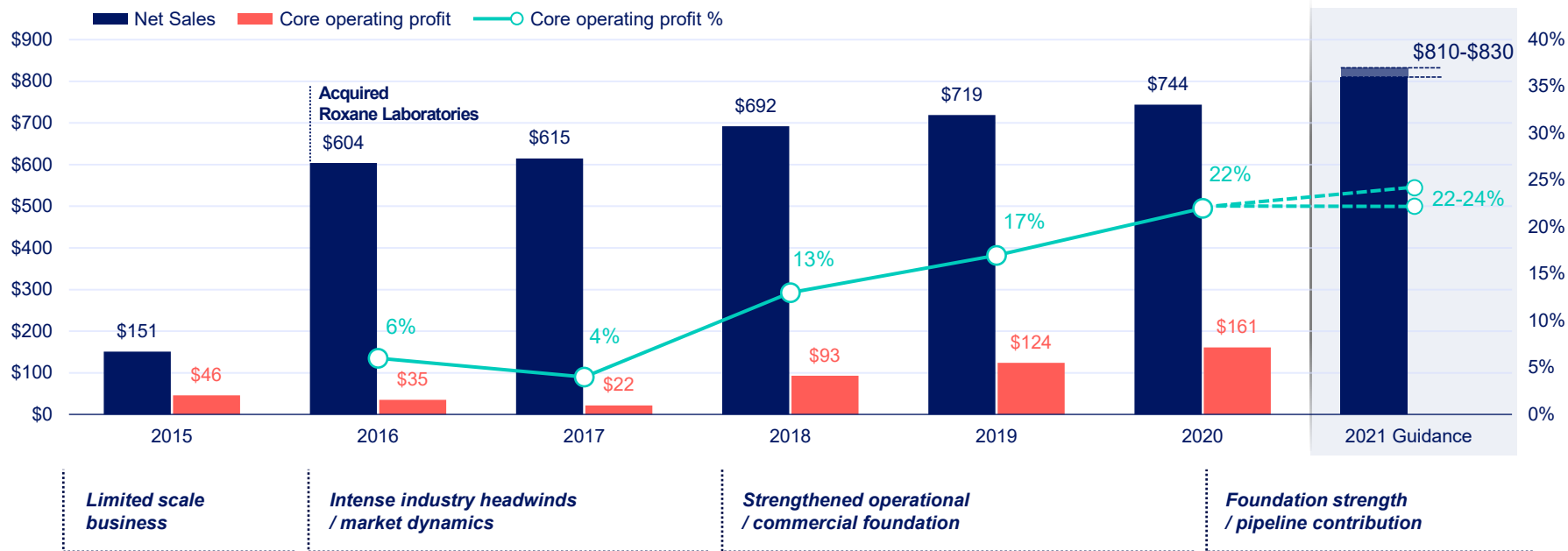
>fourfold increase in core operating profit since Roxane acquisition in 2016

¹ Core operating profit is \$566 million. Before unallocated corporate costs of \$98 million and operating profit from Other business of zero, core operating profit contribution from business segments is \$664 million.

² IQVIA non-injectable generic products, July 2021 YTD sales

Significant improvement in both top- and bottom-line

Generics financials (\$m)



Delivering on promised business improvements

2018 Capital Markets Day



Near-to-medium term priorities

- Sale of Eatontown manufacturing facility
- Consolidate warehousing and distribution
- Tech transfer products to Columbus and Jordan
- Optimise workforce according to business needs
- Implement operational efficiencies
- Identify and implement cost savings initiatives across the business
- Improve service levels and enhance reputation with customers

Achievements



- Sold in 2018
- Centralised in Ohio in 2019
- Completed in 2019
- Streamlined management layers and reduced headcount
- Significantly increased throughput per employee
- Significantly lowered overhead cost per unit
- Achieved 95%+ service level rating across key customers

2021+ priorities



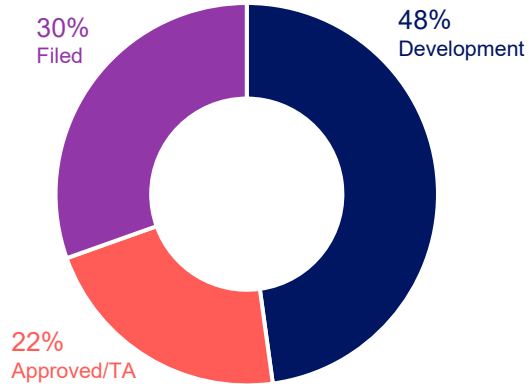
Long-term priorities

- Maintain highest quality standards
- Continually identify operational efficiencies to improve cost base
- Add new technologies and capabilities to improve pipeline and portfolio
- Expand respiratory and Hikma Specialty businesses
- Identify strategic inorganic growth opportunities, including licensing, CDMO opportunities, and M&A

