# Augment Therapeutics

*Revitalizing Old Medicines*

## OUR MISSION

**Use of our proprietary platform technology to convert some widely used "Old Generic Drugs with some drawbacks" into potentially "Super Generic Drugs" via 505(b)(2) NDA Approach, which is the most economical and shortest regulatory pathway to new super generic drug development and approval by US FDA**

Presented by
Apparao Satyam, PhD
Chief Scientific Officer

[Date of Incorporation in India: 06-Apr-2017; CIN: U74999TG2017PTC116352]

# AUGMENT THERAPEUTICS TEAM

## SCIENTIFIC TEAM – Responsible for Preclinical and Clinical Development

- **Dr. Apparao Satyam**, PhD: CSO and Head of Chemistry & Patents
  - 30+ years R & D experience in US & Indian Pharma Industry
- **Dr. Kumar Nemmani**, PhD: Director Preclinical Research
  - 15+ years experience in preclinical pharmacology
- **Dr. Kulkarni**, MD: Director Clinical Research
  - 15+ years experience in clinical research

## SCIENTIFIC ADVISORS – Deal with USFDA on Regulatory issues

- **Dr. Somesh Sharma**, PhD [35+ years in US & Indian Pharmaceutical industry]
  - CEO & Founder, Anergen, Inc., Redwood City, CA, USA
  - CSO & CEO of Piramal Life Sciences, Mumbai, India.
- **Dr. Larry Kauvar**, PhD [35+ years in US biotech industry]
  - VP, CSO & Founder, Telik (South San Francisco, CA; USA)
  - VP, CSO & Founder, Trellis Bioscience (Redwood City, CA; USA)

## ADMINISTRATIVE TEAM:

1) **Veeraveni Baddireddi**, B.Com., B.Ed., MMS (Finance)
   Managing Director – Administration & Finance
2) Auditors: Sankaran & Krishnan Chartered Accountants, Hyderabad, India

**A Regulatory Consultant from USA:** We will hire a regulatory consultant, who is an expert in 505(b)(2) NDA submissions and who will guide us through the process.

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## PROJECT OBJECTIVE:

**Development of a potentially "Value-Added/Super Generic" version of omeprazole via 505(b)(2) NDA route.**

## OMEPRAZOLE USES:

- It is the **only Proton Pump Inhibitor (PPI)-based anti-ulcer drug included in WHO's List of Essential Drugs**
- Widely used for treatment of: duodenal and gastric ulcers, gastro-oesophageal reflux disease (GERD), dyspepsia, Zollinger-Ellison Syndrome, NSAID-induced gastric ulcers and to eradicate *Helicobacter pylori* infection (i.e., in combination with antibiotics clarithromycin and amoxicillin/metronidazole in triple therapy)

## OMEPRAZOLE MARKET:

- **7th largest prescribed drug in 2017 with >70 Million prescriptions.**
- **Global market currently at $2.67 B and projected to surpass $4.0 B by 2026**

## PROBLEMS or DRAWBACKS WITH OMEPRAZOLE (and also with other approved PPIs):

- **Decomposes in acidic stomach and shows poor bioavailability**
- **Must be enteric coated to protect it from acidic stomach, which leads to:**
  - **Delayed therapeutic action due to delayed absorption of the drug**
  - **Increased cost of making the enteric coated drug**
- **Inconvenient to patients as the drug must be administered 1 hour before breakfast**

**Hence, it is desirable to discover "Better or Superior" versions of PPI-based antiulcer drugs that do not show the above-mentioned problems/drawbacks.**

