





# DR. REDDY'S LABORATORIES LTD 2015 INVESTOR DAY

MONDAY, 18-MAY-2015 HYDERABAD, INDIA

NYSE: RDY, NSE: DRREDDY, BOM: 500124, ISIN: INE089A01023

#### **Agenda**

**Setting the context: Generics:** GV Prasad, CEO and 25 mins 25 mins **Amit Biswas** Abhijit Mukherjee, COO **Proprietary Products: Biologics:** 25 mins 25 mins Cartikeya Reddy Raghav Chari **Aurigene:** 5 6 20 mins **BREAK** 30 mins **CSN Murthy** Q&A 60 mins

#### Safe harbor statement

This presentation contains forward-looking statements and information that involve risks, uncertainties and assumptions. Forward-looking statements are all statements that concern plans, objectives, goals, strategies, future events or performance and underlying assumptions and other statements that are other than statements of historical fact, including, but not limited to, those that are identified by the use of words such as "anticipates", "believes", "estimates", "expects", "intends", "plans", "predicts", "projects" and similar expressions. Risks and uncertainties that could affect us include, without limitation:

- General economic and business conditions in India, Emerging markets and other key global markets in which we operate;
- The ability to successfully implement our strategy, our research and development efforts, growth & expansion plans and technological changes;
- Changes in the value of the Rupee and other currency changes;
- Changes in the Indian and international interest rates;
- Allocations of funds by the Governments in our key global markets;
- · Changes in laws and regulations that apply to our customers, suppliers, and the pharmaceutical industry;
- · Increasing competition in and the conditions of our customers, suppliers and the pharmaceutical industry; and
- Changes in political conditions in India and in our key global markets.

Should one or more of such risks and uncertainties materialize, or should any underlying assumption prove incorrect, actual outcomes may vary materially from those indicated in the applicable forward-looking statements.

For more detailed information on the risks and uncertainties associated with the Company's business activities, please see the Company's Form 20-F for the fiscal year ended March 31, 2014, and Form 6-k for the quarters ended June 30, 2014, September 30, 2014, December 31, 2014 and its other filings with the Securities and Exchange Commission. Any forward-looking statement or information contained in this presentation speaks only as of the date of the statement. We are not required to update any such statement or information to either reflect events or circumstances that occur after the date the statement or information is made or to account for unanticipated events.

G V PRASAD

CHIEF EXECUTIVE OFFICER



#### Dr. Reddy's Today ...

- FY15 global revenues of \$2.4Bn. Well diversified across India, US, Emerging markets & Europe.
- Steady improvement in capital efficiency & productivity over the last five years.
- Excited about profitable growth opportunities in the future. Well placed to harness these opportunities.
- R&D driven strategy [spend at ~12% to sales]. 1200+ scientists involved in process & product innovation.
- Last three years characterized by sustained focus on Portfolio management, Operations excellence, Science & Technology capabilities and superior Commercial choices across markets.
- Strong visibility of realizing full potential of our Emerging businesses of Proprietary products,
   Biologics and Aurigene.

#### Our dialogue to be focused on:-

 Which are the identified areas in which we are investing for talent, infrastructure and technologies?

What are some of our early successes and milestones across the businesses?

How is our portfolio evolving to ensure superior value creation?

#### **Our Purpose**

# WE ACCELERATE ACCESS TO AFFORDABLE AND INNOVATIVE MEDICINES

# Our Purpose has guided our customer value propositions leading to specific strategic choices ...

#### **PURPOSE**

 We accelerate access to affordable and innovative medicines

#### **OUR PROMISES**

- Bringing expensive medicine within reach
- Addressing unmet patient needs
- Helping patients manage disease better
- Enabling and helping our partners ensure that our medicines are available where needed

#### **OUR STRATEGIC CHOICES**

- First-to-market, tough-to-make products
- Differentiated formulations for unmet medical needs
- Value added services for patients and customers
- Reliable & flexible supply chain

# These key strategic choices are core part of the priorities of each business

#### PURE GENERICS & APIs

Focus on first-to-market and tough-to-make products through flexible & reliable supply chain

#### **BRANDED GENERICS**

Deliver first-to-market & differentiated products in chosen therapy areas through a flexible supply chain while providing credible knowledge, innovative care and services to key stakeholders and patients

#### PROPRIETARY PRODUCTS

Improve patient outcomes by identifying unmet needs and addressing them through innovative products & services that are affordable and accessible in addition to providing credible knowledge to key stakeholders

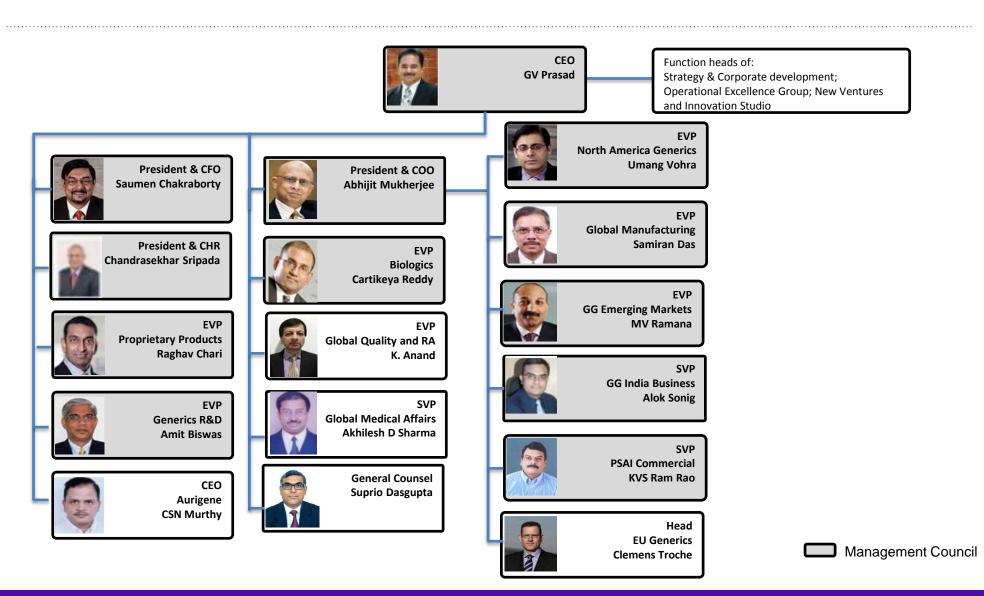
#### **BIOLOGICS**

Accelerate global access to high-quality and affordable biosimilars

#### **AURIGENE**

Collaborate with large Pharma and biotech partners addressing unmet needs in Oncology and Inflammation while building options for innovation based businesses in these therapeutic areas

#### Professional organization geared for growth

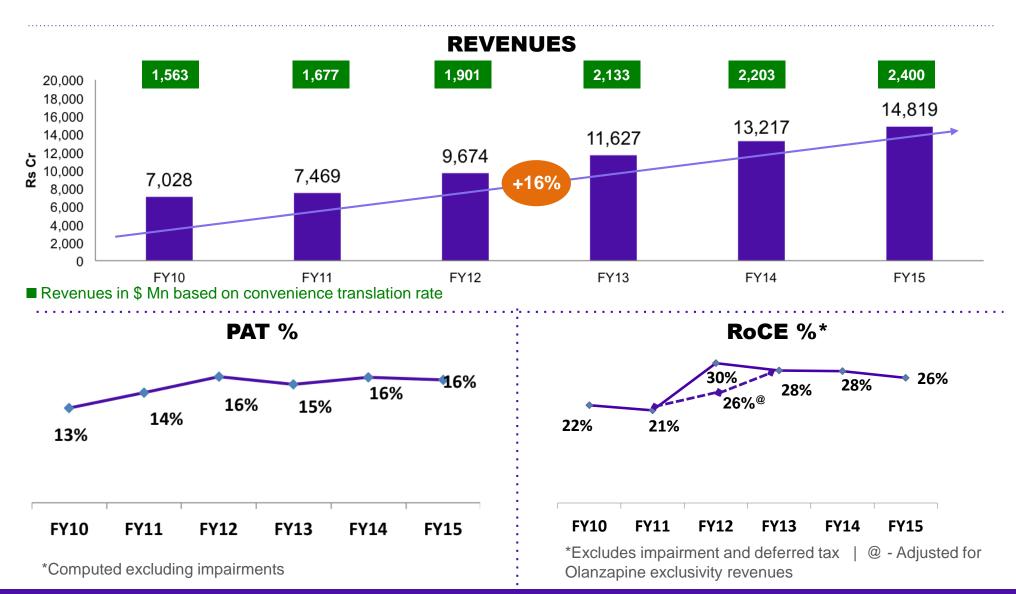


# We are known for our distinctive culture as well as strong people & governance practices

- Entrepreneurial and customer focused
- Culture of 'respect for individual' and 'empowerment to professionals'
- Structured processes for leadership development and talent management
- Mechanism to anticipate future requirements and build a bench of internal talent
- Strong succession slate.

- Continue to abide by high corporate governance standards. 14 years of NYSE listing compliance.
- Recognized by 'India's Best Managed Boards' award.
- Best in class financial reporting system supported by strong internal controls and risk management processes.

#### Our financial performance has been steady



#### In FY15, we achieved several important milestones

- US Generics crossed \$1Bn in revenues
- US Injectables business scaled-up to \$280mn+ in 3 years.
- Superior supply chain enabled strong market share gains in US and serviced significant scaleup in demand from Venezuela market.
- Improvement in global generics margins.
- High-quality pending ANDA pipeline. Increasing share of complex molecules.