Maintaining balanced pipeline to deliver sustainable organic growth

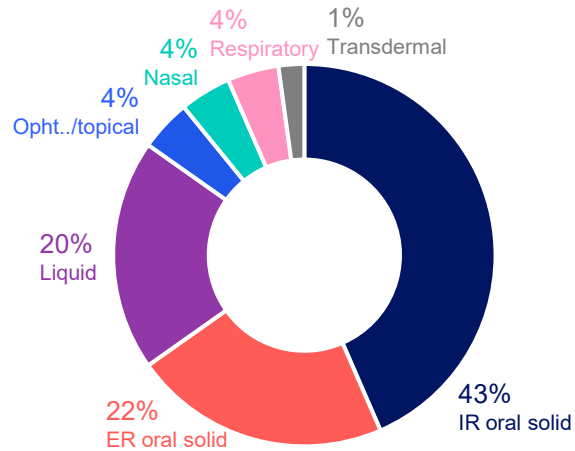
Key pipeline metrics

Development phase



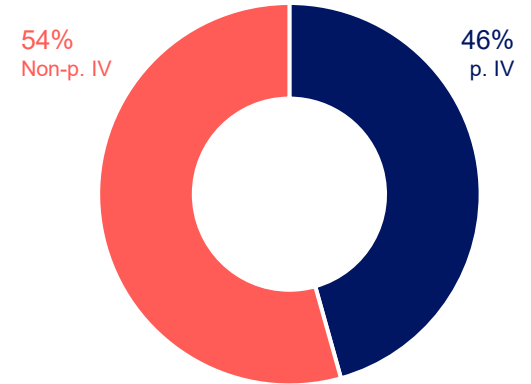
Pipeline being continually replenished; over half of programs are late stage

Dosage form



Over half of pipeline comprised of more differentiated dosage forms

Filing type



Balanced pipeline of p. IV and non-p. IV products

Attractive pipeline assets driving continued portfolio growth

Our disclosed pipeline programs

Specialty

Hikma product (market comparator)	Filing type (status)	Potential U.S. market size (\$m) ¹
Bilastine (2nd gen. antihistamines)	NDA (near-term filing)	~\$300 ²
Epinephrine (EpiPen[®])	505(b)(2) (development)	\$893 ³
Ryaltris[™] (antihistamines/steroids)	505(b)(2) (filed)	\$171 ⁴

Respiratory

Product (Innovator)	Filing type (status)	Potential U.S. market size (\$m) ¹
Ellipta[®] portfolio (GSK)	ANDA (development)	~\$1,970 ⁵
Partnered pMDI (undisclosed)	ANDA (approved)	>\$200

¹ IQVIA July 2021 MAT;

² Internal estimate, second generation antihistamine Rx + OTC market;

³ Total Viatris EpiPen/AG and Teva generic market;

⁴ Rx sales of monotherapy components and competing antihistamine/corticosteroid products (i.e., Dymista[®]/generics);

⁵ 2020 GSK reported U.S. Net Sales at 1.30 GBP-to-USD exchange rate;

⁶ 2020 Corcept reported Net Sales;