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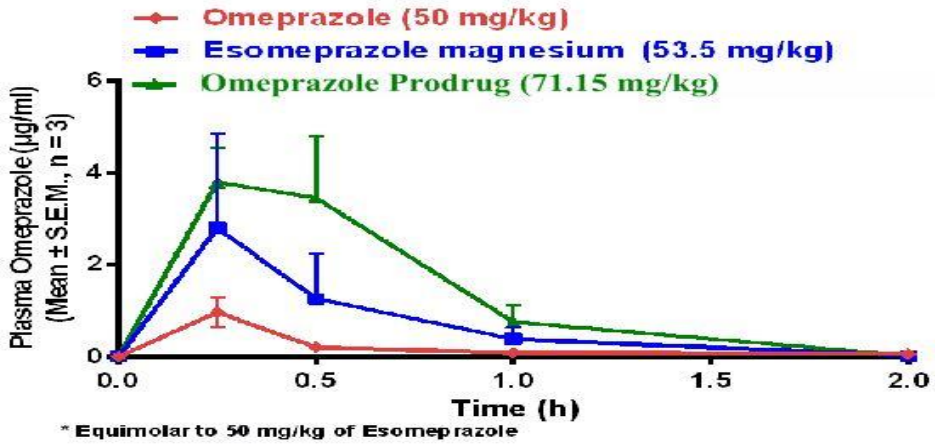
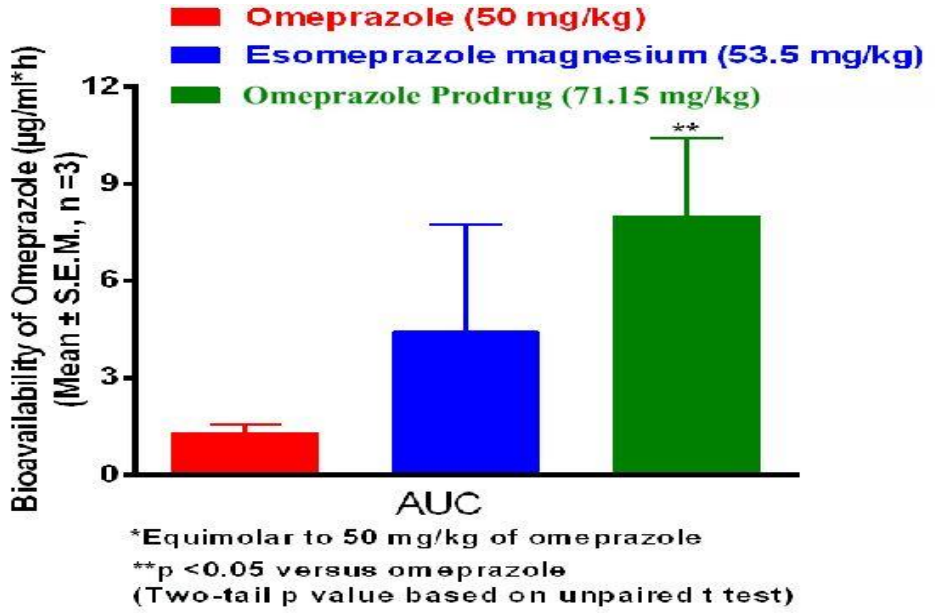
## OUR SOLUTION

**We discovered a potentially super generic version of omeprazole, which shows the following advantageous properties:**

- **High Stability in stomach acid – may not need enteric coating – reduced cost & faster onset of therapeutic action**
- **Statistically Significant improvement in oral bioavailability over that of omeprazole**
- **May lead to Improved Patient convenience and compliance – drug may be taken anytime a patient needs it**
- **Lower doses may reduce side effects such as osteoporotic fractures that are believed to be dose-dependent**
- **An ideal candidate for development through 505(b)(2) NDA route**
- **A New Chemical Entity (NCE) – 5 years exclusivity/20 years if it is patented**




**Our Expectation: The above-shown pharmacokinetics data support our expectation that the effective equimolar dose of our promising omeprazole prodrug could be <25% of the recommended dose of generic omeprazole.**

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## A case study supports marketing opportunity

**Santarus's Zegerid is a combination product containing omeprazole and the antacid sodium bicarbonate:**

- **Zegerid was also approved via 505(b)(2) NDA route in 2006 based on its better oral bioavailability**
- **It achieved worldwide sales of $307M in 2016 (IMS Health)**

**However, due to presence of sodium bicarbonate, Zegerid is not recommended for patients with:**

- **Hypocalcaemia**
- **Respiratory alkalosis**
- **High blood pressure**
- **Chronic heart failure**
- **Renal failure**
- **and those patients who are on salt-restricted diet**
- **Other Known adverse reactions with $NaHCO_3$ include: headache, abdominal pain, flatulence, nausea, gas formation, diarrhoea, hypernatremia, metabolic alkalosis, peripheral edema, seizures, tetany and tremor.**
- **There were many instances of stomach rapture on consumption of sodium bicarbonate immediately after a heavy meal.**

**Hence, our super generic version of omeprazole has the highest potential to grab better omeprazole market share than Zegerid to become "the antiulcer drug of choice" over generic omeprazole or Zegerid!**

