BIO 2017

Overview of Lean Startups for Life Science/Biotechnology

Panel Discussion for BIO 2016 Arthur A. Boni, PhD Tepper School of Business Carnegie Mellon University

Two Lean Startup Pioneers

Eric Reis

- "A human institution designed to create new products or services under conditions of extreme uncertainty"
- "Works in a company of any size, in any sector or industry"

Steve Blank

- "startups are not versions of larger companies"
- "a startup is a temporary organization in search of a scalable, repeatable, profitable business model"
- Requires different rules, roadmaps, skill sets, and tools to minimize risk and optimize chances for success

The Lean Startup Process BIO 2016

Sketch out hypotheses (use the scientific method)

Use Business Model Canvas

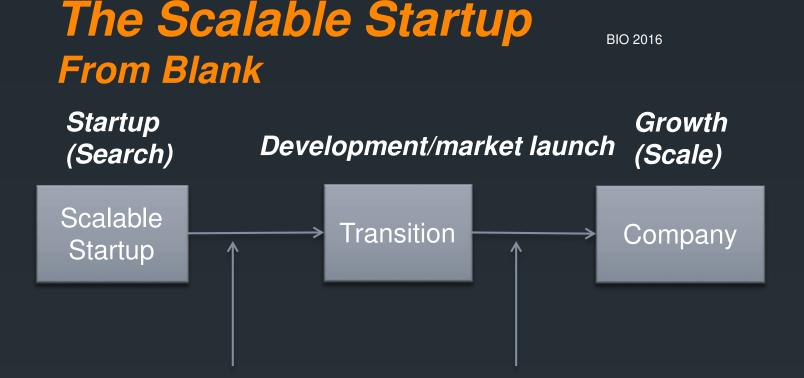
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Discover Develop Pivot Test Hypotheses Listen to Customers!

Short, repeated cycles

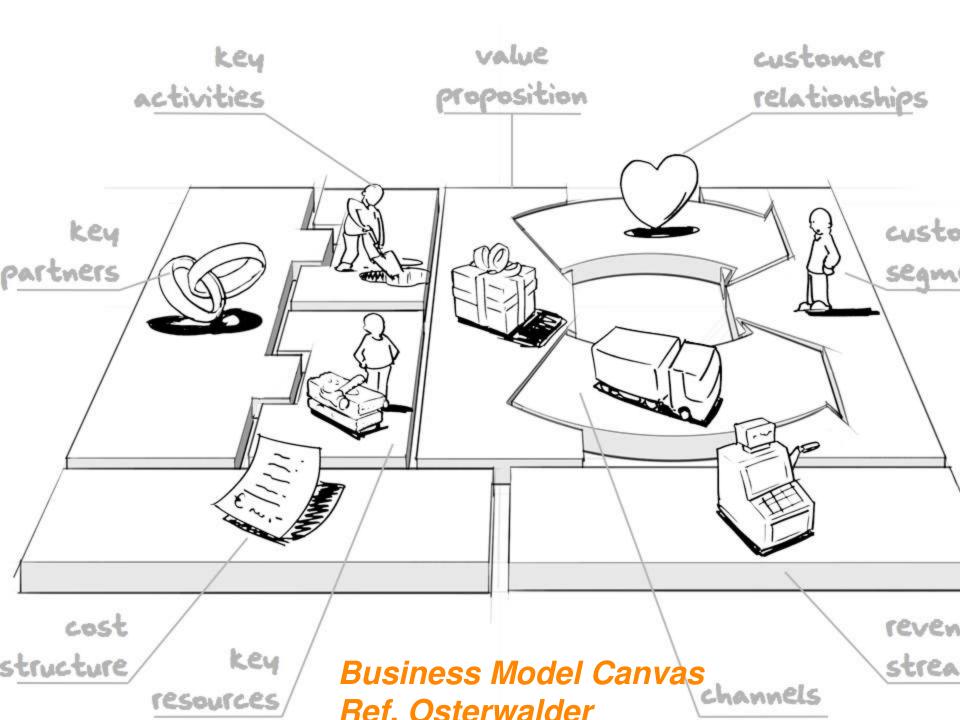
Quick, Responsive Development (agile)