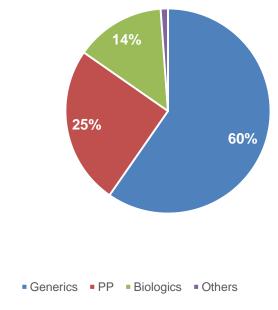
- Our new businesses of Proprietary
   products & Biologics are stepping closer to
   their desired milestones. PP filed 3 NDAs
   with the US FDA. Biologics phase-1 trials
   of Peg-filgrastim & Rituximab on track.
- Aurigene & Curis Inc.: Collaboration agreement focused on immuno-oncology and selected precision oncology targets.
- Continue to explore strategic Business
   Development and M&A as levers for
   growth: Habitrol in US and UCB's select
   portfolio in India

# 1

# RESEARCH & DEVELOPMENT

#### Our investments in R&D

#### FY15 spend of \$ 280 mn, 11.8% to sales



- Compared to FY11, reduction in CoGS and SGA as percentage to sales by 7 % → result of sustained cost management initiatives, portfolio momentum, operating leverage and currency benefit
- Deployed 5% from these savings into R&D to capture opportunities for organic growth across markets
- Current thinking largely shaped by unconstrained development subject to capability and validated business case

# Over the past 5 years, we have built strong R&D capabilities across all businesses and increased the focus towards Biologics & Proprietary products development

#### **GENERICS**

Head, Amit Biswas, Ph.D

•	Generics	40E0 <b>B</b> 40CC
•	API	1050 🕨 1066

Qualification	Head-Count
Graduate	151
Post-graduate	772
PhD	143
Total	1066

#### **BIOLOGICS**

Head, Cartikeya Reddy, Ph.D

400

540

**Biologics** 

Qualification	Head-Count
Graduate	156
Post-graduate	324
PhD	60
Total	540

#### PROPRIETARY PRODUCTS

Head, Raghav Chari, Ph.D

<ul><li>Differentiated Products</li><li>NCE Research</li></ul>	66 🕨 160		
Qualification	Head-Count		
Graduate	1		
Post-graduate	138		
PhD	21		
Total	160		

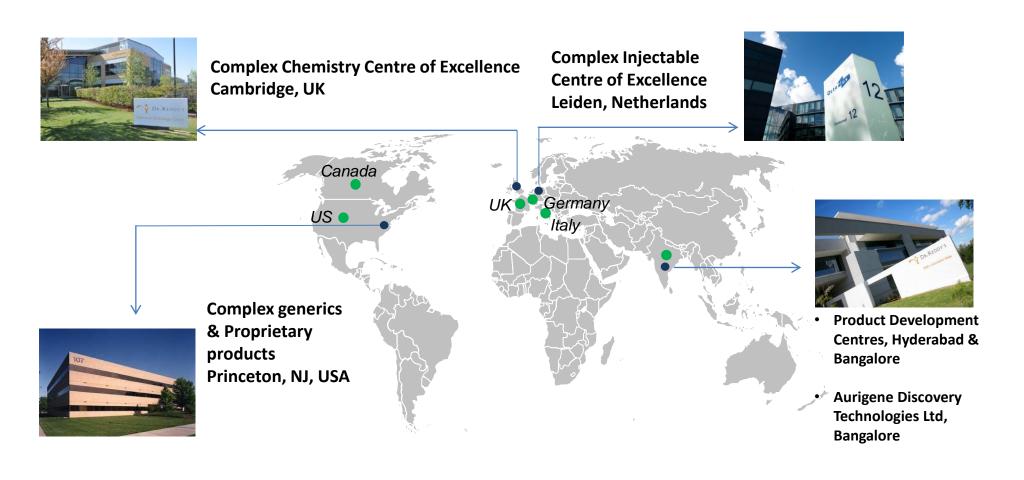
#### **AURIGENE**

Head, CSN Murthy

<ul> <li>Discovery Stage products</li> </ul>	428
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Qualification	Head-Count
Graduate	-
Post-graduate	351
PhD	77
Total	428

#### **Expanding R&D Footprint ...**



External partners

#### .... supported by a number of external partnerships



- Access to niche technologies through a wide network of strategic partners across the globe
- Dedicated co-development team to synch the efforts, project-manage the partner capabilities and ensure strong governance

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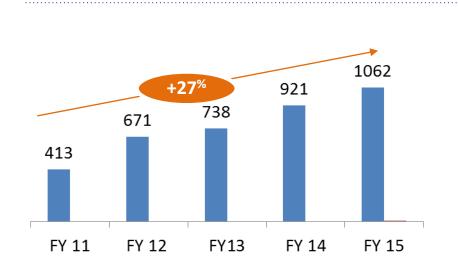
#### **UPDATE**

### ON KEY MARKETS

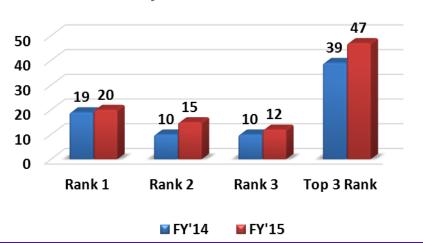
ABHIJIT MUKHERJEE
CHIEF OPERATING OFFICER



# North America Generics: Strong base, well poised for growth



#### **DRL Top 3 Rank molecules**

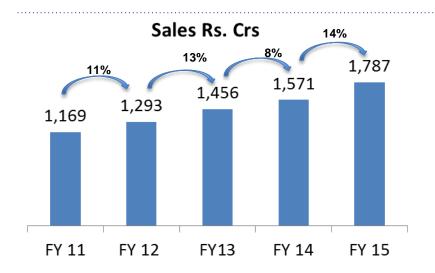


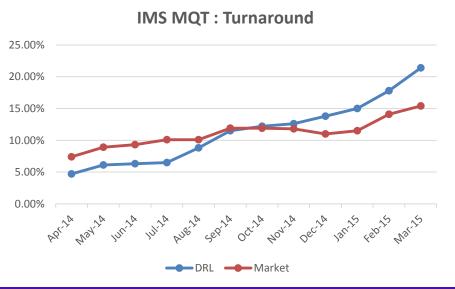
- First \$500mn took 15 years; then to \$ 1 billion in next 5 years.
- 9<sup>th</sup> IMS rank based on MAT data. 47 molecules in top 3 ranks.
- Balance of 'market share gains' with 'optimal pricing'
- Delivery of consistently high service levels
- Scaled-up the injectable business.
- Value generated per asset steadily increasing

## We have shown commendable commercial success from the complex generics and limited competition opportunities

PRODUCT	ORDER	# OF Gx PLAYERS	SHARE %	PATIENTS TOUCHED / YEAR
FONDAPARINUX	First to market	Two	51%	130,000+
AZACITIDINE	First to market	Two	60%	4,000+
DECITABINE	First to market	Three	83%	13,000+
LAMOTRIGINE XL	2nd Generic in market Two		34%	17,000+
SIROLIMUS	First to market	Two	15%*	2,000+
SUMA AUTO INJ	3 <sup>rd</sup> Generic in market	Three	24%	35,000+
ZIPRASIDONE	First to market	Six	43%	80,000+
VALGANCICLOVIR	2 <sup>ND</sup> Generic in market	Two	59%	10,000+

#### India: consistent outperformance in recent quarters





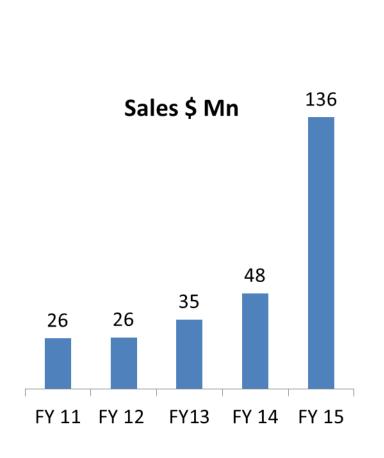
- Turnaround on the back of
  - Focused sales & marketing efforts on mega brands
  - Improving new launch productivity
  - Scale-up in institutions sales
- Deep focus on Chronic and Super-specialty therapies
- Strategic business development and M&A efforts
  - Differentiated assets in relevant therapies
  - Growth through inorganic opportunities

# Russia: deep and strategic presence. Committed to deliver sustainable long-term growth.



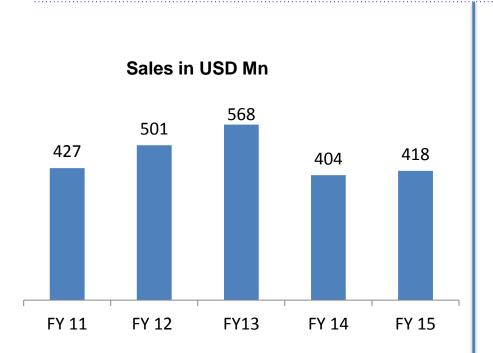
- Established strong presence in Pain
   Management, Gastro Intestinal and Anti-infectives
   therapies
- Top 5 brands occupy the No. 1 spot in their respective INNs and 12 brands in the top 3 ranks
- · Increasing mix of OTC sales.
- A number of products launched through BD efforts
   converted into mega brands

# Venezuela: fastest growth across all companies in both units and value



- Committed to the market to ensure availability
- Economic turmoil → an opportunity to stay invested in the market and strengthen the base for future
- Ranked 20th in value terms and 12th in unit terms, which clearly highlights our endeavor to provide affordable medicines to patients
- A balanced portfolio across therapeutic areas of Cardio-Vascular, Central Nervous system, Anti-Infectives and Oncology

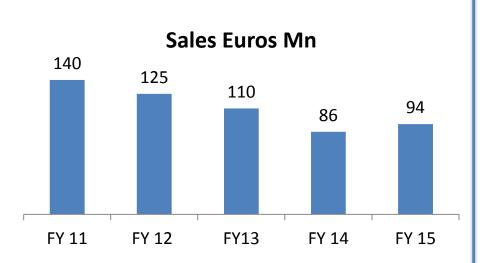
# PSAI: strong connect with large generics customers. Focus on maximizing internal value creation.



- Effective partnerships with top global Generics players: ~40% of sales contributed from global top 5 players
- >60% of Global Generics segment's sales from the vertically integrated APIs
- Focus on partnership model for Emerging Markets

 Development and manufacturing of API provides a sustainable and distinctive competitive advantage to Global Generics business

#### **Europe Generics**



- Made a conscious shift away from large singlewinner tenders
- Transitioned to a lean and cash-positive model
- Launched high-value & limited competition assets i.e. Rivastigmine patch, Pregabalin and Aripiprazole
- Future growth based on oncology and hospital platform

# There is significant ongoing collaboration across businesses

#### **Market/ Commercial collaborations**

US Emerging Markets

- Complex generics leverage to Russia, CIS, Venezuela
- Drive market expansion to Latin America
- Expand potential in China

India Emerging Markets

Bio.

- Leverage India BD deals to Emerging markets
- Launches of biosimilars in India and EM

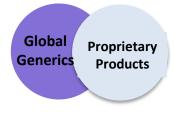
US Proprietary Products

 Overlap between Complex generics and Proprietary Products Assets

#### **R&D** collaborations

Bio. Global Generics

- Characterization of complex molecules
- Purification technologies



 Differentiated products for India & EM

AMIT BISWAS

EXECUTIVE VICE PRESIDENT, GENERICS R&D



#### **Key questions**

1 How is Dr. Reddy's Generics R&D distinctive?

- What are some of our major successes?
- What outcomes can we expect from our efforts in this direction?
- How do we see the R&D efforts evolving in the future?

