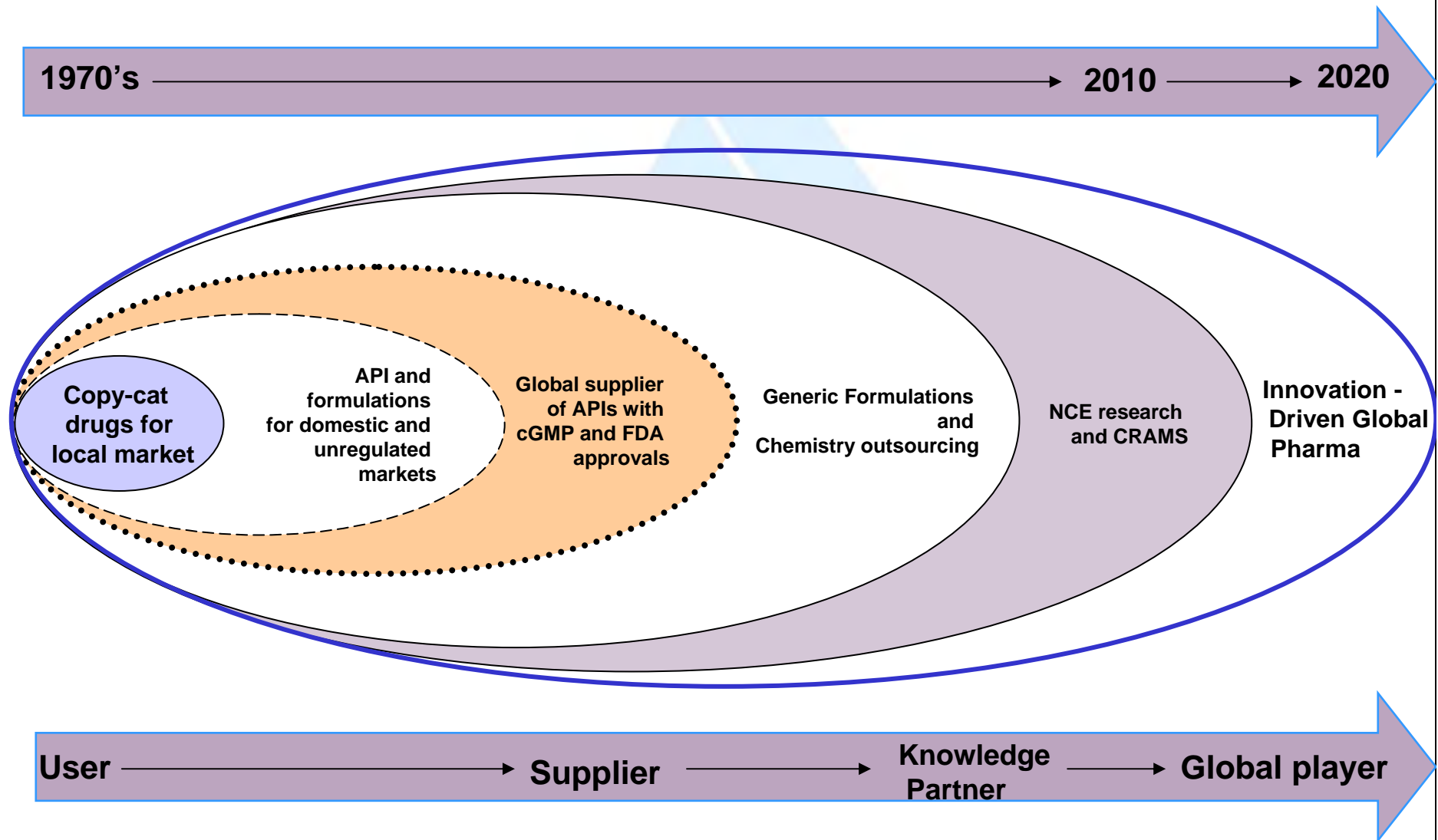


The background features a large, light blue watermark of the Advinus logo, which consists of a stylized 'A' shape with a drop inside, and the word 'ADVINUS' in a bold, sans-serif font below it.

