



I-Corps from the Trenches

Conversations with I-Corps Alum

September 28, 2016

Michael Weingarten
Director

National Cancer Institute SBIR Development Center



Q&A

sbir.cancer.gov/icorps

Submit your questions through the Q&A chat box

Please submit your questions via the chat box. We will be answering your questions throughout the webinar, with additional time dedicated at the end of the session.



Michael Weingarten
NCI/NIH I-Corps



Christie Canaria
NCI/NIH I-Corps



Edmund Pendleton
Lead Instructor



Jennifer Nichols
CEO, Jan Biotech

White House Demo Day



“We’re scaling up the National Science Foundation’s successful Innovation Corps program at six more federal agencies so we can help more of our scientists move their ideas out of the lab and into the marketplace.”

– President Obama (August 4, 2015)

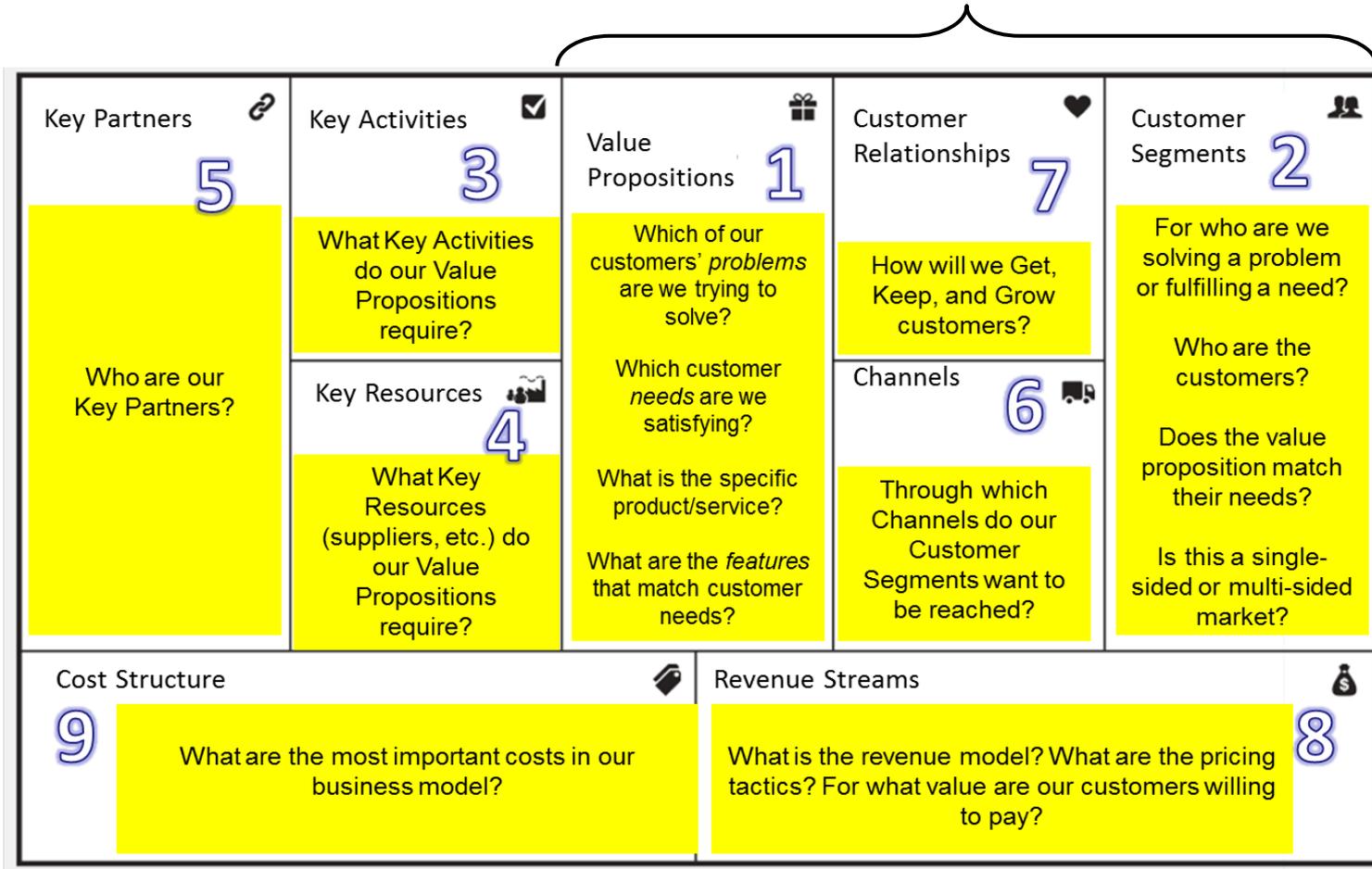
I-Corps™ Training Program

Program Description

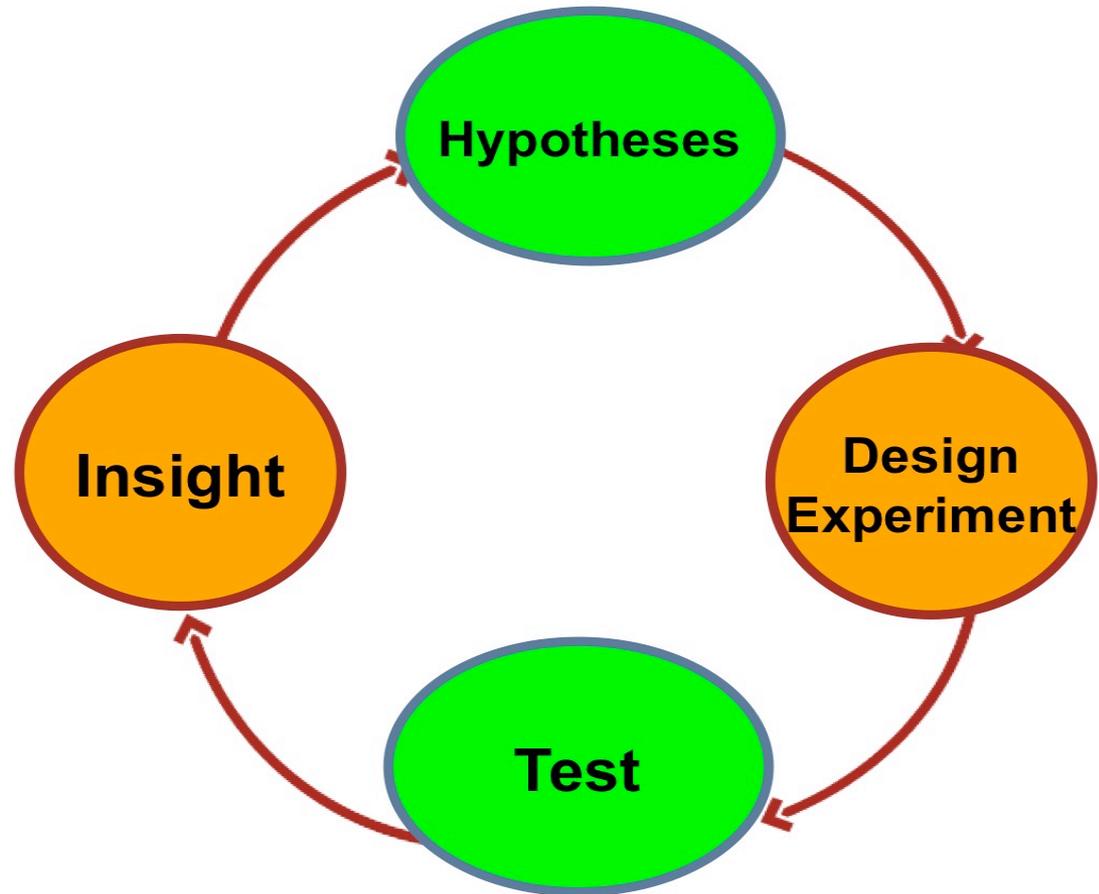
- Intensive ***Entrepreneurial Immersion*** course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes ***Reaching out to Customers*** to test hypotheses about the need and market for the technology being developed.
- Each team is expected to conduct over 100 interviews over 8 weeks.
- Format is focused on ***Experiential Learning***

Business Model Canvas

“ Product-Market Fit ”



Hypotheses Testing and Insight...



I-Corps™ at NIH

SBIR/STTR Phase II grant applications have two components

1.The Research Strategy

2.The Commercialization Plan

- Phase II applicants often focus on #1
- The strongest Phase II applications focus on both

Important goal of I-Corps™ at NIH is to inform the Commercialization Plan

Focus on Learning

Customer development is NOT sales!