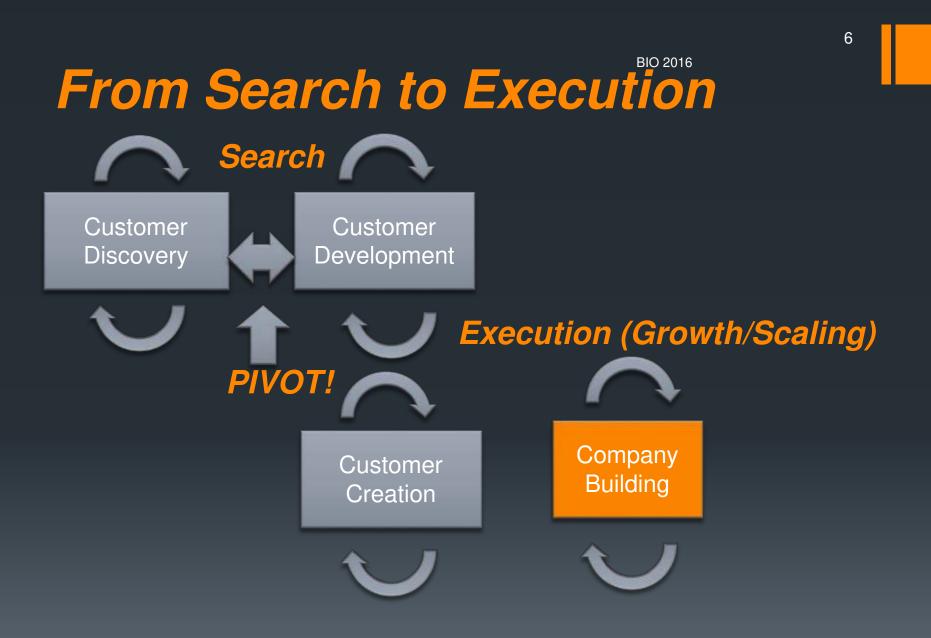
Validate the need, solution and business model (iteratively)



Business Model found
Product/Market fitCash-flow breakeven
ProfitableRepeatable sales model
Manager hiredRapid scale
New Sr. Management

- 150 people





Key Principles

Strategy is business model & hypothesis driven
Use business model canvas for testing critical elements early before spending

Validated, customer-centric learning

- Product and customer selection to validate product/market fit
- Iterative product releases to test MVP
- Supports development of a repeatable and scalable business model

Lean Biotech Startup

Good science does not necessarily translate into great products

<u>VALIDATED CUSTOMER LEARNING IN A MULTI-</u> <u>SIDED MARKET</u>

- The biotech/healthcare business model addresses multiple "customers" → get out of the building!
 - Patient
 - Physician
 - Provider
 - Payer
 - Regulator
- Must validate improved standard of care at acceptable cost

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Moving Rapidly

<u>PIVOTING BASED ON MARKET</u> FEEDBACK – from all constituents

Identify most compelling application/product attributes

Identify most receptive target entry market segments

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Moving Rapidly and Efficiently in a Regulated Market

- Identify and design 'smart' clinical demonstrations for regulatory and reimbursement issues
- Identify regulatory issues early-on in the startup phase and make that part of the growth strategy for clinical demonstration and market development
 - ISO
 - GMP
 - Reimbursement

Moving Efficiently in a Multisided Market

<u>CAPITAL EFFICIENCY THRU OPEN</u> <u>INNOVATION</u>

- Borrow or lease Cap. Ex.
- Generate revenue via fee-for-service
- Partner (lease business model elements) to offer more value at lower cost
- Non-dilutive capital
- 'Virtual teams' and Accelerators

Issues in biotech and other healthcare opportunities

Discuss application of lean startup principles

- Devices
- Mobile Health
- Healthcare IT
- Pharma
 - Small molecule
 - Protein