Research and Development in Indian Pharmaceutical Industry

**Rashmi H. Barbhैया, PhD
Advinus Therapeutics Pvt Ltd
Bangalore, India**

Evolution of Indian Pharmaceutical Companies



Transitioning from Evolutionary Progress to Revolutionary Path-breaking Future

Global Issues

- High rate of failure in Pharma R & D – a norm that is expected to continue
- Greater focus on novel targets rather than going after “me-too’s”
- Lengthening timelines for putting a new molecule into market
- Shortening period of exclusivity
- Competing priorities
- Emerging era of personalized medicine
- Cost – to put a new molecule to market as well as for consumers

Local Realities/Opportunities

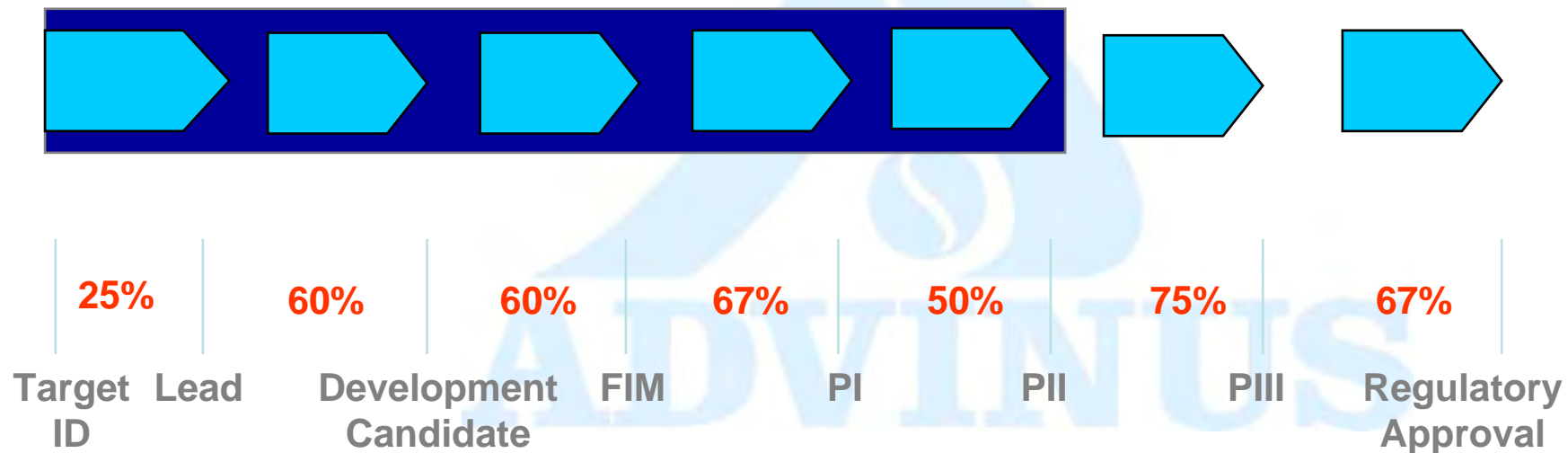
- Reinvigorated India
- Young talent hungry for success
- Government commitment to support knowledge-based industries
- Industry’s drive to make transition from copy-cat to innovation-driven
- Lessons learned from Indian IT industry’s successes and mistakes and from the Japanese pharmaceutical industry
- Converting cost-effectiveness advantage into opportunities

The R & D Roadmap for India : Becoming a Global Player

- **Converting cost-effectiveness into opportunities – more shots at the goal**
- **Creating parallel track for prioritization – giving top priority to the star project**
- **Speedup the process – candidate selection, discovery to development transition, POC, clinical trials and manufacturing**
- **Innovation-driven focus – early discovery, novel target, pharmacogenomics, biologics and Phase II/III clinical trials**
- **Synergistic partnerships**

Pharma R & D: Failure is a Norm!