- Teams are not pitching their product or technology
- Teams are **listening** to potential customers and other stakeholders and **learning** about:
 - What customers want and need
 - Pain points in their customers' daily routines
 - Features of a technology that would provide value



3 cohorts to date

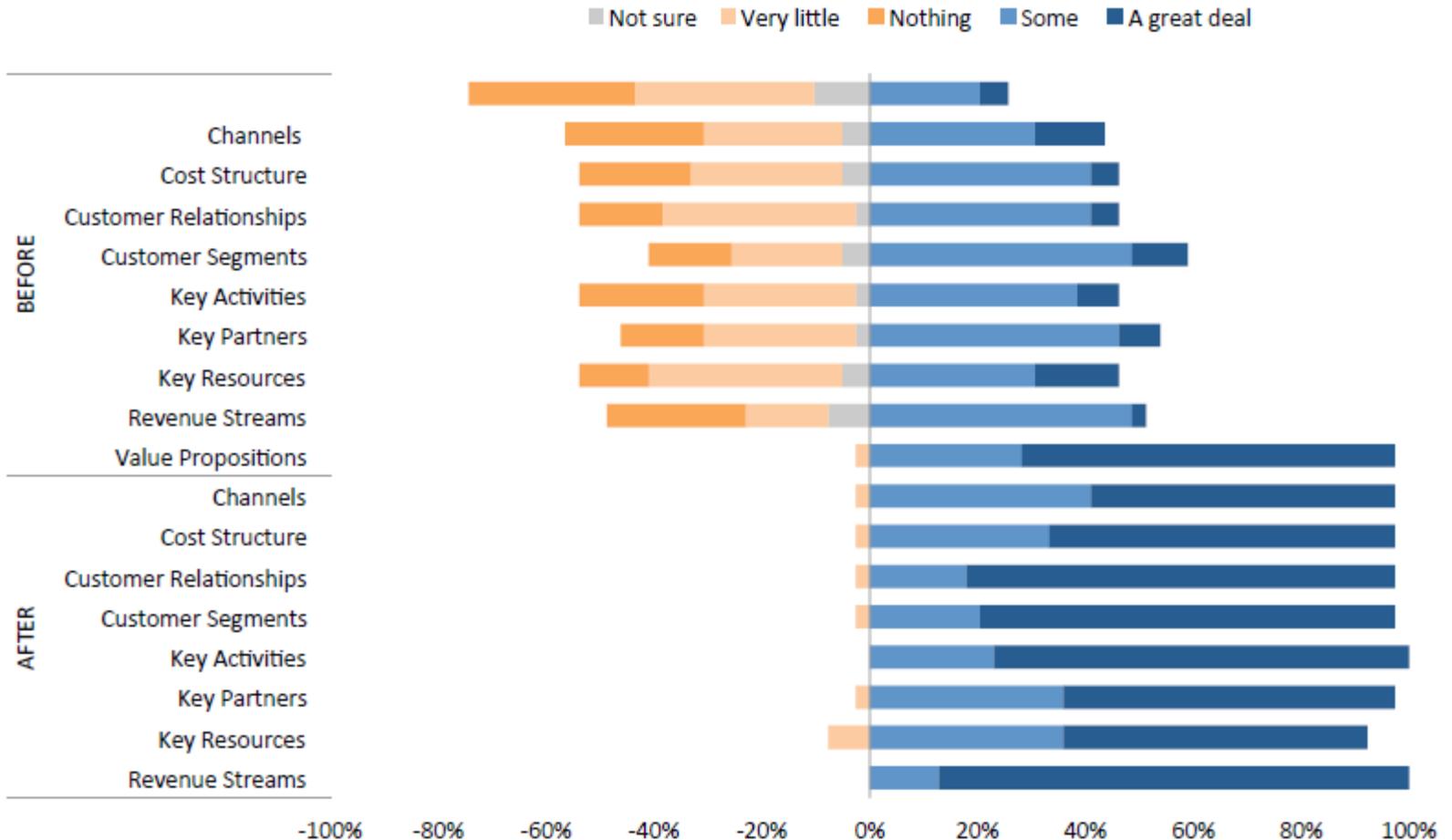
- 57 teams conducted 6,362 customer discovery interviews
- 90% found the program “very good” or “excellent”
- 90% would recommend I-Corps™ at NIH to other companies

“We clarified the value propositions, who our target customers would be, revenue streams, customer relationships...”

“After going through I-Corps we understand we have to focus on a small subset [of customers] and prioritize segments based on their value propositions.”