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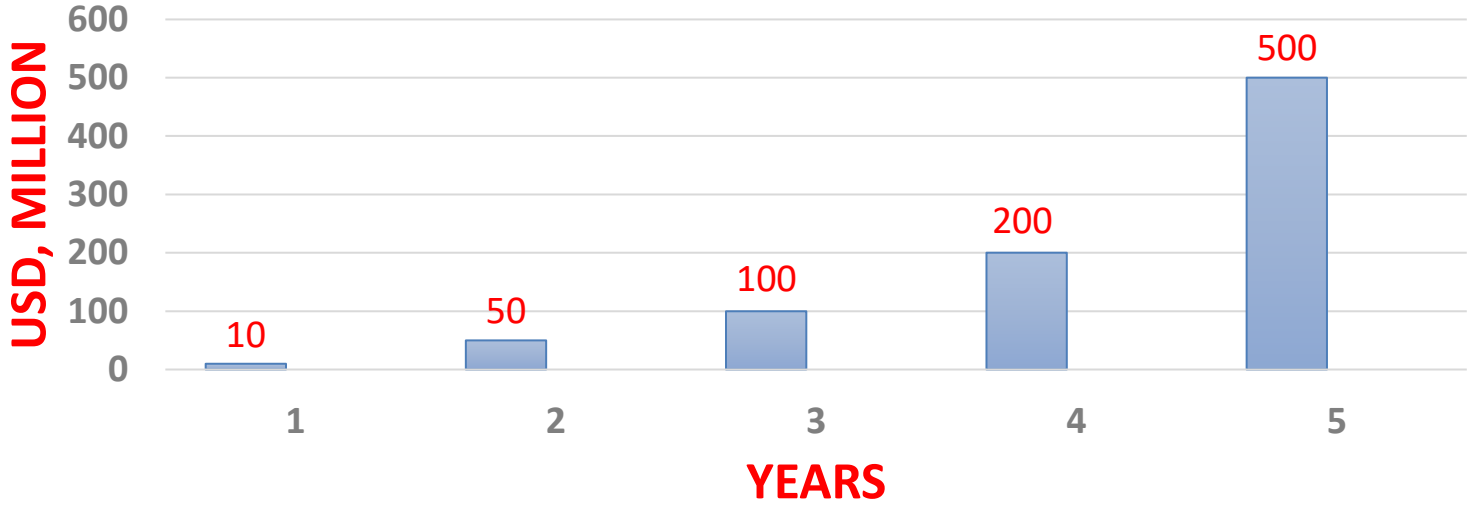
## POTENTIAL "VALUE-ADDED GENERIC/SUPER GENERIC" OMEPRAZOLE

### PRODUCT SALES FORECAST*




- *The above forecast sales figures for our super generic omeprazole are based on historical sales data on Santarus's **Zegerid**, which is a combination product containing generic omeprazole and **sodium bicarbonate**.
- **Zegerid** was approved in 2005 through 505(b)(2) NDA route.
- **Zegerid** achieved sales of $26 M in 2005, $49 M in 2006, $94 M in 2007, $130 M in 2008, $172 M in 2009 and $307 M in 2016 (According to Coherent Market Insights).
- However, **Sodium bicarbonate in Zegerid can cause many side effects**.

**Hence, our omeprazole prodrug, with its improved bioavailability and acid stability, has the highest potential to achieve a better market share than Zegerid or OTC omeprazole and can become a "Blockbuster" drug.**

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# Business Plan

## Seed funding: US$0.60 - 1.00 Million or equivalent INR (12-15 months)

- Synthesize 50-100 g of NCE (i.e., omeprazole prodrug)
- Draft & file a provisional patent application in India followed by PCT Application
- Hire Regulatory Expert on 505(b)(2) process, draft and submit the required documents for pre-IND Meeting with US FDA
- Plan and complete the required stability, pre-clinical toxicity and efficacy studies on NCE as per FDA-approved Pre-IND Meeting minutes/study plan
- Complete synthesis and *in vitro* evaluation of prodrugs of other approved PPIs to increase scope of the invention

## Lead Product Development Funding: US$4.0 - 6.00 M (12-15 months)

- Draft and file IND with US FDA
- Manufacture GMP quality NCE at an accredited Custom Synthesis Lab in India
- Conduct Phase I clinical trial in USA
- Draft and submit 505(b)(2) NDA on NCE to US FDA and seek 5 years of exclusivity
- Scale up manufacturing process in India in preparation for market launch