What makes Dr. Reddy's Generics R&D distinctive?



Robust portfolio selection

Sustainable, winning partnerships

Deep capabilities

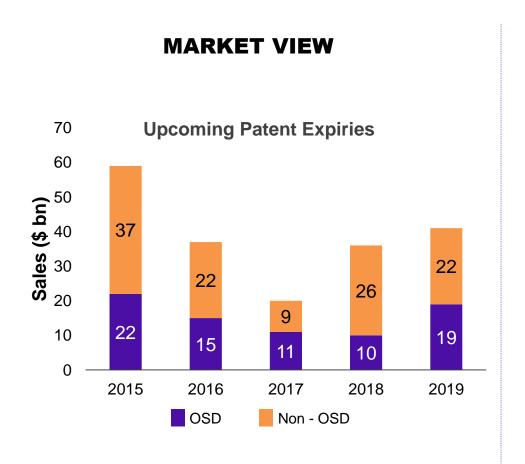
World class infrastructure

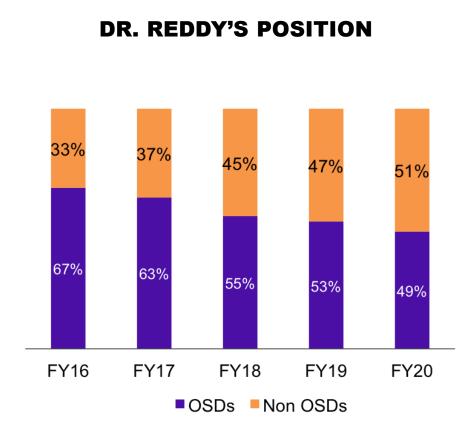
# Our portfolio philosophy has evolved along multiple dimensions

	FROM	то			
Formulations / dosage forms	Primarily simple oral solids based products	<ul> <li>Complex OSDs (extended release, multilayers), Injectables (liposomal, microspheres, RTUs) and Derma (Gels, topicals, patches).</li> </ul>			
API type	Synthetic APIs or Simple chemistry	<ul> <li>Strong position in novel crystalline and amorphous forms</li> <li>Semi-synthetic APIs, Chirals, Prostaglandins, Peptides Carbohydrates and nano-particle based products.</li> </ul>			
Analytical characterization	Requiring simple chemical equivalence and physical parameters affecting solubility and permeability	Requiring advanced physico-chemical and biological characterization such as particle morphology, sequencing, secondary and tertiary structures			
Bio-equivalence	Comparable to innovator drugs using in-vitro bioequivalence or simple pharmacokinetic studies in healthy volunteers	<ul> <li>Complex pk / pd studies with ability to manage bio-variability</li> <li>Added tools to build predictability from in-vitro to in-vivo</li> </ul>			
Process Engineering	<ul><li>Established processes</li><li>Eg: Scale up of Oral Solids</li></ul>	<ul> <li>Advanced Particle engineering solutions and complex scale ups.</li> <li>Eg: Microsphere and liposomal technologies</li> </ul>			
Marketability	Primarily based on PIV / FTF type opportunities	<ul> <li>Complex products/dosage forms requiring differentiated 'go to market' approaches.</li> <li>Multiple 505(b)(2) products</li> </ul>			

# Conscious shift in the product-mix in line with opportunity canvas

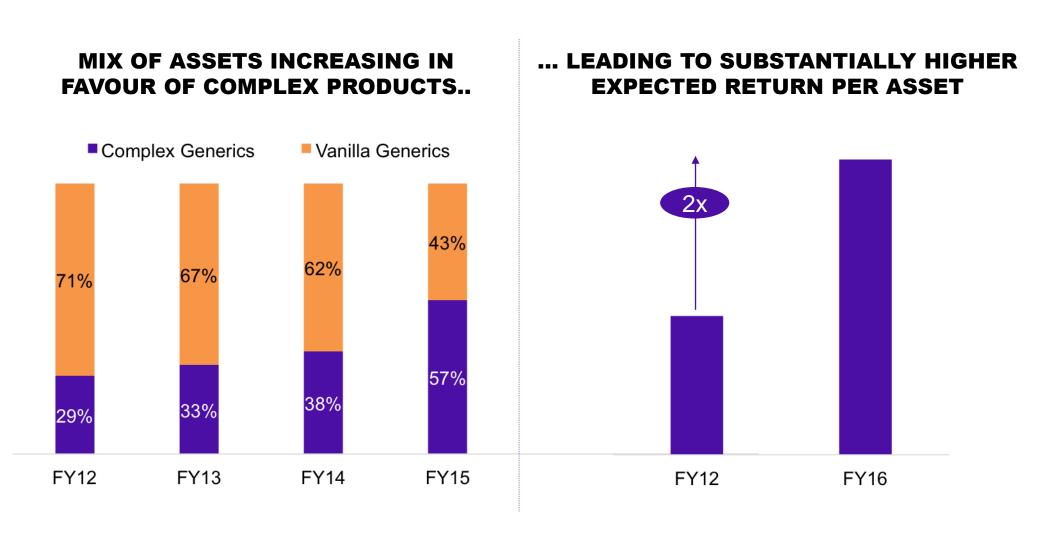
Over the next 5 years, non-OSDs will contribute ~ 50% of the value\*





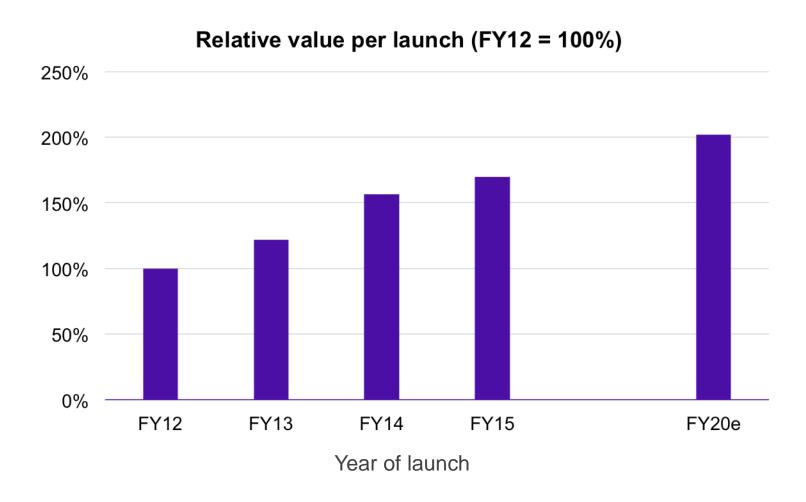
Source: IMS, Public documents

# Our development pipeline is further expected to enhance value\*



#### We are preparing for a string of high-value launches\*

#### Average sales value of our US launches continues to increase consistently



#### Secured synergies between API and Formulations

Value in multiple successful launches has been driven by leveraging our advanced inhouse API R&D capabilities

Generic Name	Brand Name	Brand Sales *	# of Gx Players	Our Market Share (Mar '15)	API Capabilities leveraged
Decitabine	Dacogen	251	3	83%	Oncology API
Azacitidine	Vidaza	380	2	60%	Oncology API
Amlodipine- Atorvastatin	Caduet	340	4	18%	Novel Form API, Supply Flexibility
Fondaparinux	Arixtra	340	2	51%	Complex Pentasaccharide API
Ziprasidone	Geodon	1,340	6	43%	Polymorph Play, Obtained FTF

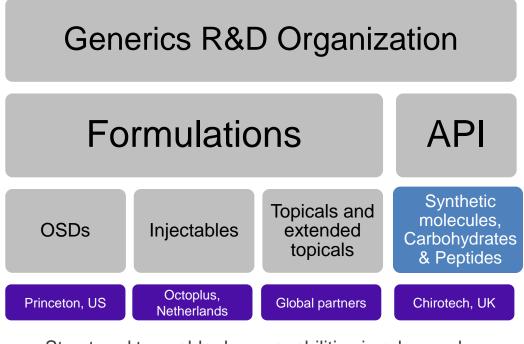
Our current API portfolio is well positioned to drive value in our Global Generics business

APIs Under Development



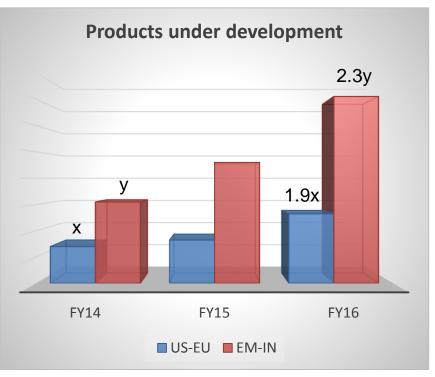
<sup>\*</sup> Annual sales in the year of Launch (\$mn)

### We have organized R&D around four verticals ...



- Structured to enable deep capabilities in advanced products in each dosage form
- Enables collaboration and integration with our global R&D network and partners

In addition to deepening our expertise, this has also helped us expand our development pipeline



<sup>\* -</sup> Support functions include Intellectual Property, Regulatory Affairs, Development quality assurance, Biostudies

### ...and we are building strong capabilities

#### **COMPLEX CLINICAL TRIALS**

- Significant increase in the number of clinical-trial based assets
- Deep engagement in protocol finalization, site Selection and monitoring

## COMPLEX SCALE UP / TECH TRANSFER

- Multiple scale up batches with different batch sizes for process optimization
- Smooth process transfer between formulation scientists and chemical engineering teams
   Eg: Sirolimus

## ADVANCED DEVICES AND PACKAGING

- Building world class inventory of Non-Infringing devices to support future portfolio for injectable & respiratory products
- Aided by strong supply chain and manufacturing systems
- Eg: Isotretinoin, Sumatriptan Auto Injector

#### **REGULATORY FRAMEWORK**

- Improving the connect and quality of dialogue with regulators
- Taking innovative approaches on regulatory matters to stay ahead of competition E.g. Azacitidine

# In Oral solids, we have successfully solved challenges for several complex assets

#### Formulation complexity

#### **Divalproex ER**

- Efficient handling of manufacturing scale-up challenges
- Secured high market share even after being a late entrant to the market

#### **API** complexity

#### **Fexofenadine**

- High degree of API process complexity
- Fortified non-infringing positions on multiple process patents

#### **IP** complexity

#### **Ziprasidone**

- API polymorph play
- Launched as a shared exclusive product

#### **Bio-equivalence**

#### **Omeprazole**

- High bio-variable drug with challenging fed- state biostudies
- Sustained meaningful revenues over several years

#### **Process Engineering**

#### Metoprolol

 Highly complex product with a 7-layer coating process

#### Go to Market

#### Isotretinoin

- REMS program working as a barrier for entry
- Use of our Promius team to promote the branded product

## .... same is true in Injectables & Soft gels

#### **Formulation complexity**

- Will be filing our first drugdelivery based injectable soon.
- Overcame complexcharacterization and sameness related hurdles

#### **API** complexity

#### **Fondaparinux**

- Complex pentasachharide
- A number of purification steps to reach ICH guidelines.
- Highly sensitive analytical method

#### **Analytical complexity**

#### **Azacitidine**

- Established sameness of Viscocity, Osmolity and pH with innovator drug.
- Complex in-vitro characterization to prove sameness of particle size and morphology.