⁷ 3Q 2020 through 2Q 2021 Jazz reported Net Sales

Paragraph IV ANDAs

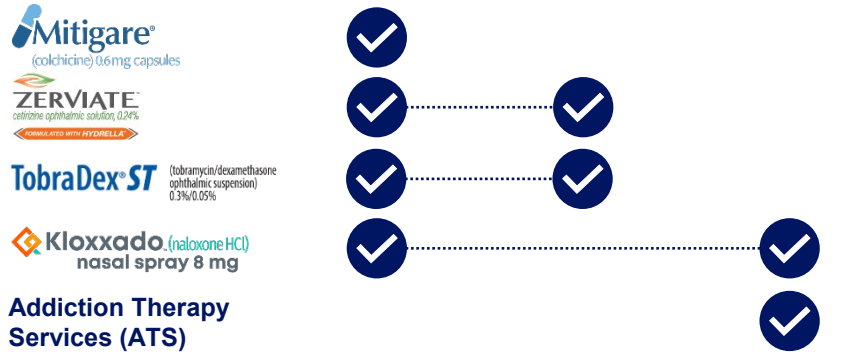
Reference listed drug (molecule)	Status	Potential U.S. market size (\$m) ¹
Fanapt[®] (Iloperidone)	Estimated launch 2027	\$153
Korlym[®] (Mifepristone)	Active litigation	\$354 ⁶
Noxafil[®] (Posaconazole)	Settled; estimated launch 2022	\$18
Nucynta[®]/Nucynta ER[®] (Tapentadol)	Estimated launch 2025	\$360
Revlimid[®] (Lenalidomide)	Active litigation	\$2,238
Vyvanse[®] (Lisdexamfetamine)	Estimated launch 2023	\$3,897
Xtandi[®] (Enzalutamide)	Settled; undisclosed launch	\$1,635
Xyrem[®] (Sodium oxybate)	Settled; launch by Jan 2023	\$1,157 ⁷

Building robust Hikma Specialty branded portfolio

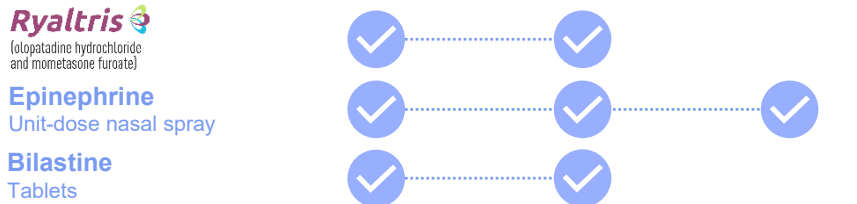
Hikma Specialty portfolio

Call points: Primary Care | Allergy / ENT | Community Health

Commercial



Pipeline



Infrastructure and growth strategy

- **Building upon strong foundation** with demonstrated success growing Mitigare[®], despite late entry into a challenging market
 - Well-established Primary Care field force and market access team
- **Expanding** into Allergy/ENT specialties and Community Health with attractive pipeline products that address established markets with key unmet needs
- **Actively investing** to grow Hikma Specialty organically and via partnerships
- **Synergies** with generics business reduce cost for overall division and allow for dual-channel lifecycle management (i.e., authorised generics)

Investing in differentiated respiratory franchise

1 Fluticasone/salmeterol DPI

- Successfully launched our generic Advair Diskus® in April 2021
- Steadily gaining market share

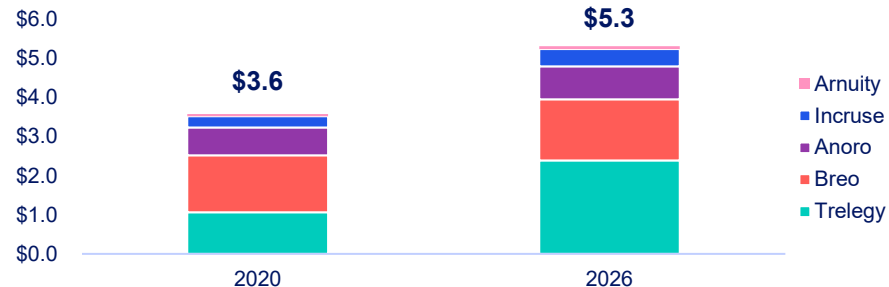


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2 Generic Ellipta® portfolio

- Collaboration with Vectura to develop AB-rated versions of at least three GSK Ellipta® products
- Leverages DPI development expertise and manufacturing capabilities
- Logical progression toward next generation of asthma/COPD inhalers with large addressable market