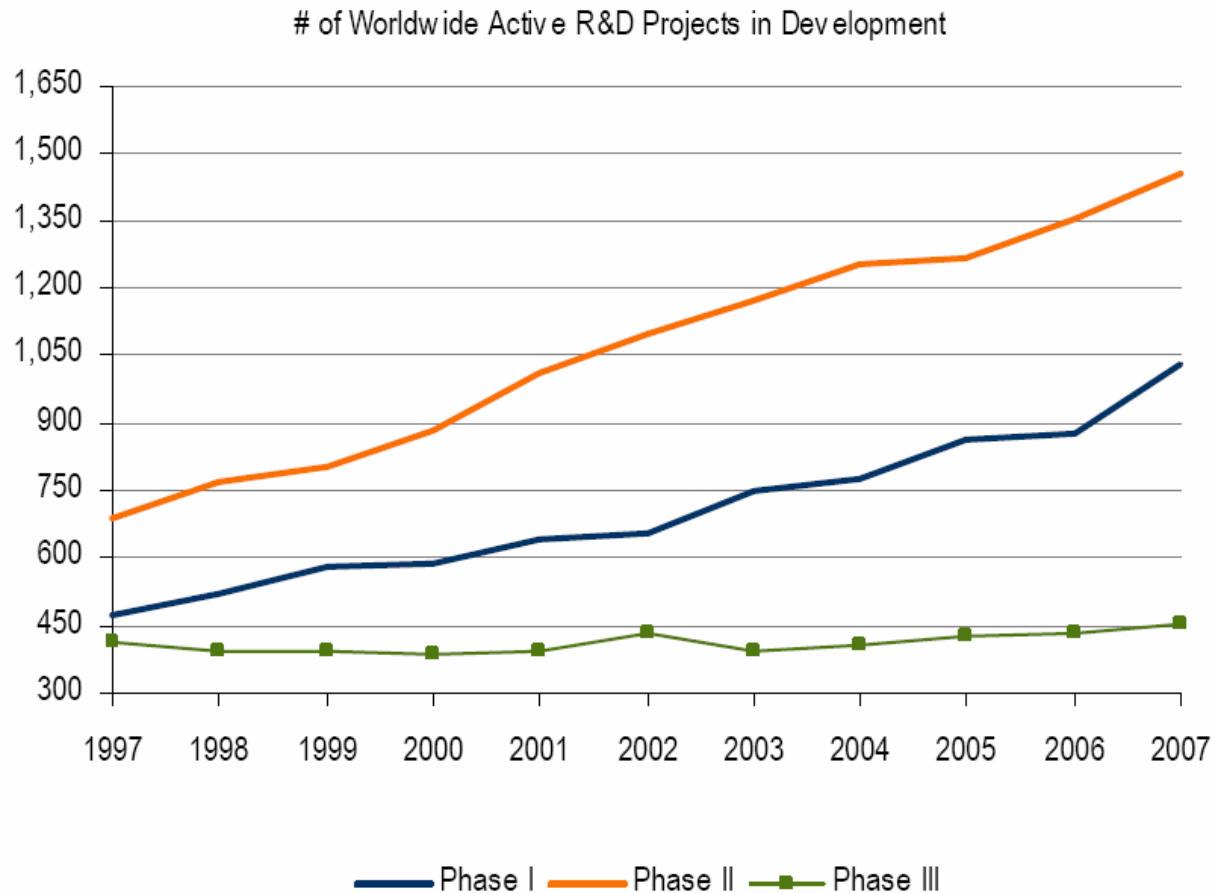
Pipeline Success Rate



Cumulative Success Rate for a Program: 1.5%

Opportunities for improving success rate, speed up development while leveraging the cost-effectiveness paradigm.