#### **Bio-equivalence**

#### Soft gel product

- Clinical trial study in ~ 900 patients
- ~ \$ 350 mn of brand sales

#### **Devices**

#### Sumatriptan

Auto Injector Device

#### **Go to Market**

#### **Zoledronic acid**

 First wave successful launch with label carve out

# Injectables: at advanced stage on multiple platform technologies

	# Current Pipeline	# Future Products	Addressable Market /Brand Sales	Key developments
Microspheres	2	2	\$ 2.5 bn	Full Integration of     Octoplus synergies     with Global injectable     platform completed
Liposomals	2	1	~ \$ 1.0 bn	<ul> <li>Two near term filings i.e. One each in FY'16 and FY'17</li> </ul>
Particulate Syste	ems 2	2	~ \$ 2.0 bn	<ul> <li>Early POC work through academic partnerships</li> </ul>
Ready-to-Use	4	Multiple	~ \$ 3.1 bn	<ul> <li>Four near terms filings, working on 505b(2) approach on a large number of candidates</li> </ul>

## ... similarly for Topicals, Soft gels and Respiratory

_	# Current Pipeline	# Future Products	Addressable Market /Brand Sales	Key developments
Derma				
	7	>5	~ \$ 3.5 bn	<ul> <li>Filed Three ANDAs in FY'15</li> </ul>
Transdermal	3	1	~ \$ 1.9 bn	<ul><li>Two patches filed till date</li><li>Acquisition of Habitrol</li></ul>
Soft gels	3	3	~ \$ 1.0 bn	<ul> <li>Commercialised         Isotretinoin in US         both as a branded         and generic product     </li> </ul>
Respiratory	3	2	~\$ 3.0 bn	<ul> <li>Launched Levalbuterol</li> </ul>

## Semi-synthetics: our play in the \$ 10 billion space

#### **Technologies**

## Bio-catalysis & Chemo-catalysis

#### **Pegylation**

Complex, Fermentation & Recombinant technology- based products

Semi-synthetics & Peptides

#### **Use/Infrastructure**

- To generate Chiral and achiral building blocks in API synthesis.
- Leveraging Chirotech capabilities
- To generate pegylated bio-similars and pegylated APIs.

- Dedicated Kilo lab.
- Strong business rationale for Fermentation technologies.

Oligonucleotide synthesis capability.

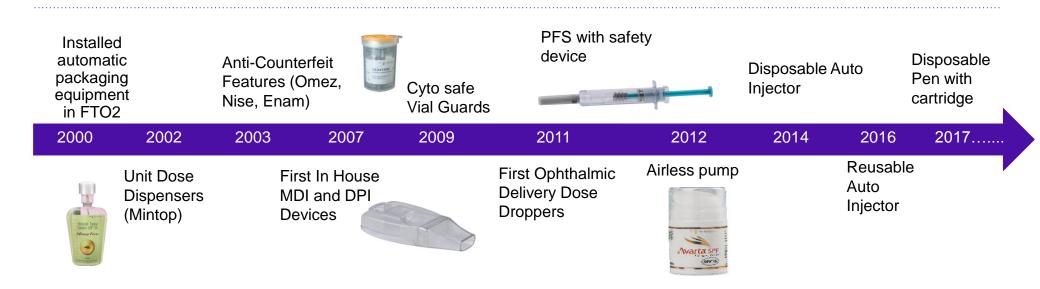
## **Emerging Markets & India: Leveraged Filings**

#### Number of leverage filings



- FY'16: 100+ NA/EU leverage filings
- FY'15 achieved: 60 NA/EU leverage filings
- Majority of leverage comes from Injectable and OSD pipeline
- FY16 Injectable leverage filings is key to entry into new EM markets
- Three reasons that leverage is more viable now than 3 years back:
  - Global development with R&D, manufacturing capability going up
  - Products going off-patent are more related to lifestyle diseases
  - Innovator maturity on patenting led to similar patent scenario across global markets

## Continue to hone our capabilities in drug device combinations



#### Future... Developing Capabilities in Injectable and Inhalation Space

- Developing deep capabilities in drug device combination products in space of Injectable (AI and Pen Systems) and pMDIs
- Cost of each device development ~ \$ 3-4 mm
- Developing key strategic partnerships for devices





## Infrastructure investment has enabled multiple complex assets

#### **KEY CASE STUDIES**

Advanced
Characterization
Capabilities

#### **Azacitidine**

- Used Advanced Characterization methods to prove particle size & morphology
- Proved Physico-chemical equivalence

#### Glatiramer:

Filed the injectable drug for relapsing multiple sclerosis

Implementation of Process Analytical Tool

- Characterization and in-process control for extended release oral solids
- In-process monitoring of chemical reactions

Advanced Topical Development Capabilities

- Advanced PK & complex CT studies for patients
- Reverse Engineering capabilities

## Built a thoughtful co-development agenda

#### **OUR EXTERNAL PARTNERSHIPS ARE...**

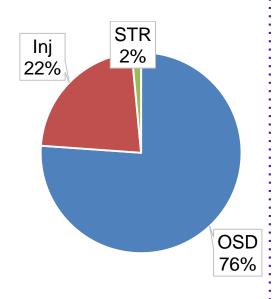
- Selectively contracted to accelerate access to new technology platforms and dosage forms, e.g.
  - Transdermal Patches
  - Inhalers
  - Controlled Substances
- Designed to leverage our complimentary capabilities
- Long-term in outlook

We are currently working with 25+ partners on 12+ dosage forms on the pipeline addressing > \$10 bn of brand value

# Complex products now make up about half of our filed generics portfolio

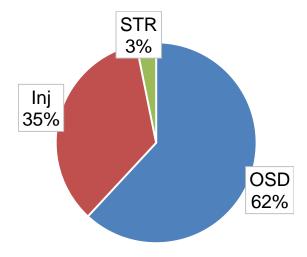
#### Mar 2011

76 pending ANDAs with 37% complex products



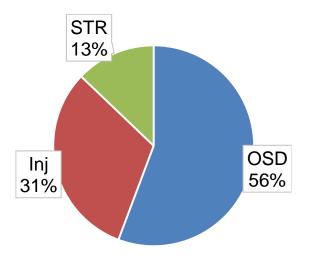
#### Mar 2013

65 pending ANDAs with 38% complex products



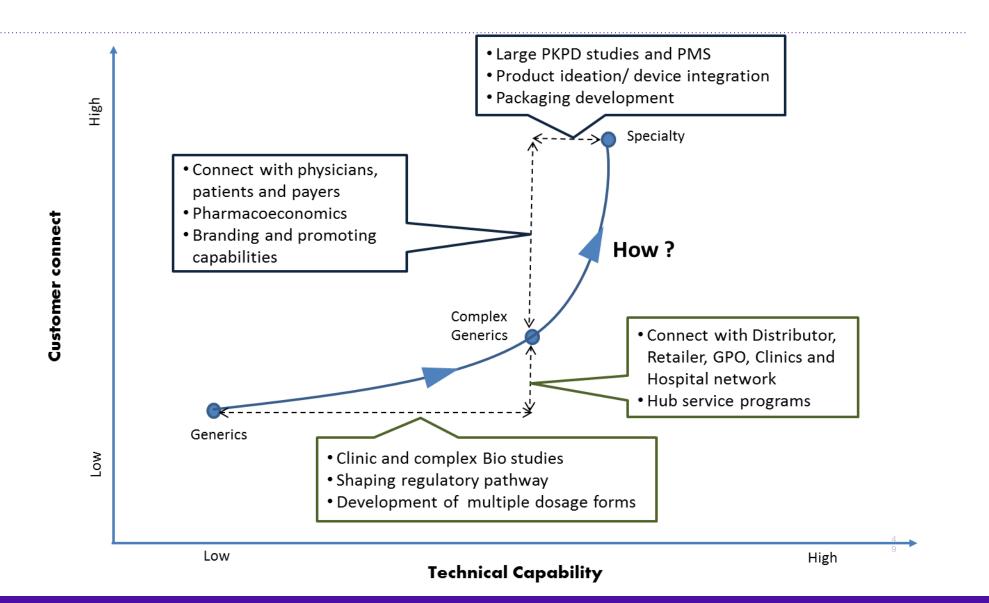
#### Mar 2015

68 pending ANDAs and 3 pending NDAs (505b2s) with 51% complex products



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### **Evolving journey**



## **In Summary**

 We are committed to investing in products with high barriers of entry and thereby fueling strong organic growth in the coming years.

 Our deep technical capabilities, world-class infrastructure and winning external partnerships ensure a design-for-success in Generics R&D.

 While there will always be learnings as we move forward, the early commercial successes give us enough conviction about our roadmap and future trajectory.