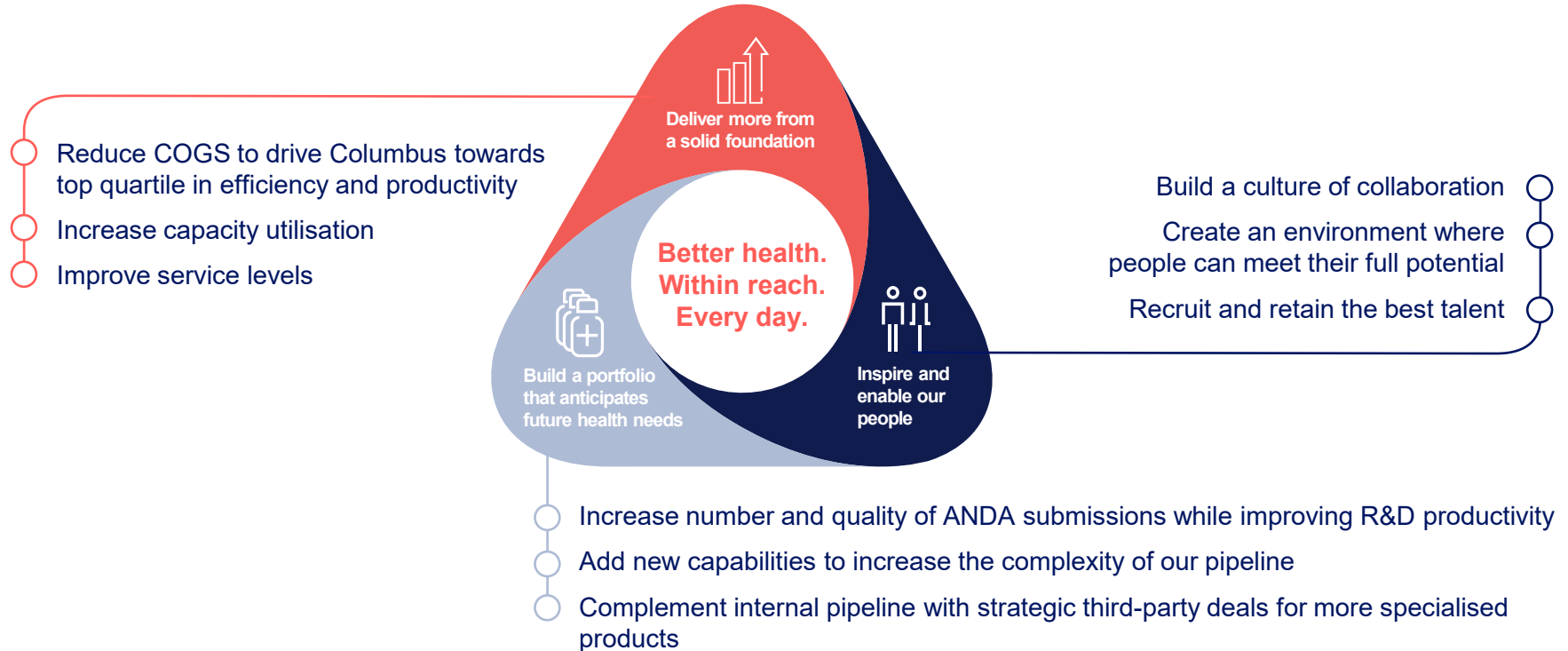
GSK Ellipta® portfolio (\$b)¹



- 3 **Complementary initiatives:** actively pursuing avenues to enhance the value of our DPI capabilities and capital investment, such as branded CDMO opportunities, product in/out-licensing, and international expansion

¹ 2020 GSK reported global Net Sales at 1.30 GBP-to-USD exchange rate; 2026 EvaluatePharma consensus
Hikma Pharmaceuticals PLC

Generics strategic priorities



Operations & Quality

Mike Balog
SVP Operations, Generics



World-class infrastructure supporting Generics development and manufacturing

Global capabilities

	U.S. (Columbus, OH)	Jordan (Amman, Sahab)
API		✓
Development	✓	✓
Manufacturing capabilities		
Oral solids	✓	✓
Oral liquids	✓	✓
Nasal sprays	✓	✓
Dry powder inhalers	✓	✓
Cytotoxic/high containment	✓	✓
Controlled substances	✓	✓
Antibiotics		✓
Warehouse/distribution	✓	✓