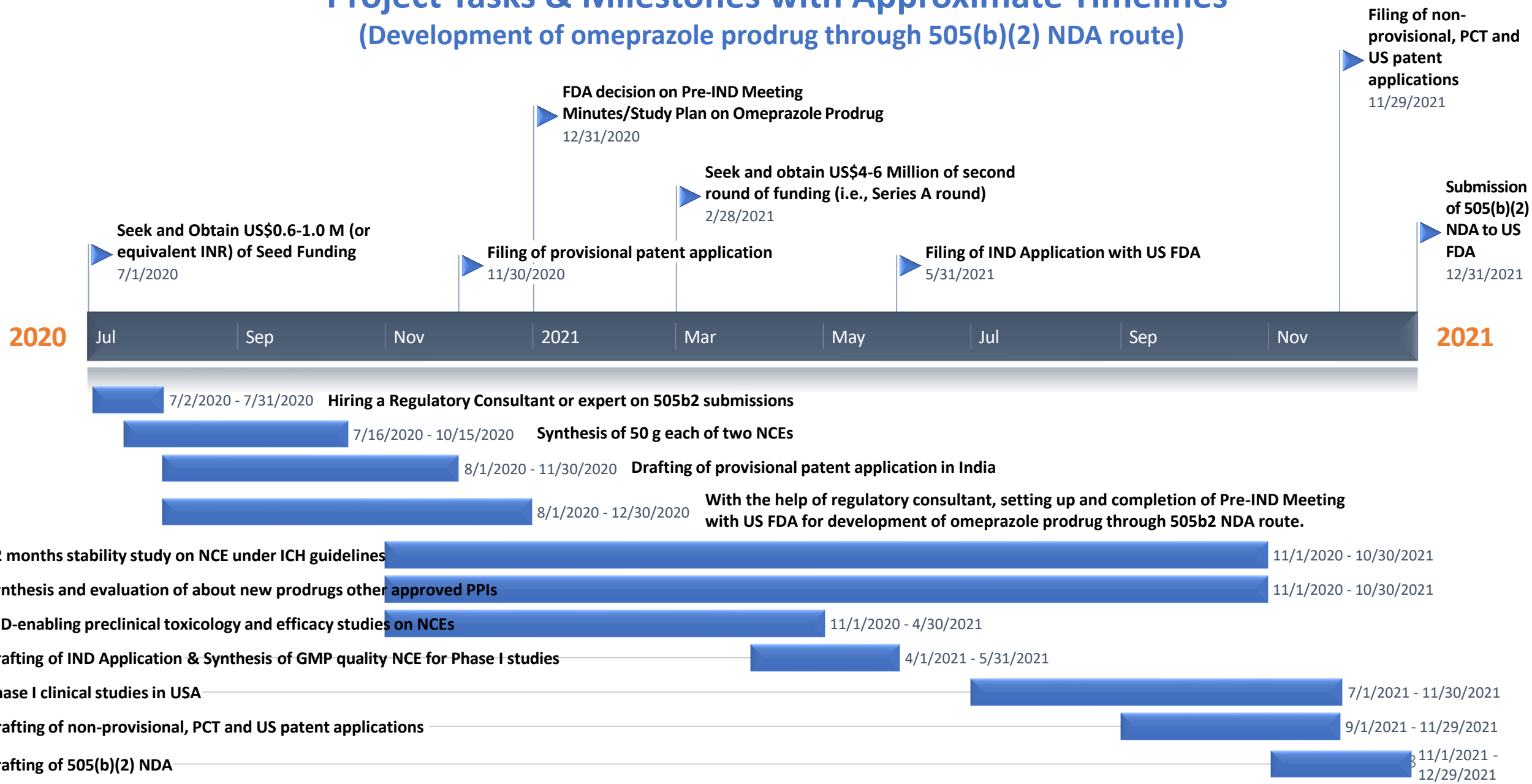
## Monetize Assets

- Pharma licencing deal for the lead product
- IPO if market conditions permit
- M&A

## Development Plan, Line extension & Pipeline

# Project Tasks & Milestones with Approximate Timelines

## (Development of omeprazole prodrug through 505(b)(2) NDA route)




**Note: Shortest possible timelines are projected above. However, it may take additional 6-12 months if some of the above-mentioned tasks take more time than projected.**

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## Line Extension:

**Development of the following potentially high-value combination products via 505(b)(2) NDA route:**

- **Omeprazole prodrug and aspirin.**
- **Omeprazole prodrug and diclofenac**
- **Omeprazole prodrug and ibuprofen.**
- **Omeprazole prodrug and naproxen.**
- **Omeprazole prodrug and a prokinetic agent such as domperidone.**
- **Omeprazole prodrug, clarithromycin and amoxicillin/metronidazole in triple therapy for eradicating *helicobacter pylori* infection.**

## Pipeline of Compounds:

**Development of other potential 505(b)(2) candidates include:**

- **Super Generic Naproxen and Super Generic Aspirin**
  - **Granted patents: US9,844,599 (Dec 19, 2017) & CA2897571C (Dec 18, 2018)**
  - **Related Indian patent is still under prosecution**
- **Super Generic Irinotecan (major cancer chemotherapeutic)**
  - **USP: Releases more active species (i.e., SN-38) *in vivo* than irinotecan**