CARTIKEYA REDDY
EXECUTIVE VICE PRESIDENT, BIOLOGICS

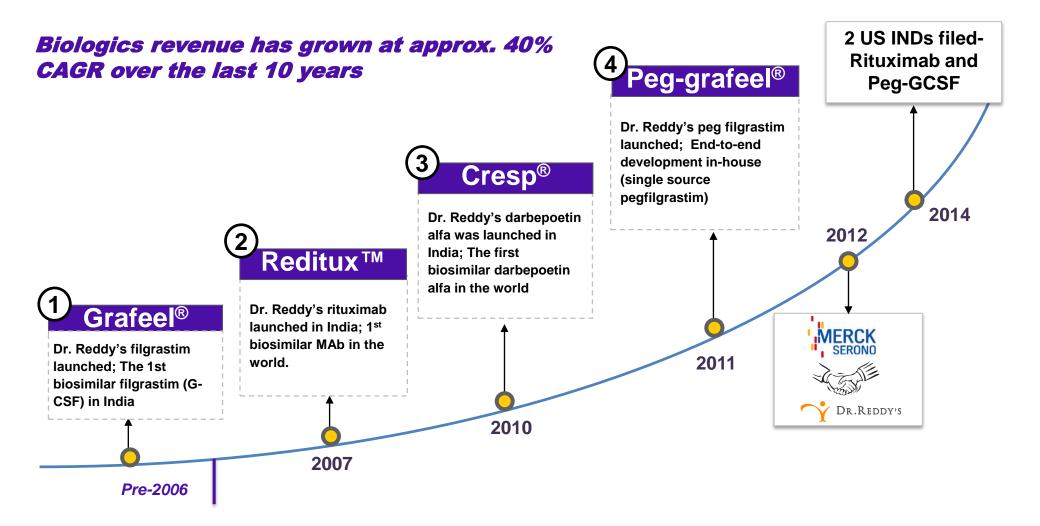


### **Biologics FY16 – FY20**

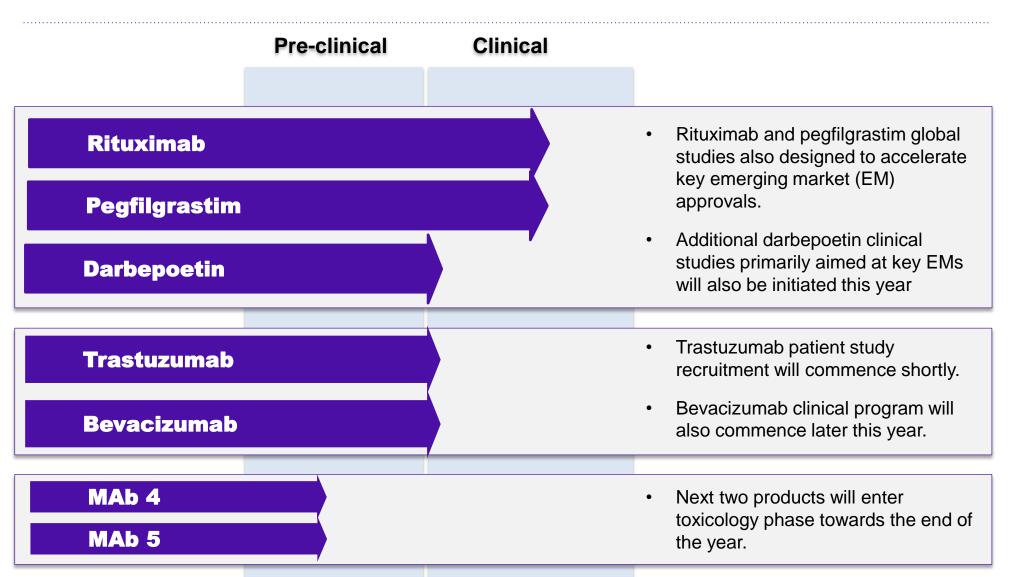
- 1. Maximizing value from current assets in the near to mid-term while pursuing global development
- 2. Creating substantial value in the long term from new portfolio choices while driving R&D productivity

Maximizing value from current assets in the near to mid-term while pursuing global development

## Biologics Today: 4 Biosimilars commercialized in Emerging Markets with 2 INDs filed with US FDA



## Comprehensive Portfolio including two additional Oncology Antibodies entering Clinical Development



## End-to-End Capabilities and Integrated Organization connecting Hyderabad, Basel and Princeton

## Product Development

- State-of-the-art technology in cell line and process development
- Significant advances in analytical and bio-analytical capabilities

## Clinical Development

 Extensive experience with complex healthy volunteer and patient studies both for emerging and developed markets

#### Regulatory

First-hand experience with all key regulatory agencies including EU and US

#### **Manufacturing**

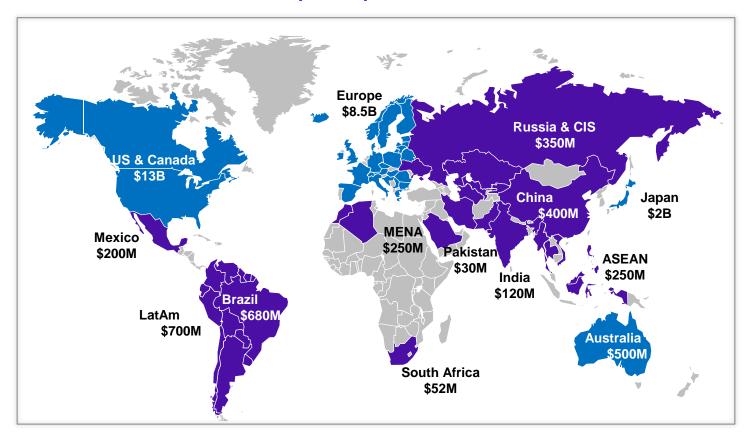
- Consistent manufacturing and quality track record; successful audit history
- Multiple successful technology transfers to partners

#### **Commercial**

- Significant presence across EMs including select strategic partnerships
- Strategic partnership with Merck Serono for multiple markets

## Very Significant Opportunity for our Portfolio across Emerging and Developed Markets

- 2014 Market Size of Our Current Portfolio\* in EMs is approximately \$3B and in DMs is approximately \$25B
- Significant increase in volume and value expected post biosimilar launches in EMs



Emerging Markets Regulated Markets

<sup>\*</sup> Only includes products that are currently commercialized and those in late-stage development (Rituximab, Pegfilgrastim, Darbepoetin, Trastuzumab and Bevacizumab)

## Combination of Strategic Partnerships and Direct Presence across Key Regions

## **Current Market Opportunity (FY2014)** India **\$120M** Russia & CIS **\$350M** LatAm & Mx **\$900M MENA \$250M ASEAN** \$250M

China

**Global** 

- In-depth understanding of commercial dynamics in all key countries
- However, regulatory dynamics are still maturing

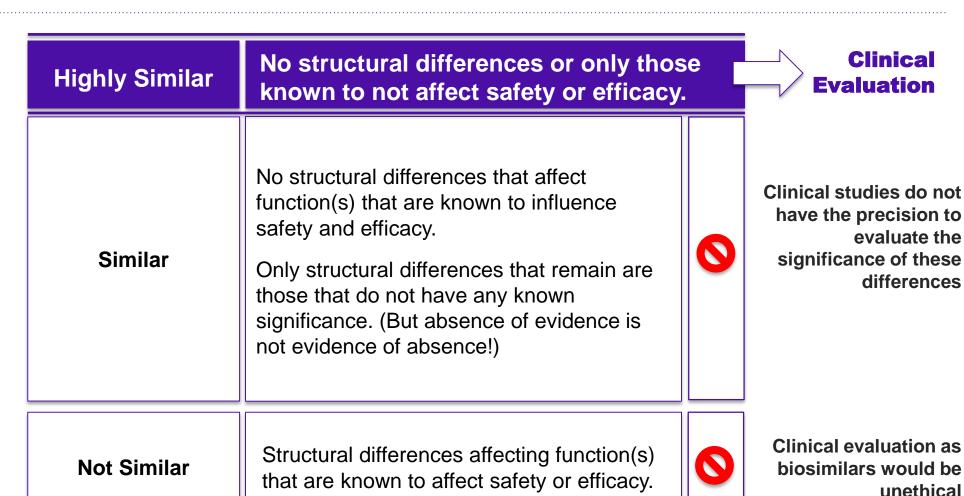
 Global partnership with Merck Serono for part of the portfolio

DR. REDDY'S 2015 INVESTOR DAY

\$400M

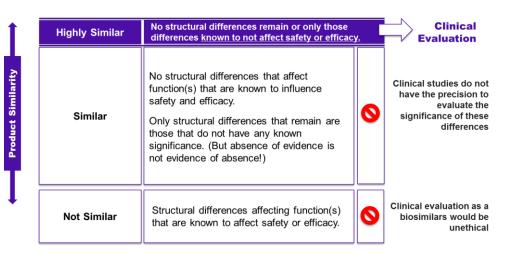
\$25B

## Regulatory Expectations in Developed Markets are Clear & Consistent (while remaining onerous!)



## Development aimed at both Emerging and Developed Markets Mandates a Highly Similar Product

Each of our products today and all new products will meet these criteria.



- This establishes a <u>scientifically</u> <u>sound regulatory basis</u> for a confirmatory clinical evaluation.
- 2. Adaptive study designs facilitate preliminary assessments while allowing for the continuance of a study towards more robust end-points.
- Clinical studies designed with the benefit of deep product understanding can significantly reduce cost and timelines.
- 4. However, approval-enabling studies for developed markets are likely to remain expensive and time-consuming.

## Targeting Emerging and Developed Markets: Key Aspects of our Strategy

Product Quality

One Product. One Quality.

Clinical Evaluation

Integrated clinical development programs serving both emerging and developed markets.

The level of R&D spends for developed markets coupled with commercial uncertainty means that partnering remains a key risk-sharing strategy.

#### **FY20 View of Current Portfolio**

R Rituximab Pegfilgrastim D Darbepoetin Trastuzumab B Bevacizumab





**FY16 – 17 Filings: (P) (D)** 

**FY17 – 19 Filings: (T) (B)** 



US, EU

China

All Products in Development First Wave of Launches

## Creating substantial value in the long term from new portfolio choices while focusing on R&D productivity

## Next Wave of Portfolio choices will build on our Strengths

- 10 Molecules in Evaluation, Pre-development Stage
- Cumulative Market Size = \$37Bn
- 2 Molecules will move into active development in FY16

#	Molecule	2014 Sales (\$B)
1	Adalimumab	12.5
2	Cetuximab	1.9
3	Infliximab	9.2
4	Ustekinumab	2.1
5	Tocilizumab	1.4
6	Denosumab	2.3
7	Aflibercept	2.8
8	Pertuzumab	1.0
9	Abatacept	1.6
10	Omalizumab	1.6

#### Rationale for Selection

- ✓ Therapeutic area of focus
- ✓ High Emerging Markets potential
- ✓ Patent expiry in regulated markets

Given the rapid expansion in the originator biologics portfolios and pipelines, the ability to scale R&D productivity is critical.