Phase III Drug Count Only Increased 1% Annually Since 1997



Source: Parexel's Pharmaceutical R&D Statistical Sourcebook 2007/2008

From Merrill Lynch, Global Pipelines Quantified, 23 August 2007

Leveraging Local Opportunities to become a Global Player

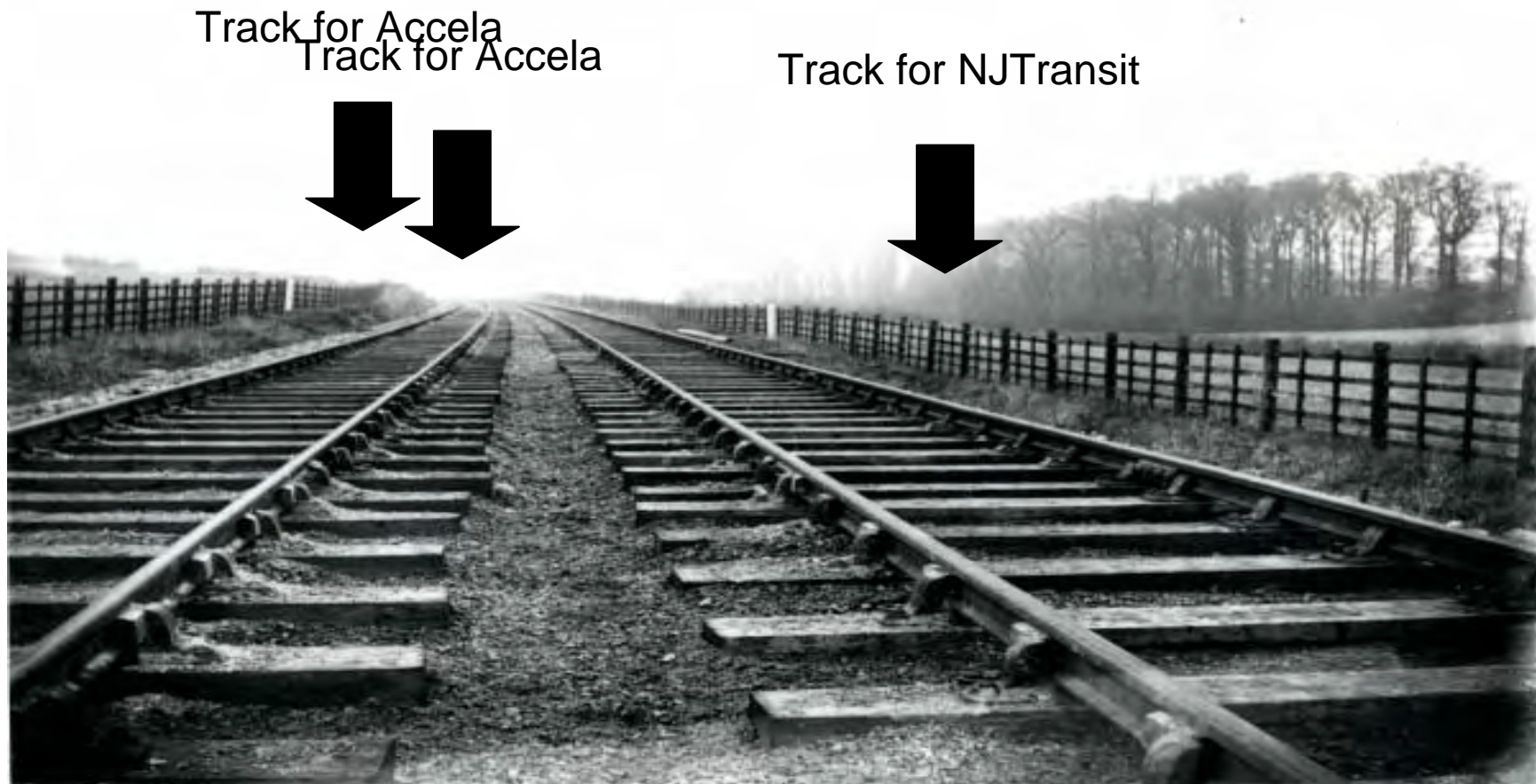
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- Synergistic partnerships