Business Model Canvas Knowledge

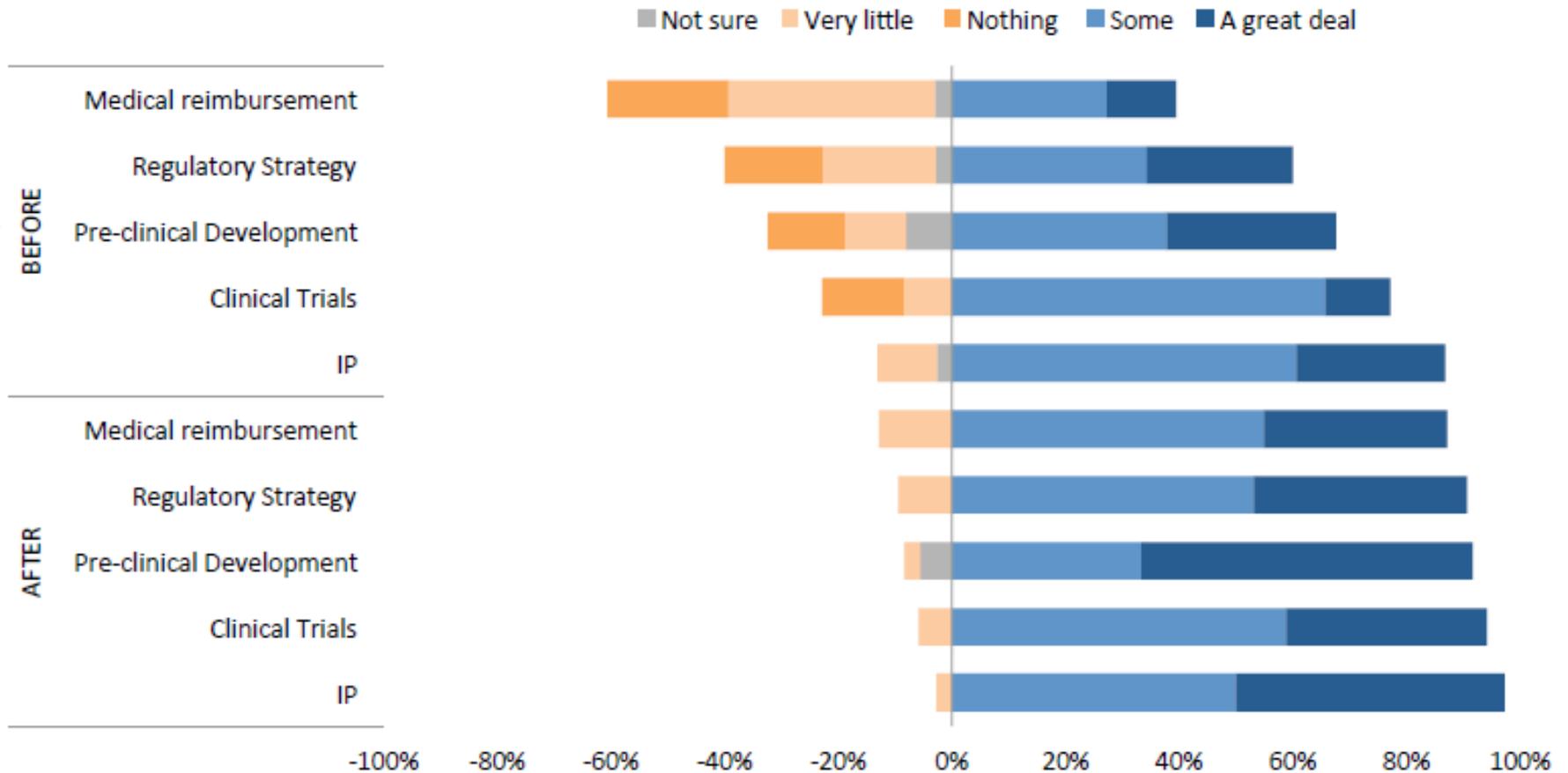
Spring 2016 Cohort



Life Science Commercialization Knowledge

Spring 2016 Cohort

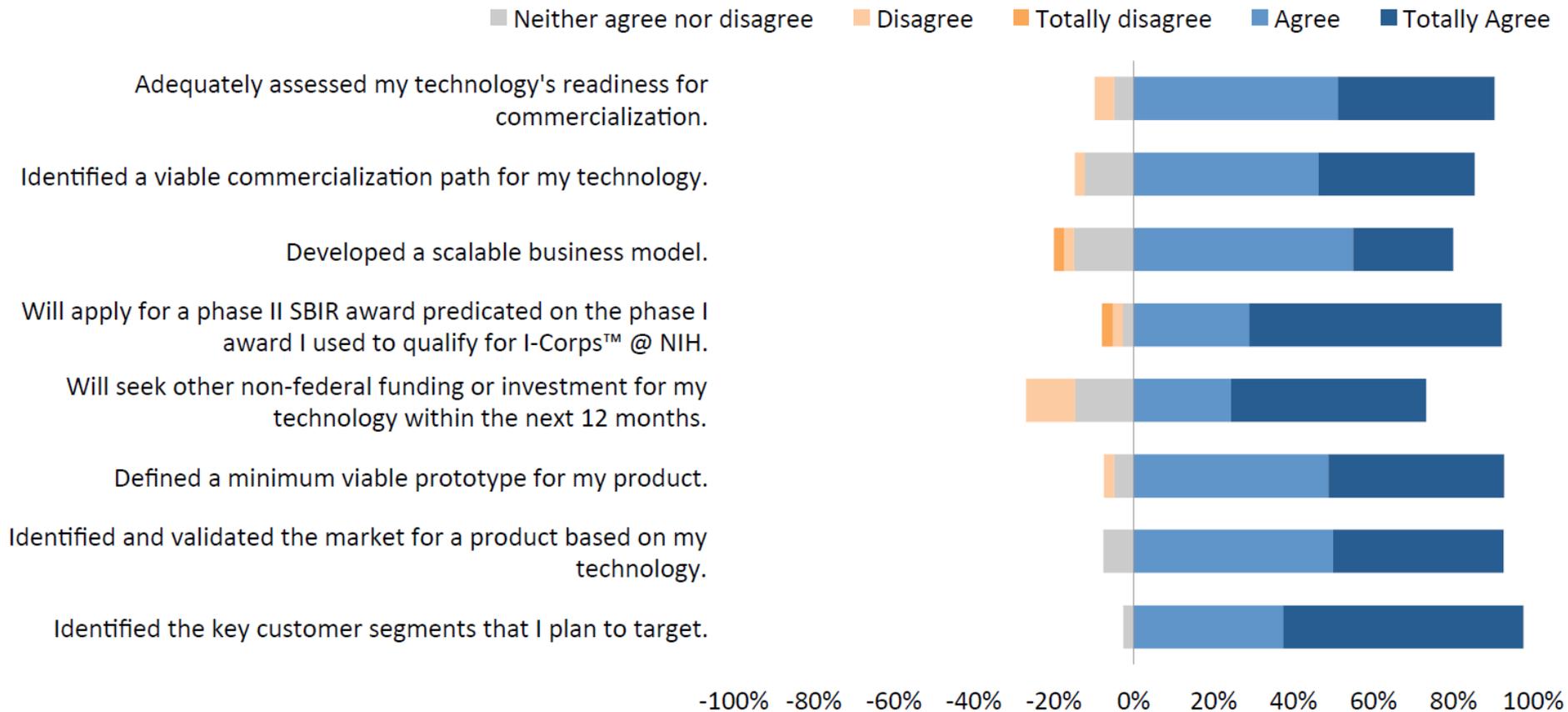
Knowledge of areas of Commercialization & Life Sciences



Status of Technology and Future Plans

Spring 2016 Cohort

Company Status





A new drug to restore function after spinal cord injury (SCI)

Learnings & Pivot

No one was interested in early-stage SCI drugs
...but they are interested in **Multiple Sclerosis**

Timeline

- December 2014 - Novoron graduates from I-Corps at NIH
- August 2014 - Phase 1 NIH grants received to develop SCI and stroke therapeutics
- November 2012 - Dr. Travis Stiles' discovery published in *Journal of Cell Science*

Novoron Bioscience Awarded NIH Grant to Evaluate New Treatments for Multiple Sclerosis (Dec 2015)

Negotiating **2** deals (including HubertBio in Korea)

Negotiating **2** strategic partnerships (with mutual NDAs)

Xconomy Recognizes Novoron as San Diego Life Science Startup to Watch in 2016 (Feb 2016)



17 Participating ICs in 2017

- National Cancer Institute (NCI)
- National Center for Complementary and Integrative Health (NCCIH)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Allergy and Infectious Diseases (NIAID)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Mental Health (NIMH)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Injury Prevention and Control (NCIPC/CDC)
- National Institute for Occupational Safety and Health (NIOSH/CDC)



PA-14-616 I-Corps at NIH Administrative Supplement
\$50,000 budget cap

Application Due Date	November 1, 2016	January 9, 2017
Phone Interview (estimated)	December 5-9, 2016	February 13-17, 2017
Notice of Award (estimated)	January 6, 2017	March 17, 2017
Kick-off/Close-out Venue	TBD	TBD
Course Kick-off	February 5-8, 2017	April 23-26, 2017
Web-Ex Courses	February 14	May 2
(1-5PM ET)	February 21	May 9
	February 28	May 16
	March 7	May 23
	March 14	May 30
	March 21	June 6
Course Close-out/ Lessons Learned	March 27-28, 2017	June 12-13, 2017
Cohort Size	24 teams	24 teams



Edmund Pendleton

Lead Instructor, NIH & NSF I-Corps
Asst. Faculty Director, NSF I-Corps

Why *I-Corps*



I WANT YOU

FOR  **CORPS**
NSF Innovation Corps

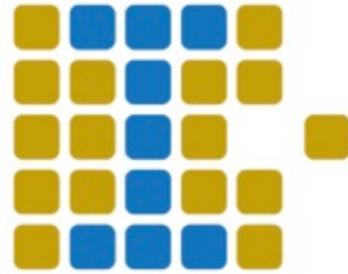
NEAREST RECRUITING STATION

\$7 *Billion*

***"How can we increase the
economic impact of the
research dollars invested
every year?"***







CORPS
NSF Innovation Corps

Lean LaunchPad Course

Developed by
Entrepreneurs

Taught by
Entrepreneurs

Lean *Startup*

Steve Blank is a consulting associate professor at Stanford University and a lecturer and National Science Foundation principal investigator at the University of California at Berkeley and Columbia University. He has participated in eight high-tech start-ups as either a cofounder or an early employee.

Why the Lean Start-Up Changes Everything

by **Steve Blank**

HARVARD Business Review

MAY 2012

85 Idea Watch
The Limits of Social Influence
Simon Aral

92 Spotlight
In Search of the Next Big Thing
An interview with Marc Andreessen

141 Case Study
The Unmanageable Star Performer
Abhishek Goel

TURN A GREAT IDEA INTO A GREAT BUSINESS



“Lean” is changing everything you know about starting a new venture [PAGE 63](#)

by Harvard Business School’s Shikhar Ghosh shows, 75% of all start-ups fail.

But recently an important countervailing force has emerged, one that can make the process of starting a company less risky. It’s a methodology called the “lean start-up,” and it favors experimentation over elaborate planning, customer feedback over intuition, and iterative design over traditional “big design up front” development. Although the methodology is just a few years old, its concepts—such

“minimum viable product” and “pivoting”—have quickly taken root in the start-up world, and business schools have already begun adapting their curricula to teach them.

The lean start-up movement hasn’t gone totally mainstream, however, and we have yet to feel its full impact. In many ways it is roughly where the big data movement was five years ago—consisting mainly of buzzword that’s not yet widely understood, whose applications companies are just beginning to grasp. As its practices spread, they’re turning the conventional wisdom about entrepreneurship on its head. New ventures of all kinds are attempting to improve their chances of success by following its principles of failing fast and continually learning. And despite the methodology’s name, in the long term some of its biggest payoffs may be gained by the *large* companies that embrace it.

In this article I’ll offer a brief overview of lean start-up techniques and how they’ve evolved. Most important, I’ll explain how, in combination with other business trends, they could ignite a new entrepreneurial economy.

The
Economist

SPECIAL REPORT
TECH STARTUPS

January 18th 2014



A Cambrian moment

MIT Technology Review

VOL. 115 NO. 6 | \$5.99 US

HAS QUANTUM
COMPUTING
FINALLY
ARRIVED?

Upfront p24

HOW
TOMORROW'S
STARTUPS WILL
BE FUNDED

Business Report p75

TECH
TRANSFORMS
MUSIC, ART,
AND PROSE

Reviews p87



Buzz Aldrin.
Apollo 11
moonwalker,
would like a
word with you.

You Promised Me Mars Colonies. Instead, I Got Facebook.

We've stopped solving big problems.
Meet the technologists who refuse to give up. p26

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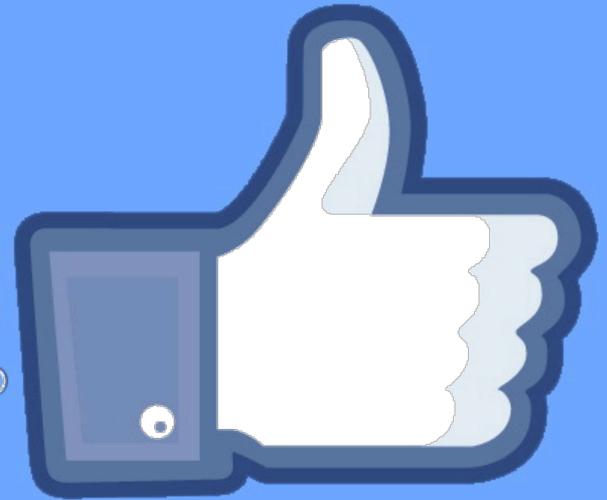


Buzz Aldrin,
Apollo 11
moonwalker,
would like a
word with you.