### **R&D Productivity is Influenced by Two Major Factors**

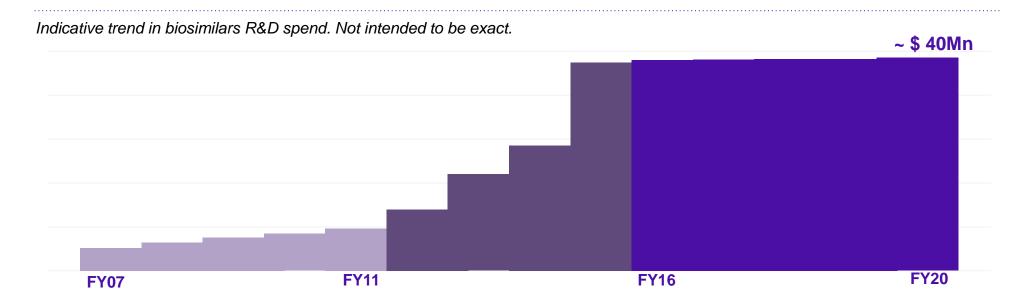
Product
Development,
Manufacturing

Minimizing cycle time from development initiation to robust manufacturing processes producing highly similar molecules

Clinical **Development** 

Cost-effective design and execution of complex, adaptive multi-center clinical designs

### **Understanding Biosimilars R&D Productivity**



#### **FY07 - FY11**

**EM-focused development of 4 products** 

#### **FY11 - FY15**

Building a global development approach, capabilities Bridging 4 legacy products; 2 products under IND 2 additional products entering clinical development

#### **FY16 - FY20**

Continued progress on current portfolio of 6 products

**5 new products entering clinical development** 

5 additional products in preclinical stages

### **Biologics FY16 – FY20**

- 1. Maximizing value from current assets in the near to mid-term while pursuing global development
- 2. Creating substantial value in the long term from new portfolio choices while driving R&D productivity

### **Biologics in FY20 (and FY25)**

## Product Portfolio

- 6 existing products; > 50 filings across 14 major countries
- 5 new products in clinical development
- 5 new products in early development

#### FY20 Business Profile

- Emerging Markets Revenue: \$150Mn \$ 200Mn
- Developed Markets Profits/Royalties expected to Kick-in
- EBITDA margin post R&D: > 25 %

#### FY25 Business Profile

- Emerging Markets Revenue: \$300Mn \$400Mn
- Developed Markets Profits: ~ \$150 200Mn
- EBITDA margin post R&D: > 35 %



EXECUTIVE VICE PRESIDENT, PROPRIETARY PRODUCTS AND HEAD, PROMIUS PHARMA



## Agenda

- 1. About Us
- 2. Key Technologies
- 3. Portfolio and Projections
- 4. Summary

# 1

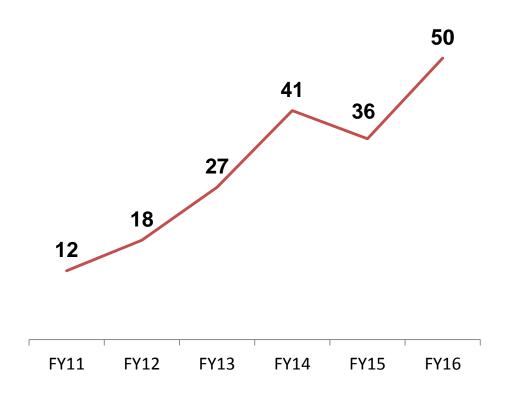
# ABOUT US

### **Snapshot: Proprietary products group**

- Possesses substantial product development, translational medicine, clinical development, regulatory, and commercial expertise (through our commercial arm, Promius Pharma)
- Pursuing significant unmet dermatology and CNS needs through a small provider audience
- Has assembled a robust pipeline of highly innovative products within the 505b2 regulatory framework
- Seasoned leadership team with 200+ collective years of industry experience, having collectively prosecuted 30+ NDAs over their careers
- On track with near-term catalysts and long term value creation for Dr. Reddy's

## **Snapshot: Promius Pharma**

#### Sales in USD Mn



- 54 sales reps targeting ~8000 medical dermatologists
- Portfolio consists of 4 products focusing on steroid-responsive dermatoses and acne:
  - Cloderm [mid potent steroid]
  - Promiseb [510k cream for seborrheic dermatitis]
  - Zenatane [isotretinoin]
  - Scytera [BTC coal tar foam]
  - Trianex [Triamcinolone Acetonide]
- High profile Scientific and Commercial Advisory Boards in place

# Key trends in the US market have defined the standards of innovation that we must pursue

Various insurers/payers will begin to drive healthcare institutions into "pay for performance" models (started with Medicare in 2012)

Higher out-of-pocket costs for patients will cramp utilization of drugs and also drive patients to postpone elective (and even some non-elective) procedures

Providers and insurers will begin teaming up to improve population health while trying to optimize their economics collectively

- Develop products that address a clearly defined unmet need for patients
- Ensure that clinical data on these products is available that demonstrates the value that these products offer
- Price the products fairly and in line with the value of the products

## Our focus is on novel differentiated formulations ...

- Address patient unmet needs utilizing previously approved active ingredients
- Pursue both product improvement opportunities and repurposed drugs
- Work primarily within the 505(b)(2) regulatory framework

# ...targeting the Dermatology and Neurology markets

- Both dermatology and neurology are highly promotionally responsive market segments, that respond both to targeted messaging, sampling and other conventional marketing tactics
- There are significant elements of complexity in patient management in both areas: in dermatology, in indications like acne psoriasis, and actinic keratosis, while in neurology, in most key indications (including but not limited to migraine, epilepsy and Parkinson's). The value of tailored patient support models is significant in these areas
- There are unique translational paradigms at play in both segments, allowing for a highly differentiated development strategy in these indications

# KEY TECHNOLOGIES

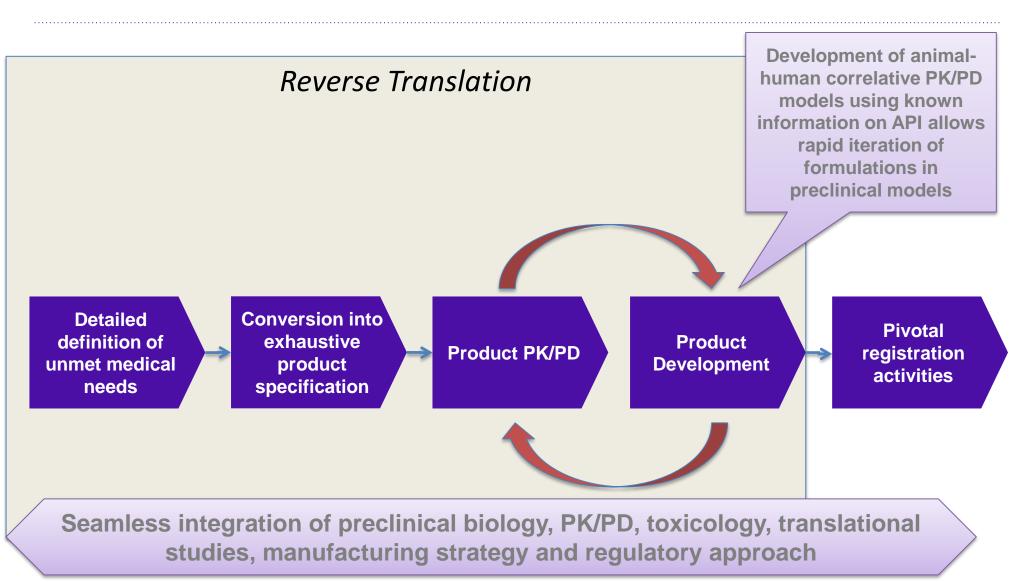
# The solutions we pursue live at the interface of science & technology and the patient experience

Reverse
Translation-based
Product
Development
Engine

Promius: A unique, unmet-need driven Specialty Dermatology and Neurology company

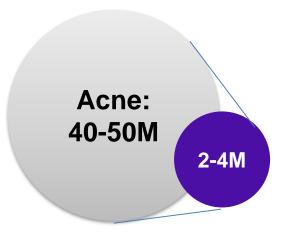
Commercialization
Model focused on
solving patient
challenges [focusing
directly on both
physician and
patient]

# Reverse translation: A platform-based integrated translational approach for the development of Repurposed medicines

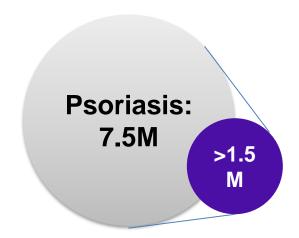


# We target underserved segments within large disease areas both in Dermatology .....

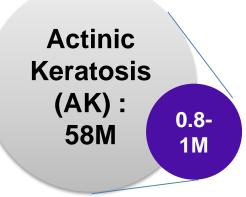
## Numbers of patients



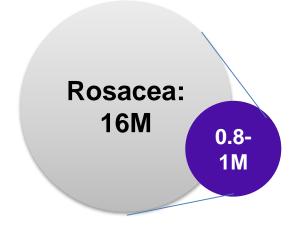
More convenient, more tolerable, safer approaches to moderatesevere acne



Topical approaches to addressing gaps in the management of acute flares



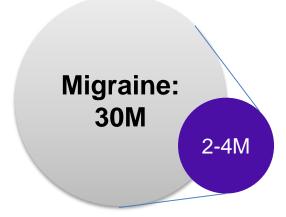
Improved efficacy, novel more convenient treatment regimen



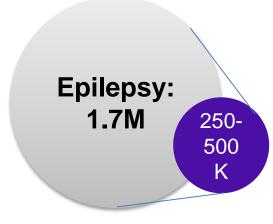
More effective approaches

## ...and in Neurology

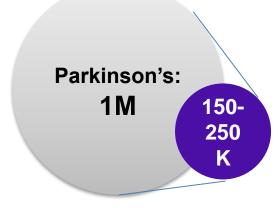
## Numbers of patients



Rapid acting approaches, new approaches to recurrent headache



More tolerable, more convenient approaches to treatment



Pursuing niche unfulfilled opportunities with dopamine homeostasis

# The product development efforts rely on bringing together drug delivery systems, translational medicine and commercial / clinical insights

## **Dermatology**

## Neurology

## Delivery technologies

- Topical gels/lotions/creams/spra ys/foams
- Injectable dosage forms (local)
- Oral modified release dosage forms