**Another Interesting Project:**

**Development of Novel Antibody-Drug Conjugates (ADCs)**

- **Leverage Augment's proprietary linker technology**

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**For more details, please contact:**
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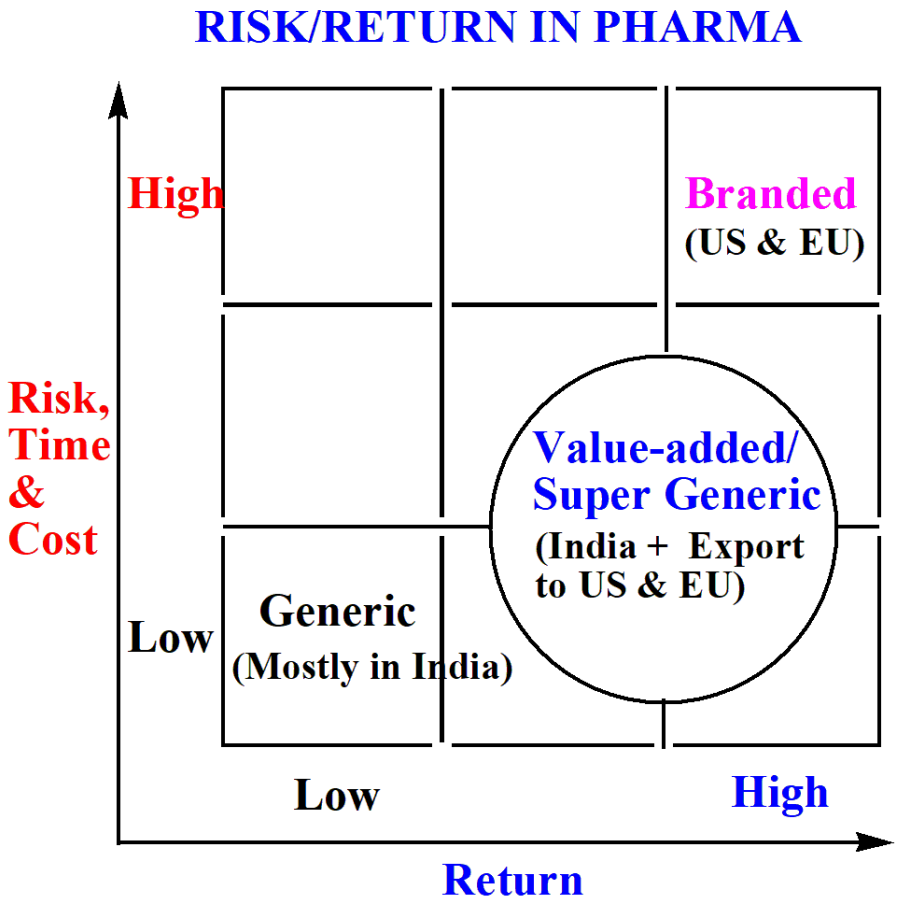
# THANKS

# 505(b)(2) Regulatory Pathway for New Drug Approvals by US FDA

- 505(b)(2) is a Hybrid pathway between full NDA 505(b)(1) and 505(j) ANDA
- Limited preclinical and clinical studies
- Short development timelines than new drugs
- Paper NDA or 505(b)(2) – pre-existing Phase II and Phase III clinical data can be incorporated by reference
- Limited financial investment but greater than me-too generics
- Low risk of failure
- May gain a significant price premium over me-too generic drugs – hence possibility of high return on investment
- Recent 505(b)(2) NDA approvals by FDA: 48 drugs in 2016, 63 drugs in 2017 & 75 drugs in 2018

- Creation of "Value-added/Super Generics" from me-too generics through:
  - Improved bioavailability/efficacy
  - Improved drug delivery and patient convenience
  - Improved manufacturing process

- Ideal 505(b)(2) candidates include:
  - Drug with new indications
  - Drugs with new formulation/strength/dosage form/dosage regimen/route of administration
  - New combination products including drug-device combinations
  - Prodrugs of existing drugs
    - 0 or 3 years of exclusivity if it is an ester prodrug (based on clinical trials data)
    - 5 years of exclusivity if the prodrug is a new chemical entity (NCE)
    - 7 years of exclusivity if the prodrug gets an orphan drug designation.
    - May even enjoy 20 years of exclusivity, if the prodrug is a patentable NCE!




Source: Teva and Corporate Research