**You Promised Me Mars Colonies.
Instead, I Got Facebook.**



facebook.®



**I-Corps first program to
apply lean startup principles
*to complex engineering,
technology, and science
based startups***

Life *Sciences?*



\$7 Billion



\$7 Billion



\$30 Billion

***"How can we increase the
economic impact of the
research dollars invested
every year?"***

Just like NSF grantees,

**Just like NSF grantees,
we believe there is a
better way to build
*life sciences startups.***

NIH *I-Corps*

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STEVE BLANK

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Entrepreneurship is a Calling

Entrepreneurship is 

[Reinventing Life Science Startups – Evidence-based Entrepreneurship](#)

Posted on **August 21, 2013** by [steveblank](#)

What if we could increase productivity and stave the capital flight by helping Life Sciences startups build their companies more efficiently?

We're going to test this hypothesis by [teaching a Lean LaunchPad class for Life Sciences](#) and Health Care (therapeutics, diagnostics, devices and digital health) this October at UCSF with a team of veteran venture capitalists.

[Part 1 of this post](#) described the issues in the drug discovery. [Part 2 covered medical devices and digital health](#). This post describes what we're going to do about it. And why you ought to take [this class](#).

When I wrote [Four Steps to the Epiphany](#) and the [Startup Owners Manual](#), I believed that Life Sciences startups didn't need Customer Discovery. Heck how hard could it be? You invent a cure for cancer and then figure out where to put the bags of money. (In fact, for oncology, with a successful clinical trial, this is the case.)

contact: info@kandsranch.com



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Linkedin



**In most cases, it's not
just about *the execution
of science.***

**You need to reduce
technology, regulatory, *and*
*market/customer risk...***

...by using an approach
driven by customer*
needs.

Why are *we here?*

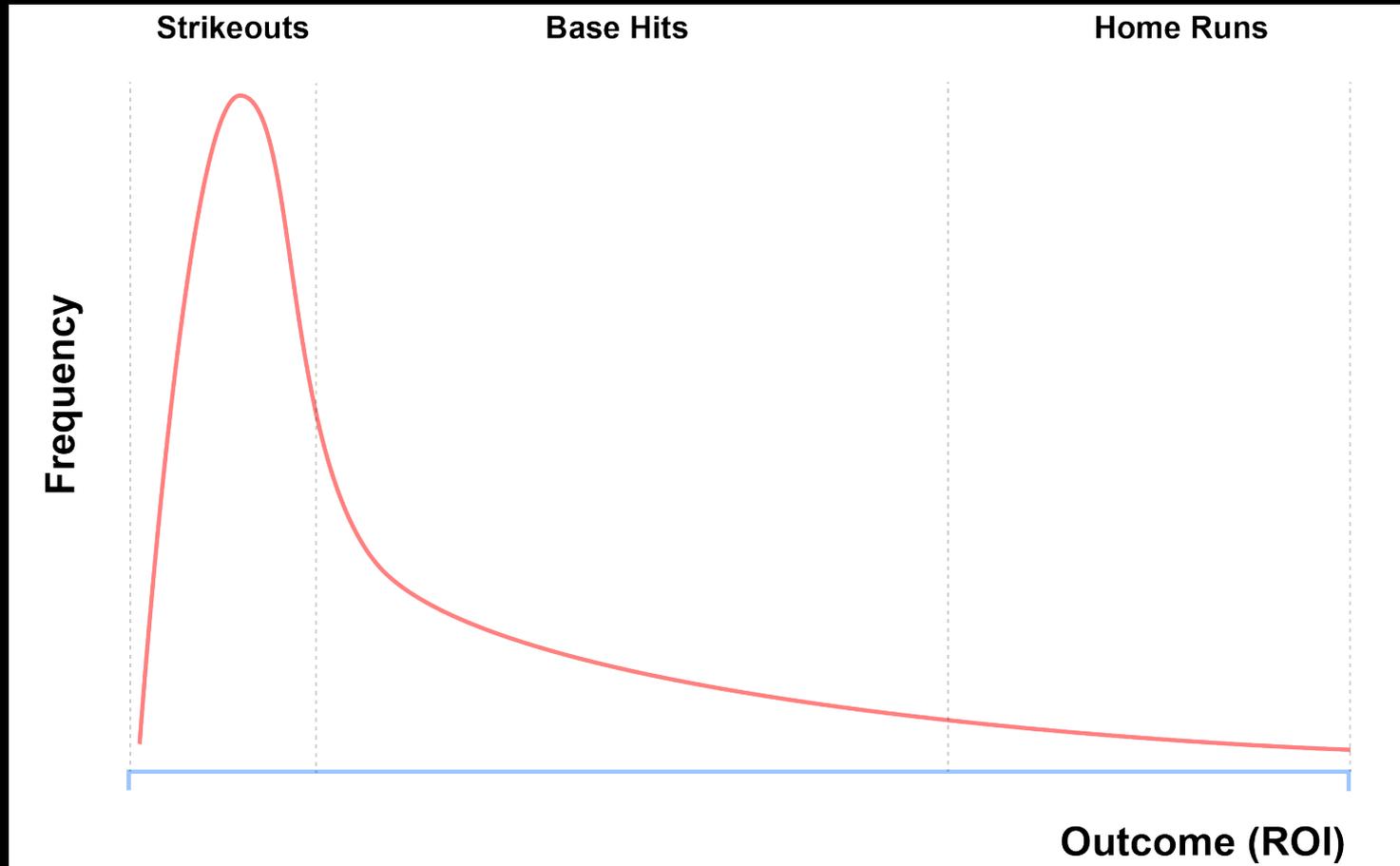
Our *Goal*

Improve *Odds*

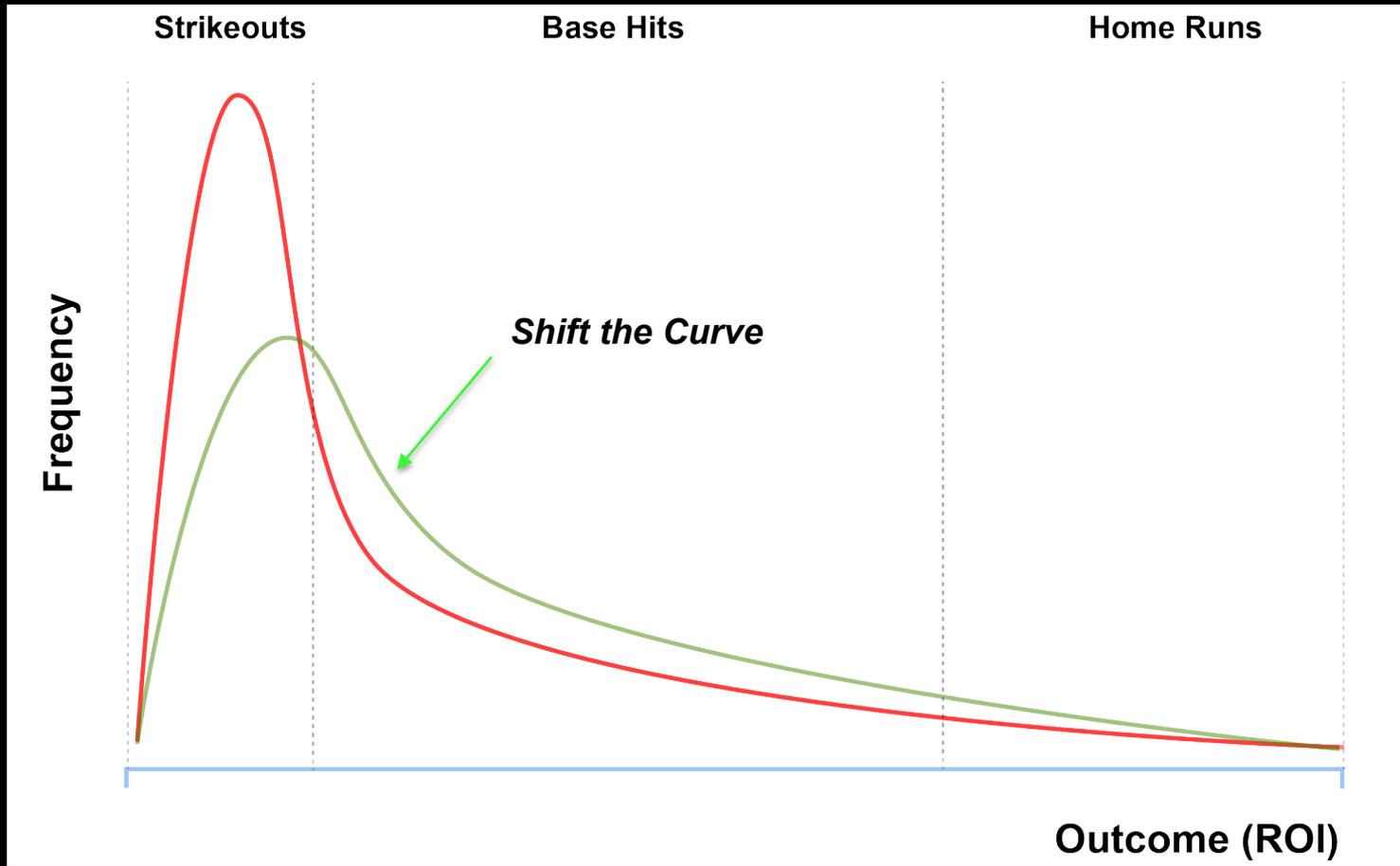
Pick *Winners*

Pick *Winners*

Startup *Statistics*



Create *More Winners*



How do we

build a startup?