- Rapid acting orally delivered dosage forms
- Buccal/sublingual delivery
- Rapid acting intranasal (= injection-like)
- Injectable dosage forms

## **Indications Pursued**

- Psoriasis
- Atopic dermatitis
- Seborrheic dermatitis
- Acne
- Rosacea
- Actinic Keratosis
- Warts
- Migraine
- Epilepsy
- Parkinson's disease

# Translational approaches utilized

- Animal and human systemic PK studies
- In vivo disease models
- Microdialysis & other approaches for local PK measurements
- Imaging (scintigraphy, confocal techniques, etc)
- Radiolabeling
- Biomarker-based approaches

(= IIIJection-like)

# PORTFOLIO AND AND PROJECTIONS

# Robust pipeline of opportunities in each disease area that we are targeting: Dermatology

## Key Programs in Dermatology Pipeline

,					
Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3/BE	Filed
<b>DFD-01: Psoriasis</b>					
DFD-09: Rosacea					
DFD-10: Acne					
DFD-06: Psoriasis					
DFD-03: Acne					
DFD-05: NGW*					
DFD-04: Rosacea					
DFD-07: AK					
DFD-08: AK					

\* Non Genital Warts

# Robust pipeline of opportunities in each disease area that we are targeting: Neurology

## Key Programs in Neurology Pipeline

preclinical programs

Key Programs in Neurology Pipeline									
Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3/BE	Filed				
DFN-11: Migraine									
DFN-02: Migraine									
DFN-15: Migraine									
DFN-10: Migraine		>							
DFN-14: Migraine									
DFN-19: Migraine									
Epilepsy: 4 preclinical programs									
Parkinson's: 4									

# Our near-term filings are intended to solve specific problems in Psoriasis, Rosacea and Migraine ....

#### **DFD-01**

- Next generation topical steroid with efficacy equivalent to a high potent steroid
- Combines all of the key benefits of creams, lotions, foams and sprays into a superior, emollient vehicle
- Strong phase 3 data, both placebo controlled and versus high potency steroid RLD in mild/moderate psoriasis
- Suitable for a broad range of psoriasis presentations and BSA types

#### **DFD-09**

- Modified release doxycycline indicated for rosacea
- Label similar to Oracea but pursuing claims for dosage without regard to meals
- Intent to supplement NDA with additional clinical trials to drive differentiation

#### **DFN-11**

- Oral triptans have poor 2 hour efficacy pain freedom rates (~25-35%)
- Patients with rapidly escalating pain have insufficient drug levels from oral meds
- DFN-11 is a drug-device combination of an approved triptan
- DFN-11 attempts to optimize receptor occupancy in the first 15 minutes while minimizing adverse events observed in currently approved injectable triptans

Potential sales of \$50-75MM per opportunity in the near term

# ... while in the mid term, we are pursuing opportunities that have the potential to be transformative for business

#### Mid-stage dermatology assets

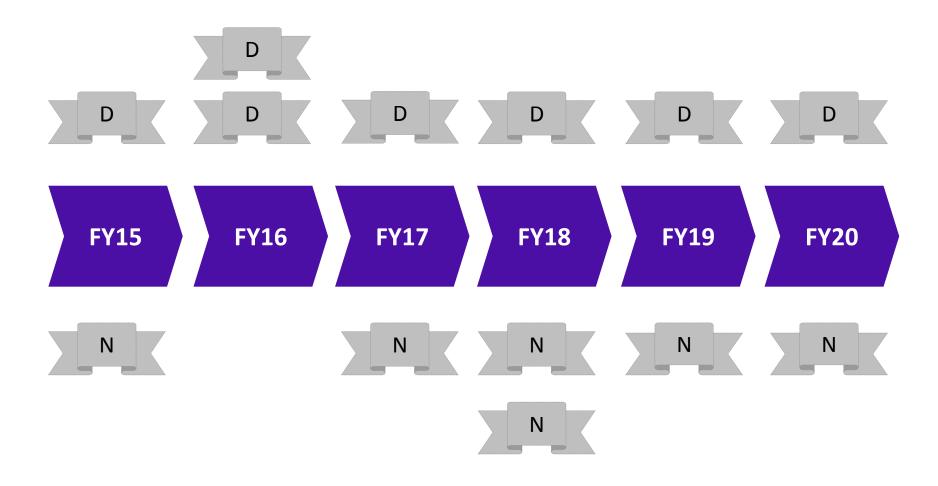
- DFD-03: zero contact time retinoid facewash
- DFD-04: novel repurposed topical API for treatment of rosacea
- DFD-05: novel combination therapy for treatment of non-genital warts
- DFD-07: novel repurposed non-cytotoxic topical API for treatment of AK

#### Mid stage migraine assets

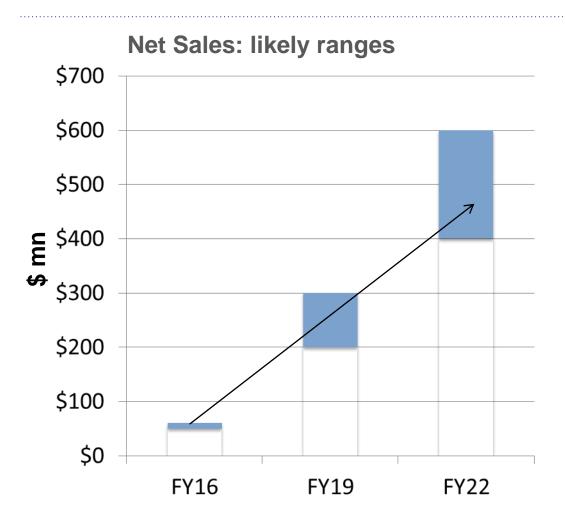
- DFN-02: intranasal triptan spray with injection kinetics (Tmax < 15 minutes)</li>
- DFN-15: novel repurposed rapid acting nontriptan oral API for treatment of migraine (for triptan intolerant or non-responsive patients)
- DFN-14: novel device-based injectable triptan play
- DFN-19: novel DHE-based formulation (with similar efficacy to Levadex, more convenient dosage form)

Potential sales of \$100-300MM per opportunity if target label is achieved, with first set of filings in FY18

# Our intent is to deliver an average of 2 NDA filings every 12 months ....



# ... which can collectively yield a business footprint potentially exceeding \$ 500 millions by FY-2022



- Indicative sales ranges from organic pipeline activities, risk adjusted for potential failures
- Assumes approval of NDAs within 12-18 months of filing
- EBITDA contribution at 40% level towards the end of the period



# SUMMARY

# Summary: market opportunity and commercialization philosophy [1/2]

- All of our products are geared toward disease areas whose health and cost burden on patients and the US healthcare system is substantial.
- We believe our products represent assets with clear medical benefit for a subset of patients within neurology and dermatology.
- All of our products are novel in either their clinical attributes, delivery device, or combination. While the products are deploying a variety of regulatory approaches for approval, spanning the spectrum of BE studies to full phase 3 clinical studies, our commercialization approach relies on the availability of clinical study data highlighting the differentiation of our products against currently available therapies.
- We expect our products to be categorized similar to other branded products. However, our pricing strategy will be more attractive to patients and payers across both franchises, thereby resulting in better market penetration.

# Summary: market opportunity and commercialization philosophy [2/2]

- We will complement our products with a variety of new, novel patient support and engagement models that are intended to address other friction points in the system that prevent these patients from achieving the optimal care for their conditions.
- While there will be some common elements to these models that cut across all products, we will tailor the offerings based on the challenges patients in each disease area face
- For all products that we bring to market, we anticipate a multi-layered approach to ring fencing that is intended to provide 5+ years of market exclusivity on the lower end, and 10+ years of exclusivity for the most innovative products in our portfolio

CSN MURTHY
CHIEF EXECUTIVE OFFICER, AURIGENE



## **AGENDA**

- 1. About US
- 2. Key Milestones
- 3. Summary

# 1

# ABOUT US

## Our objective ...

To be the most respected and valued biotech company in India

By delivering a high quality pipeline of clinical candidates addressing unmet needs in Oncology and Inflammation

# Aurigene is a fully integrated Discovery Biotech company

#### **BUSINESS MODEL**

- Focused on Oncology & inflammation disorders
- Complementing infrastructure for small molecule & peptide drug discovery
- Client value proposition characterized by collaboration & licensing
- Multi-year collaborations with 6 of top-10 pharmaceutical companies

#### **OUTCOMES**

- 60+ integrated discovery programs resulting in over 135 patents in the last 10 years
- Out-licensed multiple early-stage& three late stage programs
- 9 INDs filed under the collaboration programs with multiple assets in Phase I/II
- Pipeline of programs in Immunooncology, Epigenetics & Th17 pathway

# Business Model [1/3]: Choices of targets and platforms

## Core TAs of focus for internal pipeline development

- Immuno-Oncology
- Other oncology targets
- Anti-infectives with an immunological approach

# Ensure substantial differentiation



 First-in-class peptide & small-molecule approaches for immuno-oncology targets, offering higher potential for safety & flexibility for combination treatments

# Target difficult problems through unique hypotheses



Malt1, KRas – type targets

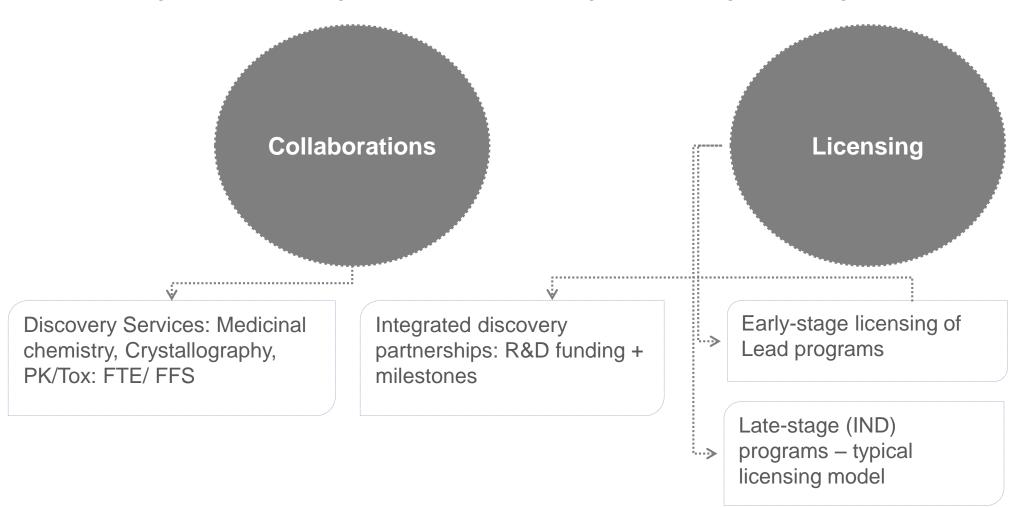
# Flexible with multiple options



 Early to late stage licensing and co-development. Also, retaining assets through Ph 3 – to be exercised based on business requirements and extant opportunities

## **Business Model [2/3]**

Generating revenues through partnerships, creating value through licensing



## **Business Model [3/3]**

## **Collaborations** [key success factors]

- Ability to achieve scale. Retain key team members and develop competencies.
- Strong reputation in the global research community as a "Discovery services company"
- Networking and exposure to different areas of biology.
- Stability in operational cash flows now, Aurigene pipeline is funded entirely through internal cash flows.