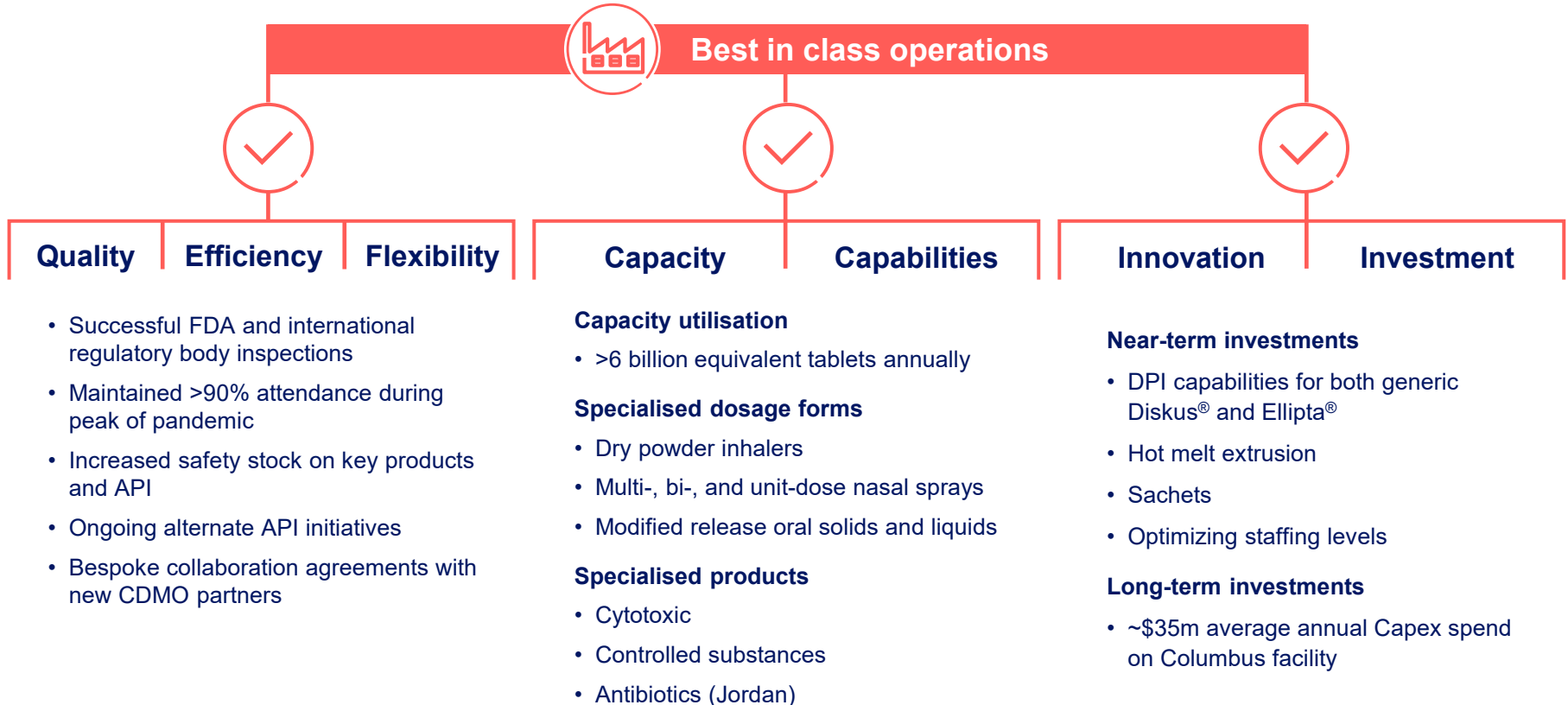
In addition, we have cephalosporin capabilities in Riyadh, KSA

Columbus, Ohio operations

- Leading US-based generic, contract, and specialty manufacturer
- ~1,200 employees
- Wide range of dosage forms, including solids, liquids, dry powder inhalers, and nasal sprays
- Excellent quality/compliance and supply continuity track record
- Flexible manufacturing approach with potential for expansion, allowing business to proactively seek new opportunities



Our comprehensive manufacturing capabilities



Quality is always our #1 priority

An uncompromising commitment to quality is engrained in our culture



Patients lean on us for Quality.

Our Quality Promise

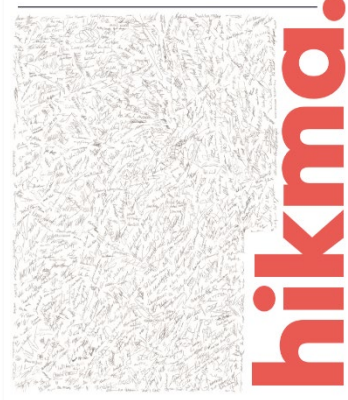
We create high quality medicines and make them accessible and affordable to people who need them.

To meet this commitment, Hikma places the highest priority on a quality-focused culture in order to ensure the safety, efficacy and reliability of our products. Quality is the responsibility of every Hikma employee and our management shares with each employee the need for quality awareness, honesty and integrity in performing a quality job at all times. Each employee is committed to ensuring product quality and patient safety.