Issue: Timelines for Critical Discovery Program or Development Candidate Getting Affected by Competing Priorities



Create separate tracks for Accela and NJ Transit

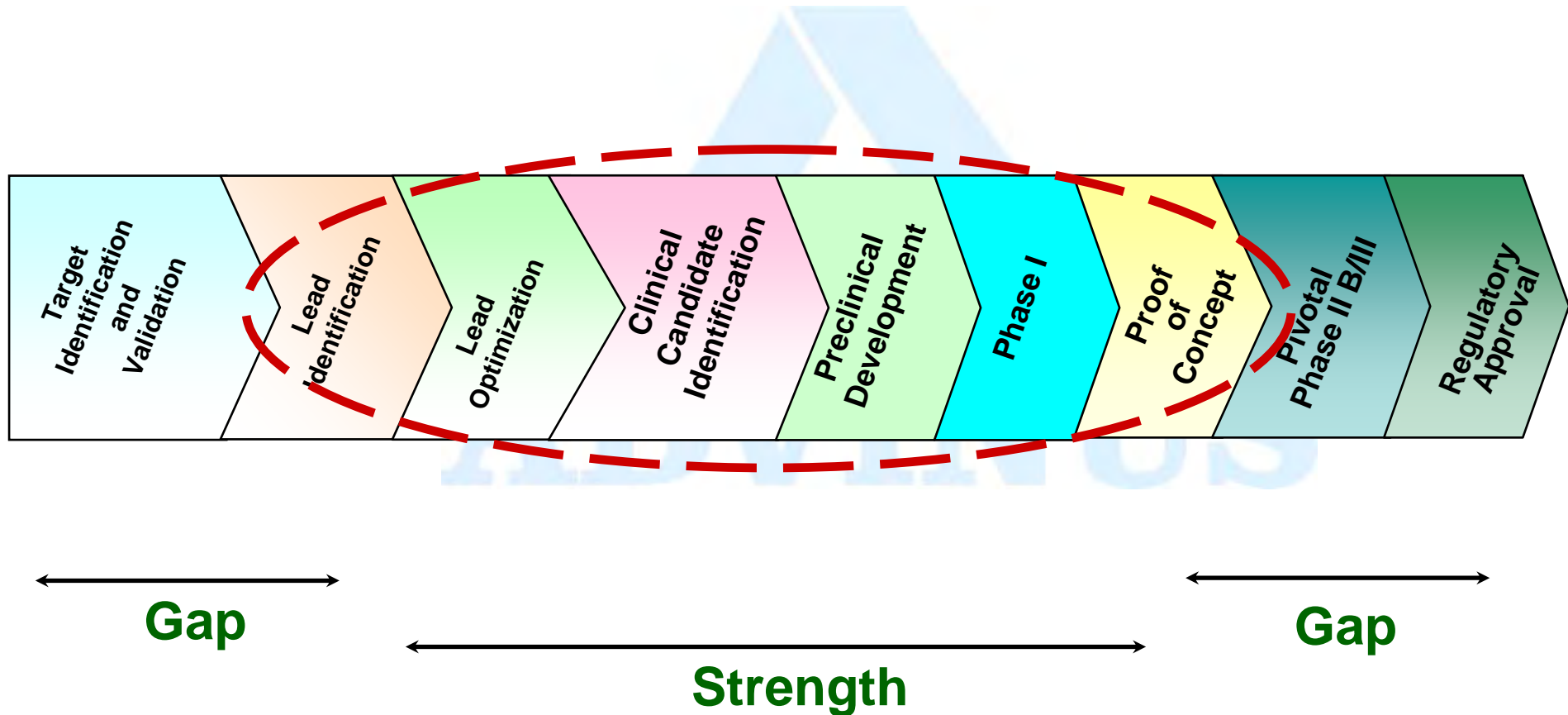
Think beyond \$\$\$ Savings – Stretch Your \$\$\$ for Opportunity Gains