## Licensing

- Provides significant value.
- Gives exposure to translational biology, regulatory & clinical practices and commercial issues

# KEY MILESTONES

# **Aurigene: Key milestones [1/2]**

#### 2002



Aurigene set up

#### 2005



1st full discovery partnership with Novo

Addition of key scientific team members

#### 2006



First early stage licensing + discovery partnership

#### 2007





Two Multi-year, multi-target strategic partnerships signed with Merck Serono & Orion Pharma

#### 2009



Integration of Dr. Reddy's Discovery unit

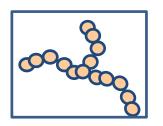


Multi-year, multi-target strategic partnership signed with Endo pharma

# **Aurigene: Key milestones [2/2]**

#### 2010

Full discovery & peptides partnership with US & EU large pharma



Initiation of Aurigene's internal programs – 1<sup>st</sup> program - peptide antagonist for PD-1

#### 2012

Aurigene Program with EU large pharma enters Ph I

First biotech shared risk partnership signed

#### 2013

Multiple partner programs enter IND/ Phase I

Two more biotech collaborations signed with H3 and Partners

#### 2014



BET optionlicensing deal with Orion

**PD-1 licensing** 

Pierre Fabre

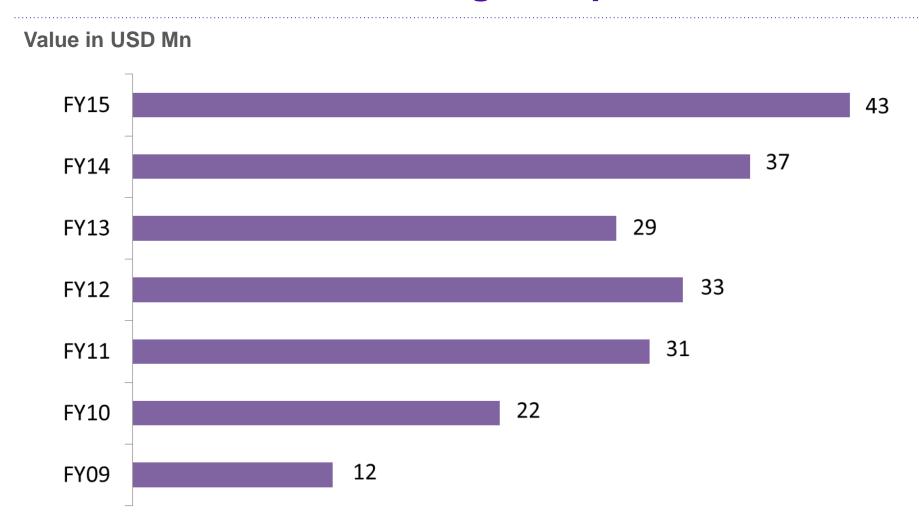
deal with

#### 2015



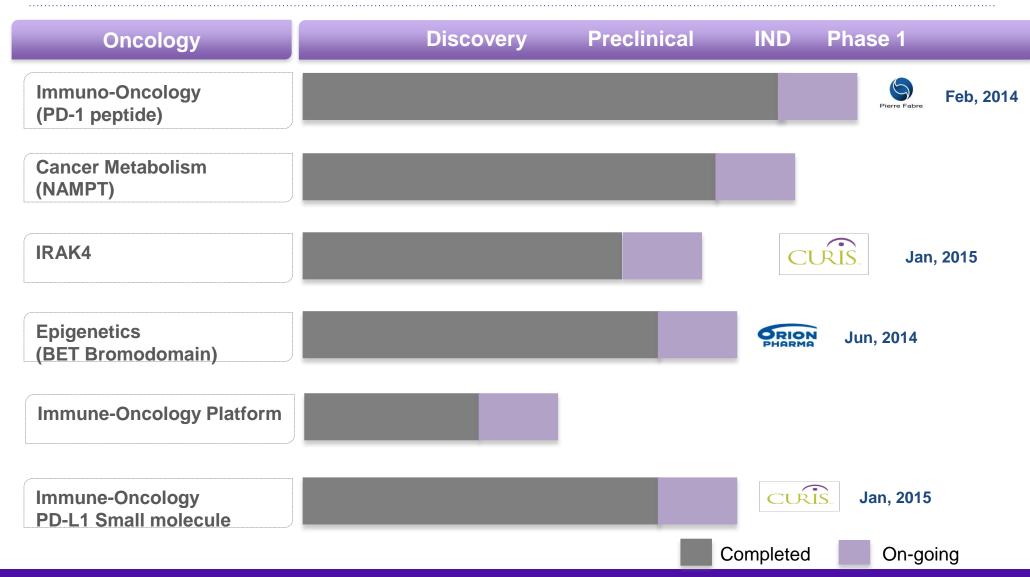
IRAK4 and PD-1 small molecule Option licensing – strategic partnership with Curis

# Value of up-front payments, milestones & research funding receipts

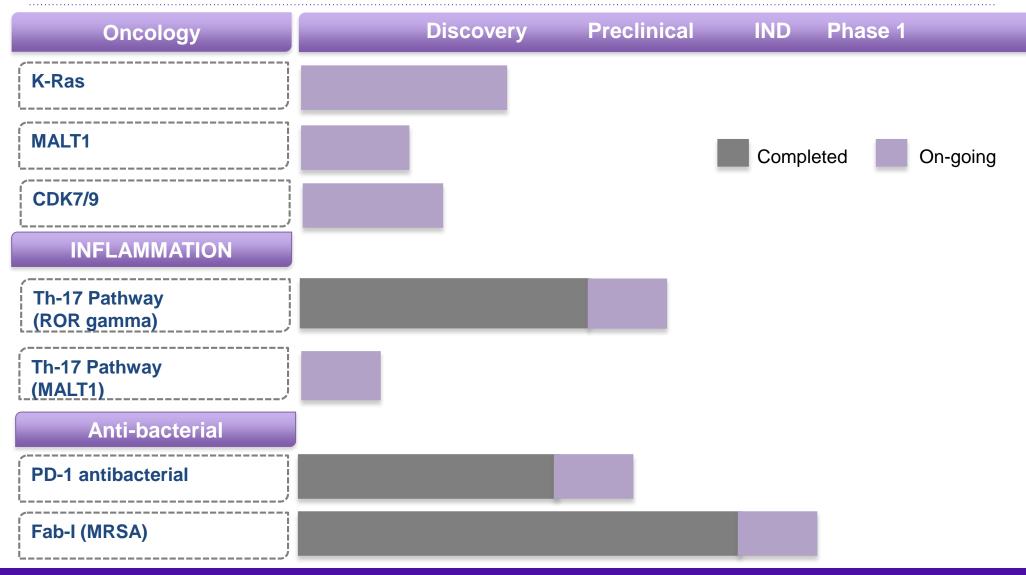


Revenue recognition under IFRS requires to apportion the up-front money received from customers over the time there is continuing Managerial involvement; hence, the revenues booked in financials will not match with above numbers.

## **Internal Pipeline [1/2]**



# **Internal pipeline [2/2]**



# SUMMARY OF RECENT DEALS

# Summary of Immuno-oncology deals: Pierre Fabre deal terms

- License, Development, and Commercialization Agreement
  - Two patent series of PD-1 peptide antagonists
  - India rights retained with Aurigene
- Deal terms include
  - Upfront
  - Research, clinical development, regulatory and sales milestone payments
  - Royalty rate on net sales by Pierre Fabre: double digit
- Sublicensing revenue sharing

# Summary of Immuno-oncology deals: Curis partnership structure [1/2]

- Strategic partnership in oncology drug discovery, development and commercialization
- Aligned interests and complimentary expertise
  - > Aurigene discovery engine: research, discovery, chemistry and preclinical development expertize. State-of the art and cost effective.
  - Curis: translational medicine, regulatory, clinical development and commercialization
     Experienced, focused and well networked
- Multi-year, exclusive partnership
  - Up to 5 years of broad exclusivity in collaboration scope
  - Immuno-oncology: immune-modulating molecular targets
  - Precision oncology: selected targets that are genetically altered in human cancers
- Option and license agreement structure
  - > Curis has option to license programs at development candidate stage
  - > Royalty-bearing, world-wide exclusive license (ex. India/ Russia) to compounds in programs

## Other important terms

- Territory Rights: India and Russia for Aurigene
- > DS & DP supply rights: Primary supplier rights for DS/ DP across all territories

# **Curis partnership structure [2/2]**

## Upfront equity grant

- > 17.1M shares (19.9% of outstanding CURIS stock prior to the transaction)
- Lock-up arrangement with 25% release every 6 months: 2-year total period
- Current value of above stock-holding at \$ 48 mn

## Research, option exercise and milestone payments

- Initial four programs: up to \$52.5M for first two, and up to \$50M for next two programs
- All programs thereafter: up to \$140 million
- Royalty rate on net sales by Curis: tiered from high single digit to 10%

### Sublicensing revenue sharing

- US/EU non-royalty and royalty payment sharing: declining percentage based on stage of development at sublicensing
- Asia: 50% sharing of all revenues

## Exclusivity option payments to Aurigene

Annual payments after first two years of collaboration

# **Medium to long-term plans**

Take some of our assets into clinic. Selectively, seek to retain strategic assets (eg: anti-infectives) all the way through Phase III

Evolve a mid-to late-stage portfolio of assets (own, co-development with specific geographical rights) over the next 4-5 years

Aim at a mixture of later-stage licensing deals and co-development deals.

Partners being mid-sized companies having clinical development capabilities.

# THANK YOU