We regularly review our performance to ensure we meet our high expectations of quality for our patients, customers, and stakeholders.

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Quality
We ensure that high quality defines everything we do, and is consistently delivered in all the communities we serve.



Training partner to educate and train new and existing FDA employees



Extensive track record of successful inspections from FDA and international regulatory bodies at four manufacturing sites



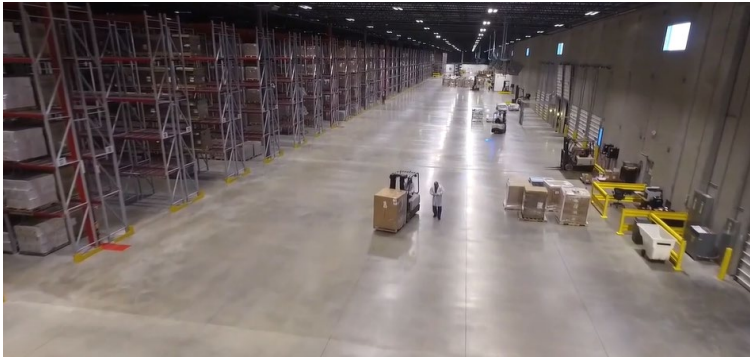
Customers and partners know the value they receive when selecting Hikma

Our in-house warehouse and distribution capabilities

Creekside (Columbus, OH) distribution center

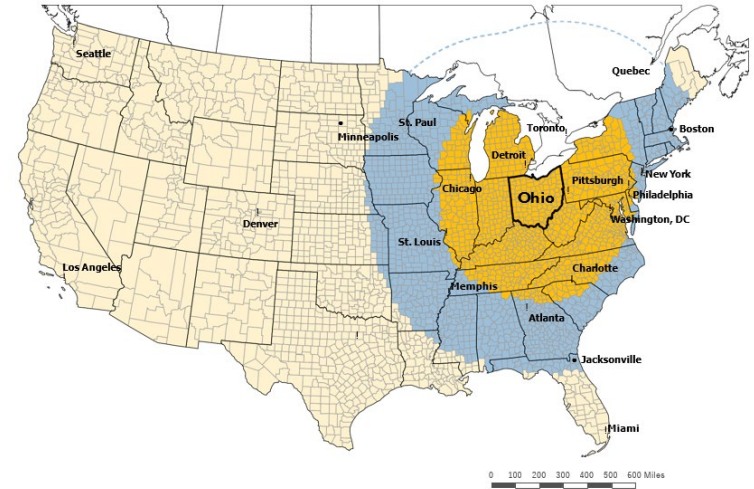
Greenfield site built in 2017 to consolidate U.S. warehousing and distribution; allows us to:

- Realise operational synergies across Generics and Injectables businesses
- Maintain high service levels
- Effectively manage inventory levels and product prioritisation
- Adapt to unforeseen circumstances (e.g., Covid)