Business Model *Canvas*



We use

Customer Development

to build Business

Models

Search for...

Problem-Solution Fit

*“Can you identify and validate a
problem or need in the market that
enough people care about?”*

Search for...

Product-Market Fit

“Can you build and deliver a product / service that **satisfies** the customer problem or need?”

Search for...

Business Model Fit

***“Can you build and validate a
repeatable and scalable (profitable)
business model?”***

Search for
Business Model

Get *out* of
the building!

Validated facts versus
untested guesses...

Evidence comes from

Evidence comes from

Customer Discovery
Interviews

This is what *we call...*

This is what we call...

Evidence Based
Entrepreneurship

What will *you do?*

Jump *In*



8 *Weeks*

100 *Interviews*

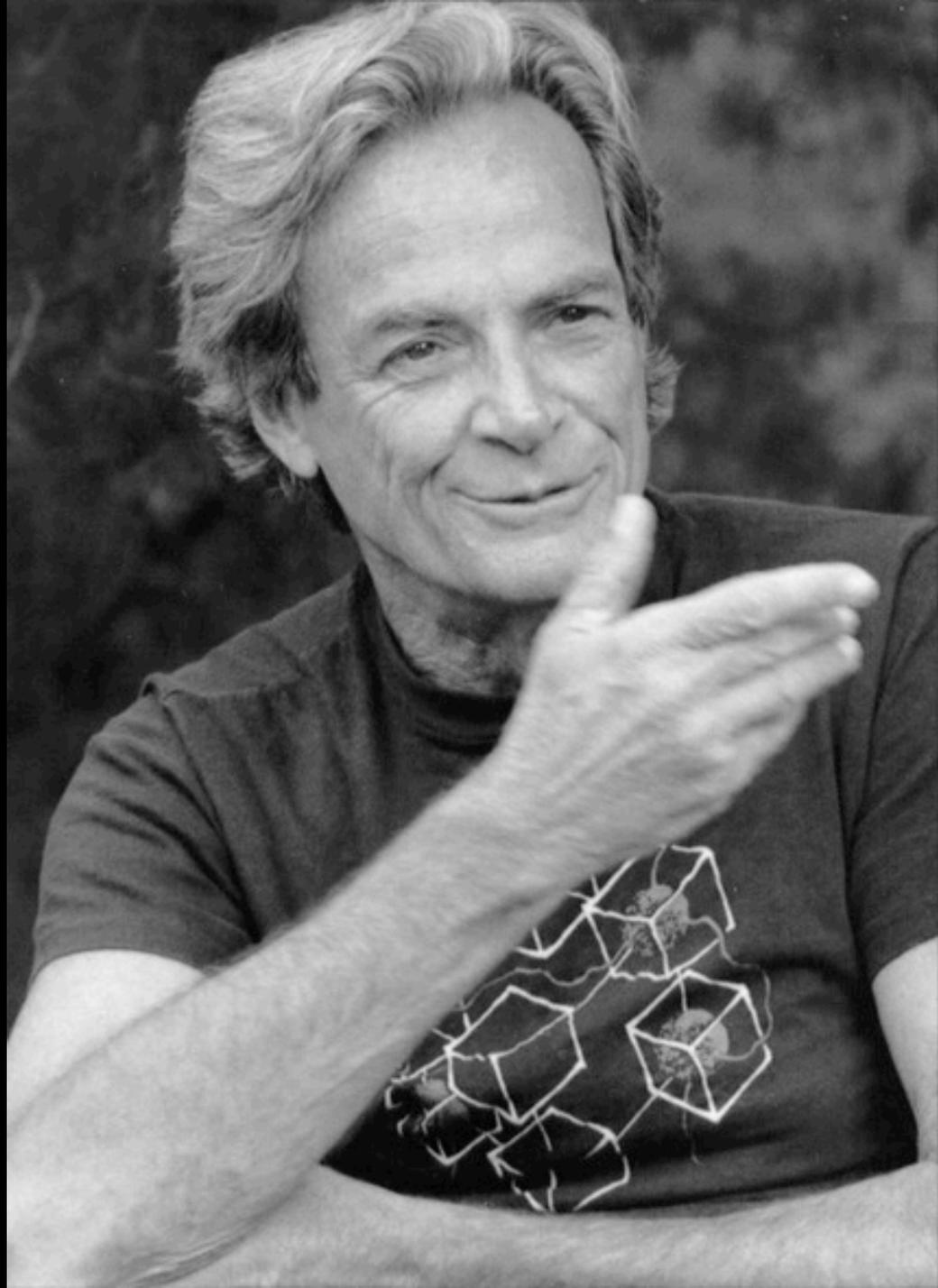
Gut *Feeling*



But *why?*

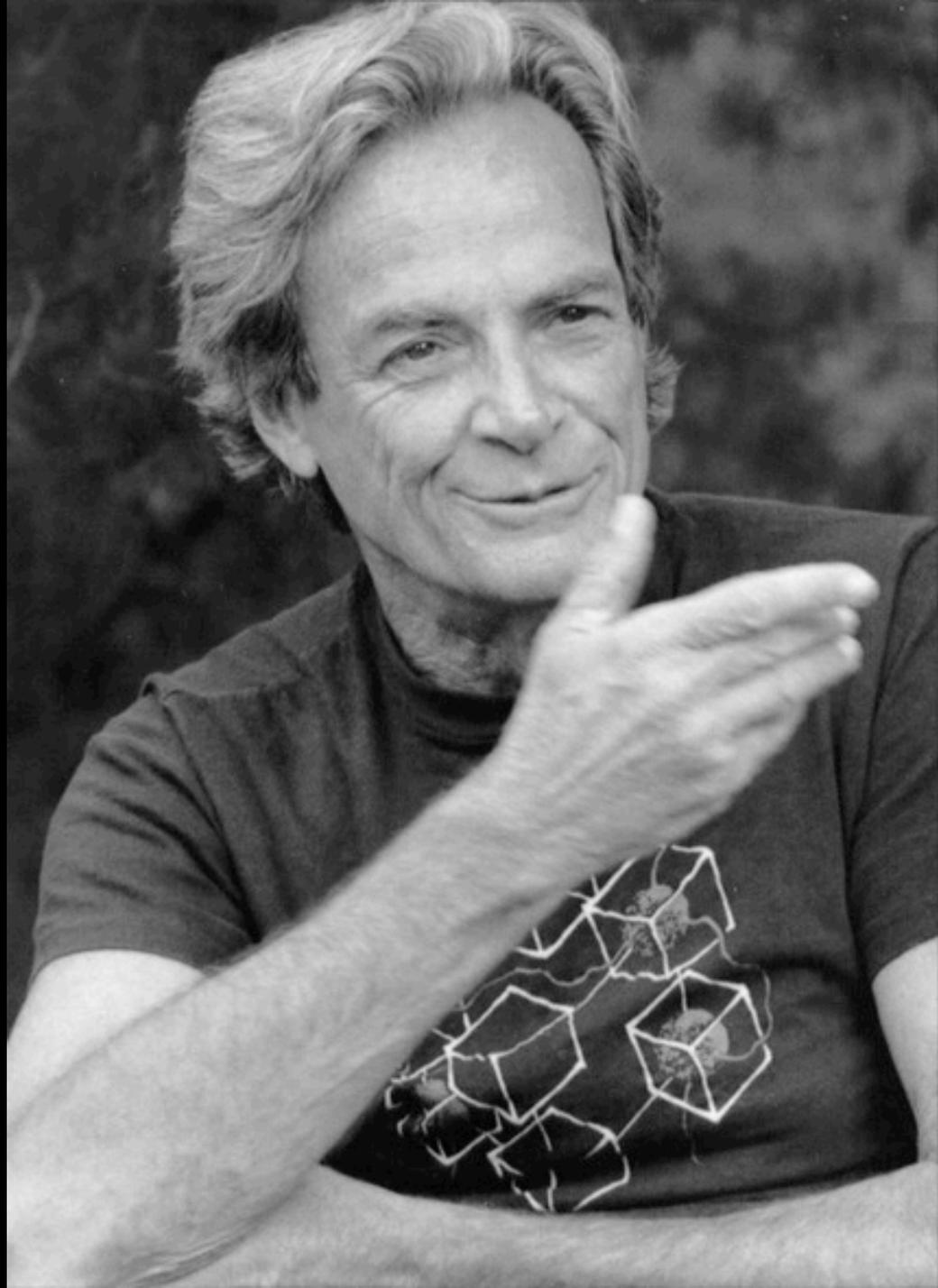
***“The first
principle is that
you must not
fool yourself***

– Richard Feynman



“The first principle is that you must not fool yourself, and you are the easiest person to fool.”