Leveraging Local Opportunities to become a Global Player

- **Converting cost-effectiveness into opportunities – more shots at the goal**
- **Creating parallel track for prioritization – giving top priority to the star project**
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Compensating Deficiencies and Leveraging Strength



Filling Gaps and Converting Deficiencies into Proficiencies

- Early discovery – identification of novel targets & corresponding hits
- Academic and industry alliances for accessing novel targets and technologies
- Greater focus on high-risk novel targets; validation in animals and humans
- Drug discovery extending to clinical POC and feedback to medicinal chemistry
- Pharmacogenomics driven clinical trials
- Phase II/III clinical trails
- Measured shift to biologics from small molecules
- Addressing unmet clinical needs of neglected diseases
- Copy-cat formulation to novel formulation for NCEs

Advinus' First Major Drug Discovery Alliance: Merck

- **One of the most respected R & D company with years of successful track record**
- **Recognition and respect for external alliance**
- **Access to novel targets and hits – allows Advinus to explore areas beyond the best in class opportunities**
- **A true collaboration rather than an FTE model**
- **Our respect for the senior leadership team of Merck's R & D – scientific and interpersonal skills**
- **Respect & recognition we received from the Merck team**
- **Merck's sensitivity towards our needs as well as limitations**
- **Merck's track record for developing drug with speed and efficiency**
- **Potential for validation of our business model, our research team and recognition that an alliance with Merck can bring**