Ideal location

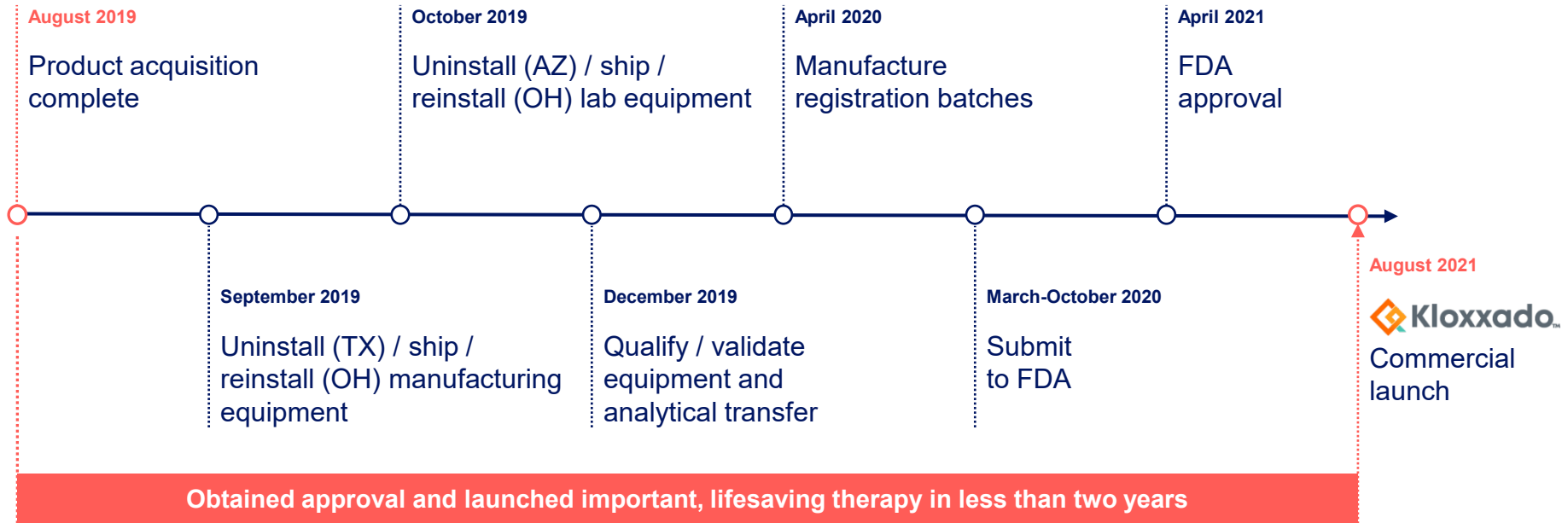
- Nearly 60% of the U.S. population is within 600 miles of Ohio¹
- Close proximity to key customers' national distribution centres
 - Cardinal: 2 miles away
 - Amerisource Bergen: 2 miles away
 - McKesson: Olive Branch, MS



¹ Ohio Department of Development, June 2019


Case study: Kloxxado™ acquisition through launch

Kloxxado™ (naloxone HCl) nasal spray 8mg timeline



Commercial

Kristy Ronco
Chief Commercial Officer, Generics

A woman with long dark hair and glasses, wearing a dark grey turtleneck, is writing on a whiteboard with a black marker. She is looking towards the right. In the background, a man in a white shirt is looking at her. The setting appears to be an office or meeting room with large windows and fluorescent lights.

Customer-centric go-to-market approach

Generics customer landscape

Buying consortia



Walgreens
Boots
Alliance



ClarusONE
Sourcing
Services

Econdisc
Contracting Solutions

Key relationships

Wholesaler:	• Cardinal	• Amerisource Bergen	• McKesson	
PBM/specialty pharmacy:	• OptumRx	• Express Scripts	• CVS caremark	• Express Scripts
Retail chain:	• CVS pharmacy	• Walgreens	• Walmart	• Kroger

- Buying consortia formed (2012-16) to leverage purchasing power to reduce generic drug sourcing costs
- “Big 4” control >90% of total U.S. generic drug purchases from manufacturers
- Increasing vertical integration and alignment between wholesalers, specialty pharmacies, PBMs, and retailers

Source: Drug Channels Institute

Hikma Pharmaceuticals PLC

Commercial infrastructure

Generics	Primary care	Allergy / ENT	Community Health
Base business	Hikma Specialty		
Dedicated	Synergies across division		
<ul style="list-style-type: none"> • VP Sales • National Account Directors 	<ul style="list-style-type: none"> • Manufacturing, Operations, Quality • Research & Development • Support functions (e.g., Regulatory, Legal, Finance) • Shared services (e.g., Contracts, Trade Operations) 		

Shared across Hikma Specialty

>100
Hikma
Specialty FTEs

- Leadership (VP, Head of Sales)
- Marketing
- Market Access
- Regional Sales Managers

Dedicated

- Field force

Dedicated

- Field force

Dedicated

- Field force
- MSLS
- Government alliances

Improving practices to become industry-leading supplier

● Focusing on the foundation

We have been successful by focusing on three key areas...



