

Lean Start-Ups Are a Biotech Business Model

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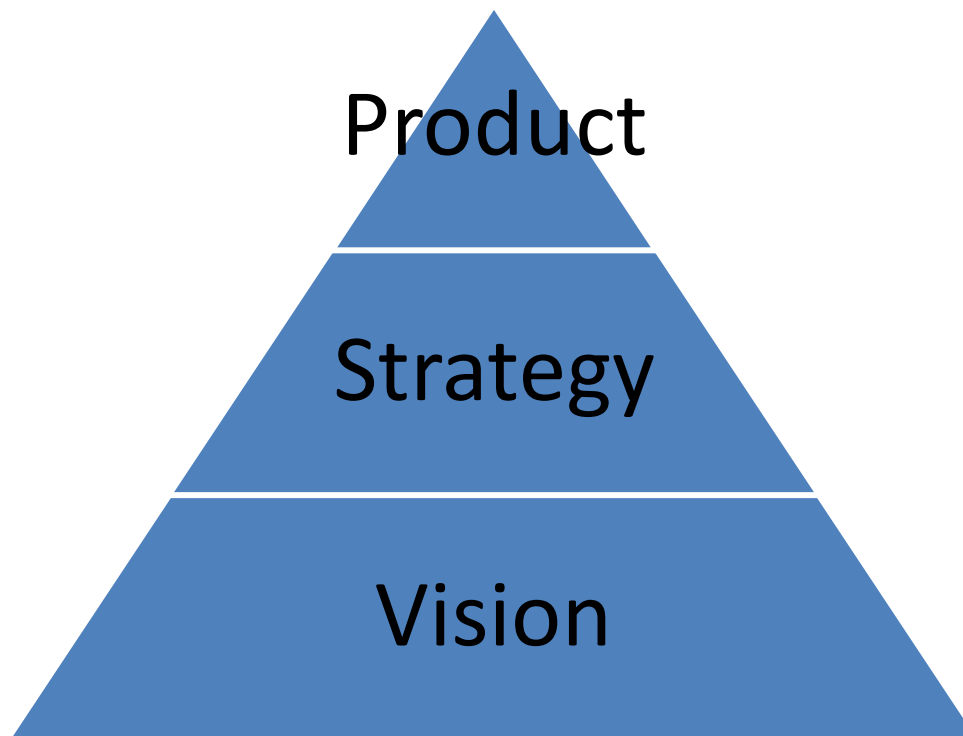
Biotech Industry – A Predecessor of Lean Start-Ups??

- Identify Unmet/Under-served Needs
 - Constant Feedback from Patients, Providers, Payers
 - Customers
- Build Minimum Viable Product
 - Establish proof-of-principle
 - Quality, Safety, Efficacy
- Measure
 - Effectiveness In Preclinical and Clinical Studies
 - Viability of the Product
- Pivot or Persevere
 - with the Minimum or Pivoted Viable Product
 - based on Measurement and Root Cause Analysis

The Concept of Validated Learning



The Lean Start-Up Principles & Process



- Start
- Define
- Learn
- Experiment
- Leap
- Test
- Measure
- Pivot (or Persevere)
- Batch
- Grow
- Adapt
- Innovate



Four Truths about Lean Start-Ups and their Methods – Applicable to Biotech

- Lean Start-up methods
 - Are not about Costs
 - They are about Speed
- Lean Start-up applies
 - To all Companies that face Uncertainty
 - About what Customers Want (and Need)
- Lean Start-Ups are
 - Ambitious and
 - Able to deploy Large Amounts of Capital
- Lean Start-ups are
 - Driven by Compelling Vision and
 - Test each aspect of the Vision Rigorously

Key Attributes Defining the Value of a Successful Biotech Enterprise

- Market
 - Addressable market in terms of size, growth potential and customer availability
- Product Differentiation
 - Uniqueness, intellectual property (IP), technical edge and profitability
- Management Capabilities
 - Domain expertise and experience in business, finance, technology and marketing needs of the venture
- Sustainability
 - Technology life cycle, barrier-to-entry, insensitivity to business cycles, inclusion of risk-mitigation and/or pivot strategies
- Exit Value
 - Future cash-out potential, opportunities for realized capital gains through IPO, mergers and/or acquisitions

My Examples of Lean Start-Up Successes

- Vertex
- Scion
- IndUS
- Cellanyx

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