– Richard Feynman





Everyone has *a plan...*

...until he gets *punched in the face.*”



TOP 10

STARTUP MISTAKES



100™

First Hits

www.100FirstHits.com

8. Spending Too Much Money 18 (2,1%)

9. Failing To Ask For Help 12 (1,4%)

10. Ignoring Social Media 6 (0,7%)

5. Not Having The Right Co-Founders 66 (7,9%)

6. Chasing Investors, Not Customers 45 (5,4%)

7. Not Making Sure You Have Enough Money 28 (3,3%)

Top *Three*



**Why is I-Corps
especially valuable for
*Life Sciences?***

**There is A LOT to learn
*in these markets.***

**Markets are often
complex with *many
stakeholders.***

**Pathways to market
are often *lengthy,*
*costly, and complex.***

Startup risks are
generally very high.

NIH *I-Corps*



JAN BIOTECH, INC. TEAM #46



Jennifer Nichols
CEO



Janet Huie
CSO/PI



Dennis Brown
Industry Expert

Our Dx determines the exact number of HIV virus particles in patients where virus is dormant.

With this tool, researchers can develop better drugs, AND doctors can decide when to stop therapy.

	In-person	Web call	Phone	Total
THIS WEEK	1	0	2	3
Total	53	9	41	103



THE TEAM



Ms. Jennifer A. Nichols, President & Co-Founder

- 10 years biotech startup experience
- Commercialization, Licensing
- Regulatory compliance, Patents



Dr. Janet L. Huie, PhD, CSO & Co-Founder

- PI for NIH, DoD, NOAA Grants & Contracts
- IRB Chair
- FDA validation



Mr. Dennis Brown, Industry Expert

- Software, Finance, Logistics
- CEO/President with \$47M in sales
- Launch stage for latest venture



MS. KNOW-IT-ALL



INITIAL HYPOTHESIS

Here's what we thought:



Design:

Testing bulk RNA



Price:

Lowest price



Partner:

Big Pharma





HARVARD
UNIVERSITY

UCSF

University of California
San Francisco

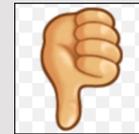


Penn
UNIVERSITY of PENNSYLVANIA

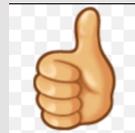
Here's what we learned:



~~Testing bulk RNA~~



**New HIV RNA
target site**



**Single cell analysis/
cell separation (FACS)**





PRICING





PRICING



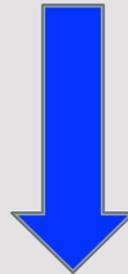
PRICING

Here's what we learned:



Price:

~~Lowest price~~



Value pricing





ORIGINAL INVESTOR ROI

The Client expects to test 6 times a year, though 3 times a year is covered by insurance. Perhaps 3% of 1.2 million could receive 3 tests in year one, and you would expect \$2,397,600 in revenues ($3\% \times 4.44 \times 10^5 \times \$60/\text{test} \times 3$ tests per year). Market access increments are 3%, 6%, 10%, 25% and 40%.



Year 1: 2.4 million dollars based on 40,000 units sold

Year 2: 4.8 million dollars based on 80,000 units sold

Year 3: 8.0 million dollars based on 133,200 units sold

Year 4: 20 million dollars based on 333,000 units sold

Year 5: 32 million dollars based on 532,800 units sold



CURRENT INVESTOR ROI

***\$3M to get to RUO (need preclinical data)**

***\$125M to get to Clinical Dx**

For a return on a \$50M investment we must exceed \$500 mil in sales within 5-7yrs assuming the company is valued at 5-10x sales (assuming they own 50% equity):

1.2M x 37% (HIV+ on ART) = 444,000 patients treated that need testing

3 tests per year = 1.32M tests/yr

x **\$1,000/test** = \$1.3B total market



Yr 1: 3% \$40M

Yr 2: 6% \$80M

Yr 3: 10% \$130M

Yr 4: 25% \$325M

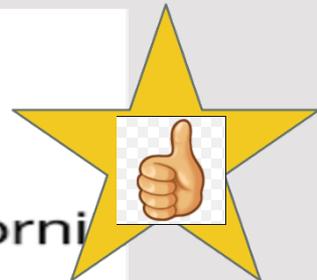


Yr 5: 40% \$520M

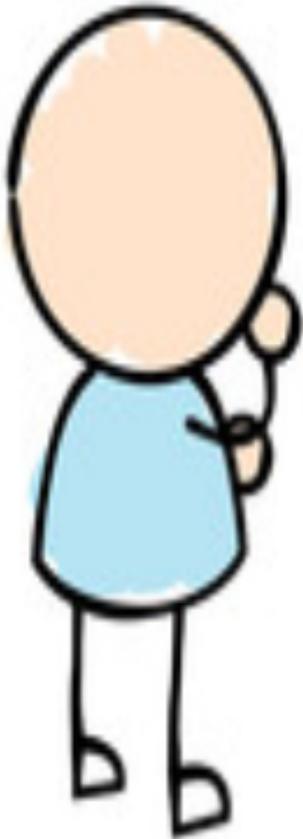


PARTNERS

Here's what we learned:



LESSONS LEARNED



Design:

Then → ~~Testing~~ bulk RNA

NOW → Single cell analysis (FACS) + new Target



Price:

Then → ~~Lowest~~ price

NOW → Value pricing



Partner:

Then: ~~Big Pharma~~

NOW → UCSF and University of Rochester





DAY 1 BMC DAY 1

OUR ORIGINAL IDEA- WHAT WE THOUGHT

Key Partners

- University of Rochester
- Southern Research
- UCSF
- ~~Cornell University~~
- ~~UCSF Hospital Clinicians~~
- Gilead Sciences, Inc.
- ~~Monogram Biosciences~~
- ~~Johnson and Johnson~~

Key Activities

- ~~We need to become~~
- ~~Clinical validation~~

Value Proposition

- ~~Improve specificity~~
- ~~Provide accurate~~
- ~~Quantification of the latent~~

Customer Relationships

- ~~By engaging in~~
- ~~offering an assay that~~

Customer Segments

- Pharmaceutical Companies
- ~~Diagnostic Companies~~
- Clinicians monitor
- ~~FDA sponsored~~

Key Resources

- Regulatory consultant
- clinical trials consultant
- chemist for synthesis

Channels

- ~~for sale via web~~
- ~~for sale via cold call and~~
- ~~Non-commercial~~
- ~~corporate seller~~