People



Processes



Systems

● Cross-functional coordination

In addition to new product launches, effective Sales & Operations Planning has led to optimal management of our in-line portfolio



Improving service levels



Improving customer scorecard ratings



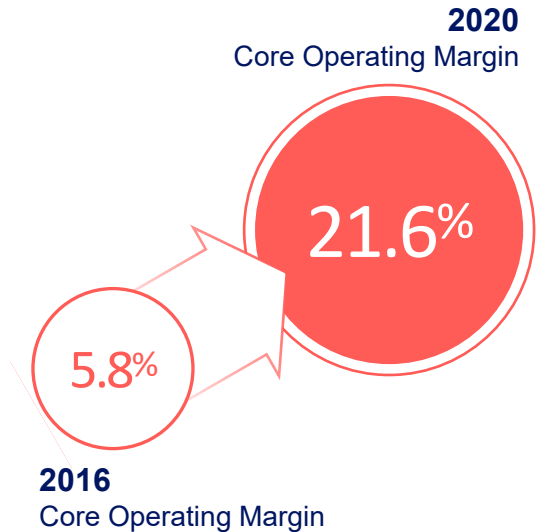
Reduction in number of products on backorder



Decrease in inventory reserves

● Delivering strong results

Impressive margin expansion in challenging environment




Bringing differentiated new products to market

● Everolimus (gZortress) tabs

Successful paragraph IV outcome, first to market with over one year as sole generic available

 Launch: **March 2020**

 Order of entry: **1st**

Strategic and tactical priorities going forward:

- Continuing to expand generic penetration
- Defending our business after second-wave generic launches

● Icosapent caps

Demonstrates ability to successfully litigate paragraph IV filings and bring difficult-to-source products to market¹

 Launch: **November 2020**

 Order of entry: **1st**

Strategic and tactical priorities going forward:

- Continuing to improve access to API
- Steadily increasing generic penetration and Hikma share

● Generic Advair Diskus[®]

Complex drug/device launch; crucial milestone in establishing broad respiratory franchise

 Launch: **April 2021**

 Order of entry: **2nd 2**

Strategic and tactical priorities going forward:

- Continuing momentum of recent contract awards
- Steadily increasing generic penetration

¹ Hikma's FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Hikma's product is not approved for any other indication for the reference listed drug VASCEPA[®]

² Second ANDA to market, not including GSK/Prasco AG

Kloxxado™ launch bringing important new product to patients and caregivers

Kloxxado™
addresses a major
unmet need

>93,000 deaths

number of Americans who died from drug overdoses in 2020¹, an increase of 32% on 2019

>30% of patients

require at least two actuations of 4mg naloxone nasal spray²

*“Today’s action meets another **critical need in combatting opioid overdose**. Addressing the opioid crisis is a top priority for the FDA, and we will continue our efforts to increase access to naloxone and place this important medicine in the hands of those who need it most.”*

– **Patrizia Cavazzoni, M.D.**, Director of the FDA’s Center for Drug Evaluation and Research

Commercial strategy

Pre-launch foundation: built incremental field force to support Community Health team

Dual-channel engagement: retail and public health channels require unique value propositions

Education: clinical experts support government and managed care discussions

Early adoption: value-based pricing and co-pay assistance



Addiction Therapy Services products

- Buprenorphine SL tabs
- Buprenorphine/naloxone SL tabs
- Methadone tabs
- Methadone oral solution



Hikma Community Health

Dedicated to providing a **holistic approach** to address **acute**, life-threatening events, as well as access to better **long-term** support products and services... **“rescue to recovery”**

¹ Centers for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Up 30% in 2020

² 2016 FDA Advisory Committee on the Most Appropriate Dose or Doses of Naloxone to Reverse the Effects of Life-Threatening Opioid Overdose in the Community Settings, Page 149

Wrap up

Brian Hoffmann
President, Generics



Leveraging our strengths to deliver sustainable growth



Our Strategy:

Operations



- Maintain **highest quality** standards
- Maximise **operational efficiency** and **capacity utilisation**
- Leverage **unique strengths** of Columbus and Jordan facilities

Commercial



- Continue to improve our reputation as a **leading, reliable supplier** and long-term partner
- Diversify our customer base and stay ahead of dynamic market trends

Pipeline development



- Increase **number and quality** of ANDA filings
- Invest in **high-barrier** technologies and dosage forms to **enhance complexity** of our pipeline
- Leverage **strategic partnerships** to supplement internal capabilities

Diversification & Expansion



- Increase portfolio of **differentiated generic** products
- Expand **Hikma Specialty** business
- Execute **inorganic opportunities** to accelerate growth

People & culture



- **Attract and develop** our employees
- Build **organisational effectiveness**
- Focus on **training and education**



Our priorities:

Revenue

Continual year-over-year growth

Launches

Achieve **10%** of revenue from new launches annually

Balance

Solidify base **generic** business while expanding **specialty** portfolio

Better health.
Within reach.
Every day.

Generics Meet the Management - Q&A

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