Possible Synergies Between Europe and India

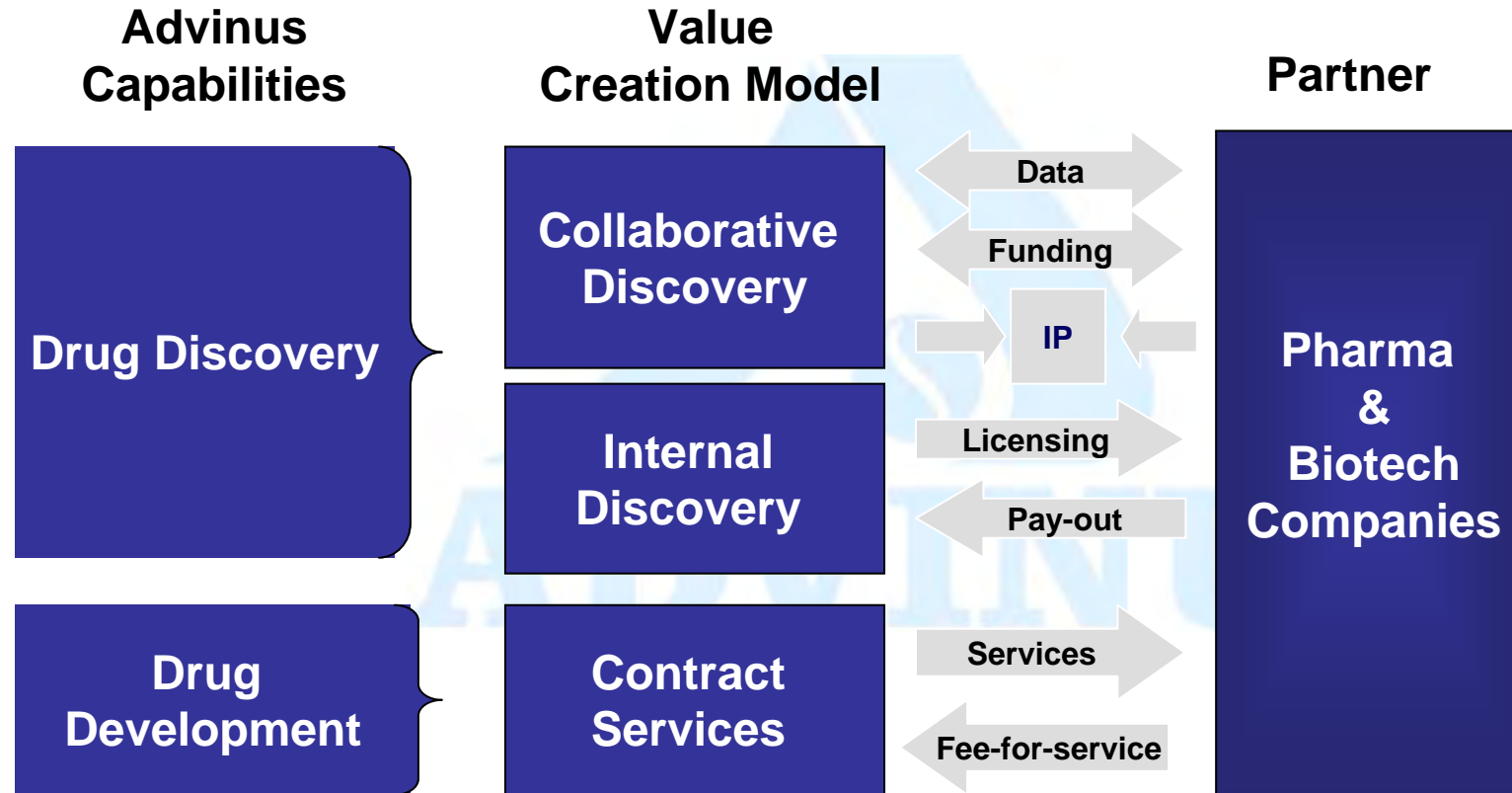
- **Academia / Industry alliance**
 - Converting academic IP into high NPV candidate
 - Access to novel targets
- **Biotech alliances**
 - Synergies in early drug discovery
 - Evaluation of Novel targets
 - Synergies between Europe's drug discovery strength and India's pre- and early clinical development capabilities for rapid and cost-effective POC in humans
 - Converting cost-effectiveness advantage into opportunities
- **Drug development services**
 - IND development
 - Early clinical development
 - Pharmacogenomics
- **Drug delivery product development**
- **Agro-chemical development**
- **Support for the REACH initiative**

India's Pharma Vision 2020

- **Becoming the biggest producer of generic drugs**
 - **API**
 - **Dosage forms**
- **Multiple NCEs invented & developed in India becoming major drugs**
- **At least three NCEs for neglected diseases in market**
- **Firmly established Pharma R & D centers**
- **Equal partnerships for R & D alliances – and some overseas MNCs having their own R & D**
- **Flourishing CRO business**
- **A major hub for clinical trial support – data management and biostatistics**
- **Regulatory bodies accepting pivotal Phase IIB/III pivotal study data**
- **A key contributor to pharmacogenomics-driven clinical trials**
- **Significantly improved regulatory approval processes**
- **A leading manufacturer of patent protected API, biologics and drug products leading to global sales and marketing**
- **At one major global pharmaceutical player**



Advinus Business Model



Leadership at Advinus

n1

Rashmi Barbhaiya, PhD, CEO, MD

Over 25 years of comprehensive Drug Discovery and Development experience

- VP Pharmaceutical Research Institute Bristol-Myers Squibb
- President R&D Ranbaxy Research Laboratories



Kasim Mookhtiar, PhD, CSO, SVP

Over 15 years of international leadership experience handling large scientific teams