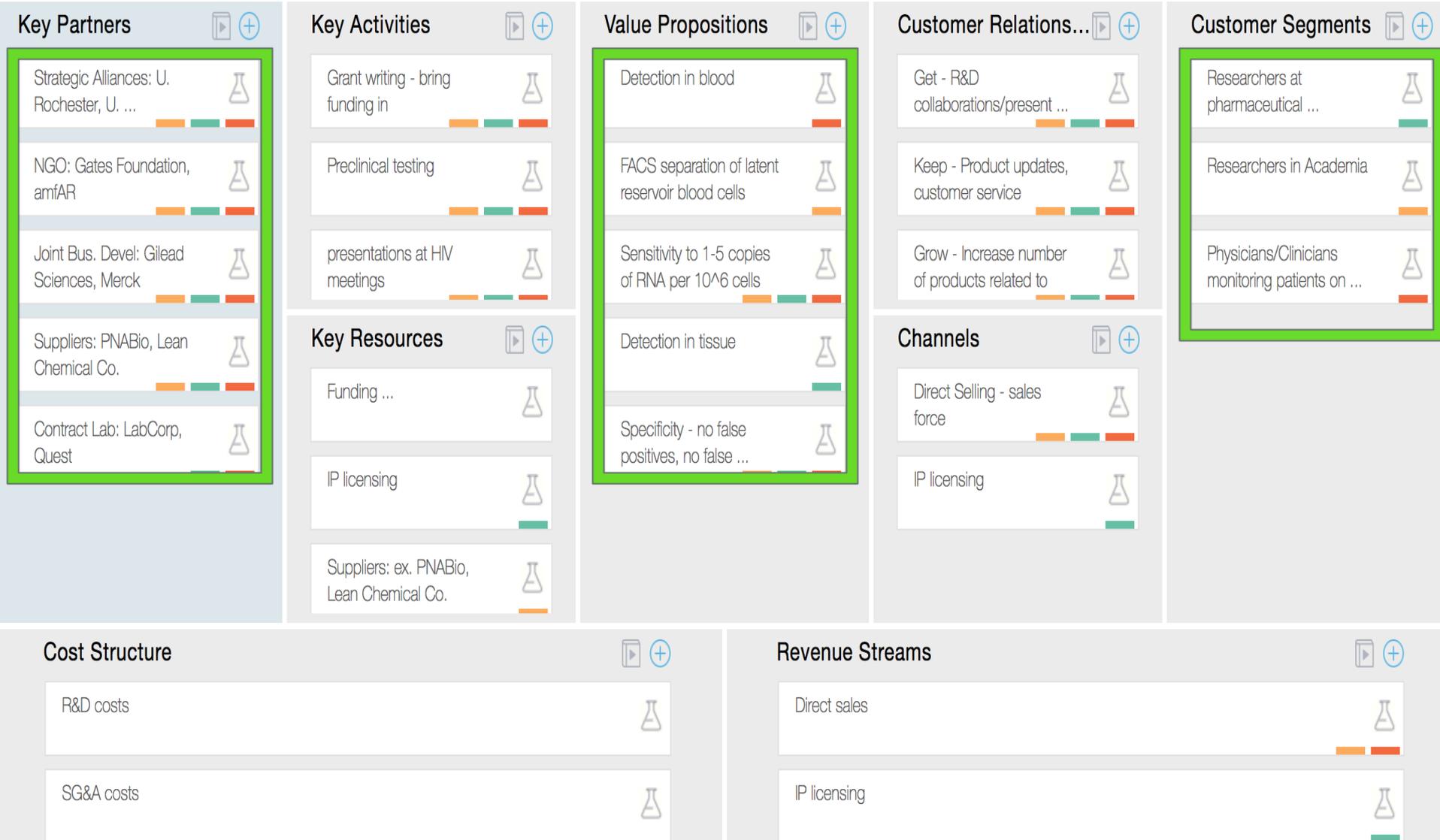
Cost Structure

- Pre-clinical trials
- Probe synthesis
- Synthesis of dye components

Revenue Streams

- ~~provide a sample assay to researchers to try in their lab~~
- ~~Provide the assay at a cost/experiment/kit for researchers to~~
- Licensing the technology to pharmaceutical companies

CURRENT BUSINESS MODEL CANVAS #8







NEXT STEPS

As a result of the I-Corps process:

Within the next 3 months

- Write an NIH/SBIR phase II
- Expand our current IP
- Enter into pre-clinical testing
- File for new IP

Partnerships

- U. Rochester (pre-clin samples)
- Southern Research (NHP Study, validation against QVOA)
- UCSF (RNA, proteomics study)
- Partner for rebound study

NON-NIH funding

- Maybe VC
- Maybe Angel



BUSINESS MODEL CANVAS #2

LaunchPad Central

Key Partners

- University of Rochester
- Southern Research
- UCSF
- Cornell University
- UCSF Hospital Clinicians
- Gilead Sciences, Inc.
- Monogram Biosciences/Labcorp
- Johnson and Johnson

Key Activities

- We need to become
- Clinical validation

Key Resources

- Regulatory consultant
- clinical trials consultant
- chemist for synthesis

Value Proposition

- Improve specificity and
- Provide accurate scientific
- Quantification of the latent

Customer Relationships

- By engaging in
- offering an assay that

Channels

- for sale via web
- for sale via cold call and
- Non-commercial
- corporate seller

Customer Segments

- Pharmaceutical Companies engaged in
- Diagnostic Companies
- Clinicians monitor
- FDA sponsored programs

Cost Structure

- Pre-clinical trials
- Probe synthesis
- Synthesis of dye components

Revenue Streams

- provide a sample assay to researchers to try in their labs.
- Provide the assay at a cost/experiment/kit for researchers to
- Licensing the technology to pharmaceutical companies

Value Propositions



Improve specificity
and sensitivity



Direct detection of
RNA



Offer accurate
testing on tissue



Detection of blood
samples



Customer Segments



Pharmaceutical
companies ...



Diagnostic
companies ...



Clinicians who
monitor latent HIV



Govt. sponsored
programs ...



Non-profit
organization's ...





CURRENT BUSINESS MODEL CANVAS #4

Week 2

Business Model Canvas



+Add New

Your hypothesis update succeeded.

Key Partners

- UCSF
- UR CFAR
- Southern Research Institute
- ACTG**
- Cornell University
- UCSF Hospital Clinicians
- Gilead Sciences, Inc.
- Monogram/AbCom

Key Activities

- We need to become experts at knowing what the
- Clinical validation

Key Resources

- Regulatory consultant
- clinical trials consultant
- chemist for synthesis

Value Propositions

- Detection of blood samples
- FACS separation of latent reservoir blood cells**
- Sensitivity to 1-5 copies of RNA per 10⁶ cells**
- Specificity - no false positives, no false negatives**
- Direct detection of RNA
- Offer accurate testing on tissue
- Improve specificity and sensitivity

Customer Relationships

- use with FACS for LR blood cell collection**
- Company/Univ vaccine/drug/etc ...
- faster time to result
- detection of LR cells in

Channels

- for sale via web
- for sale via cold call and sampling
- Non-commercial distribution to researchers
- community seller

Customer Segments

- HIV latent reservoir (LR) researchers**
- Pharmaceutical companies developing ...
- Diagnostic companies distributing diagnostics ...
- Clinicians who monitor latent HIV reservoir in ...
- Govt. sponsored programs supporting HIV cure ...
- Non-profit organization's engaged in HIV cure ...

Cost Structure

- Pre-clinical trials
- Probe synthesis
- Synthesis of dye components

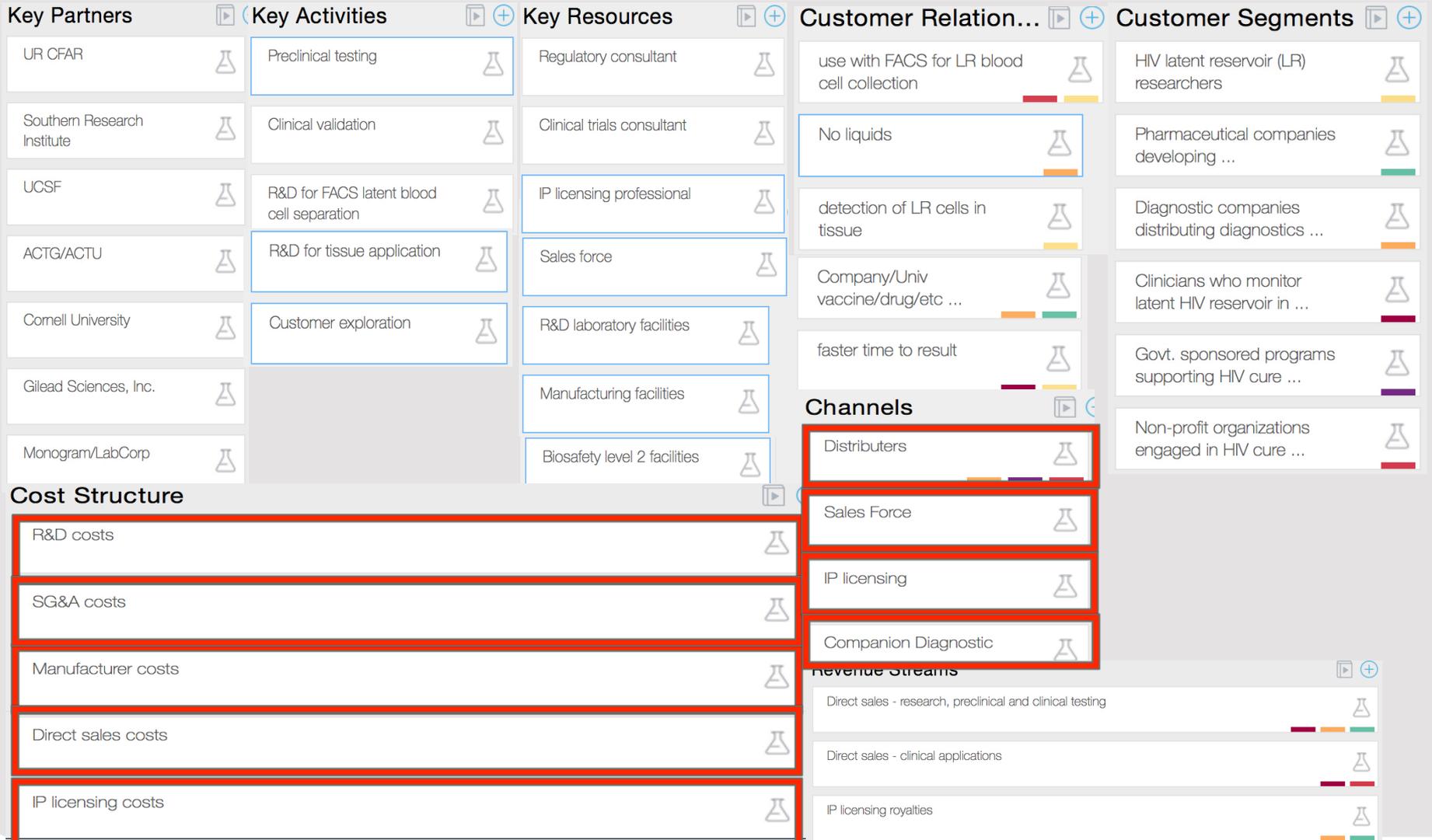
Revenue Streams

- provide a sample assay to researchers to try in their labs.
- Provide the assay at a cost/experiment/kit for researchers to use in validating their experiments and include us on manuscripts
- Licensing the technology to pharmaceutical companies