- Director, Aging Research, Drug Discovery, Pharmaceutical Research Institute Bristol-Myers Squibb
- VP, New Drug Discovery Research, Ranbaxy Research Laboratories

n2



Mr. Rajiv Malik, MBA, SVP and Chief of Business Operations

Over 19 years of experience across diverse industries

- SVP and Business Unit Head, Jubilant Organosys
- VP and Head of Operations, Aurigene



Nimish Vachharajani, PhD, VP and Head Pharmaceutical Development

Over 15 years of experience in drug development with Bristol-Myers Squibb

- Led the diabetes portfolio at Bristol-Myers Squibb from candidate selection to Phase IIB
- Has filed a number of INDs and NDAs during his tenure at Bristol-Myers Squibb



Eric Nelson, PhD, Global Head Business Development, Strategy & Marketing

Over 20 years of large pharma and biotechnology industry experience

- Vice President Business Development, Tranzyme Pharma
- AVP Global Business Development, Wyeth Pharmaceuticals



Natesan Settiagounder, PhD, Director and Head, Corporate Quality Assurance

Over 25 years of R&D experience, including over 16 years of GLP experience.

- General Manager (R&D), Rallis India Limited
- Founder President of the Indian Chapter of the SQA

n3



Thomas Putti, Head, Human Resources

Over 20 years human resource professional and industry experience, of which 10 years in life science

- Dr. Reddy's Laboratories, Bharti, Jubilant
- Founder President, National HR Life Science Foundation

Folie 18

- n1** Consider inclusion of "Natesan Settiagounder, Ph. D, Corporate Quality Assurance" and "Thomas Putti, Human Resources". Matter has been provided earlier, and included. Thomas also to check it.
natesan.s; 09.11.2008
- n2** Delete "Mr."
natesan.s; 09.11.2008
- n3** To add photographs
natesan.s; 09.11.2008

Drug Discovery Partnerships: Key Highlights

- **Merck Alliance – November 2006**
 - Risk sharing drug discovery and development collaboration in the metabolic disorders area
 - Developing drug candidates to 2 clinically validated drug targets n4
 - Upfront and milestone payments of up to \$149 M plus royalties
 - Have achieved 3 milestones
- **Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) – September 2008** n5
 - Development of drug candidates for various disease targets.
 - Advinus responsible for drug discovery and early clinical development (phase 2a)
 - OMPJI advance drug candidate into late stage clinical trials and commercialization of the molecule
 - Upfront and milestone payments of up to \$249 M plus royalties
- **Genzyme, Broad Institute and Medicines for Malaria Venture – August 2008**
 - Develop new, improved treatments for specific patient groups most at the risk for Malaria
- **DNDi (Swiss non-profit organization) – October 2007**
 - 5 year collaboration for the identification and development of novel therapies for Visceral Leishmaniasis (Kala Azaar) - a fatal disease of the Tropics

Folie 19

- n4** **Adopt a uniform acronym for million (see Mn is used in the 7th line below this line)**
natesan.s; 09.11.2008
- n5** **Consider listing as per chronology of events**
natesan.s; 09.11.2008

Advinus Drug Development Services



- Custom Synthesis
- Intermediates
- Salt forms & Polymorph Selection
- Process Development for NCEs
- Medicinal Chemistry (anti-infectives & neglected diseases)

- Process Chemistry and Preformulation / Formulation support
- Stability testing support
- Bioanalytical for preclinical and clinical
- Physical-chemical studies, characterization, method development, validation, etc.

- Mass Balance & Tissue Distri.
- Pharmacokinetics in Animals
- Toxicokinetics
- Metabolite Identification
- Discovery Support
- First time in humans
- Special Populations
- Drug-Drug Interactions
- Biopharmaceutical evaluation of NDDS
- PK/PD Correlation

- Discovery Support
- Safety evaluation - Acute / sub chronic and chronic studies
- Genotox studies
- Reprotox studies
- Safety Pharmacology

n6

This part is performed currently by DMPK
natesan.s; 09.11.2008