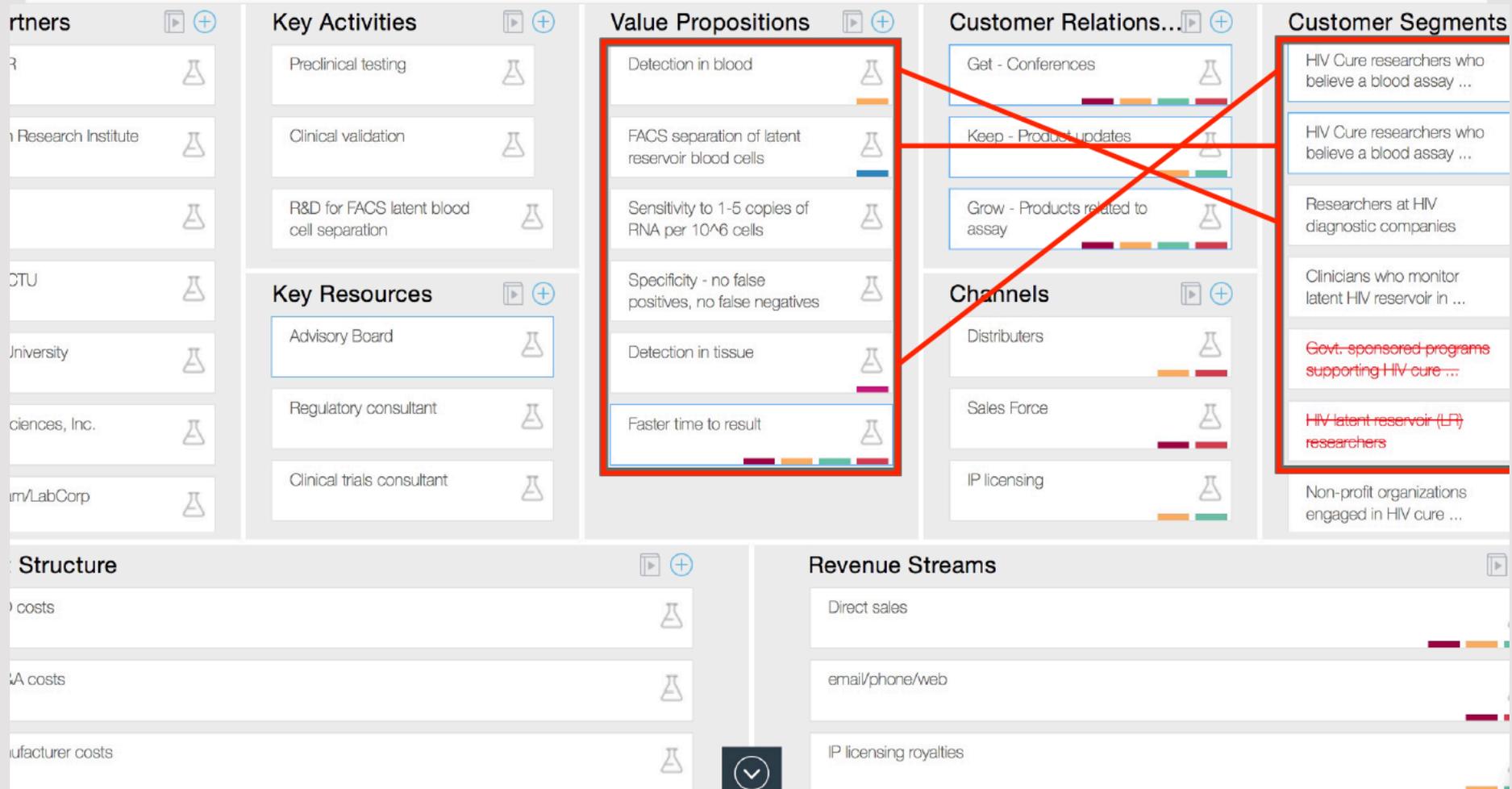


CURRENT BUSINESS MODEL CANVAS #5





CURRENT BUSINESS MODEL CANVAS #6



Customer Relations – more one-to-one connections with Customer Segments

Value Propositions



Detection in blood



Detection in tissue



FACS separation of latent reservoir blood cells



Sensitivity to 1-5 copies of RNA per 10⁶ cells



Specificity - no false positives, no false ...



Faster time to result



Customer Relationships



Get - Conferences



Keep - Product updates



Grow - Products related to assay



Channels



Sales Force



IP licensing



Distributors



Customer Segments



Researchers at pharmaceutical ...



Researchers in Academia



Physicians/Clinicians monitoring patients on ...



HIV Cure researchers who believe a blood ...



HIV Cure researchers who believe a blood ...



Clinicians who monitor latent HIV reservoir in ...



Non-profit organizations engaged in HIV cure



Revenue Streams



Kit and reagent sales



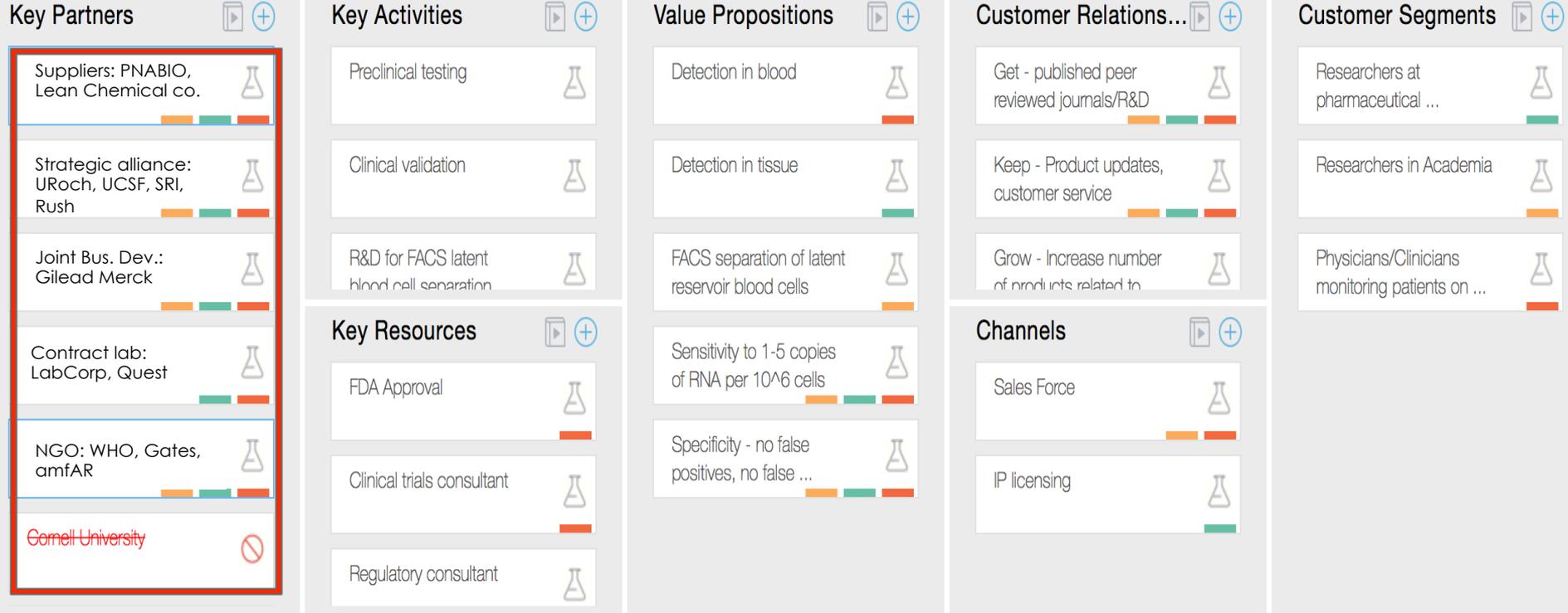
Licensing



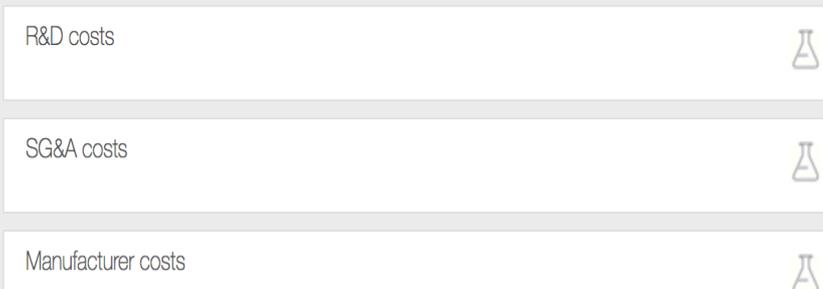
email/phone/web



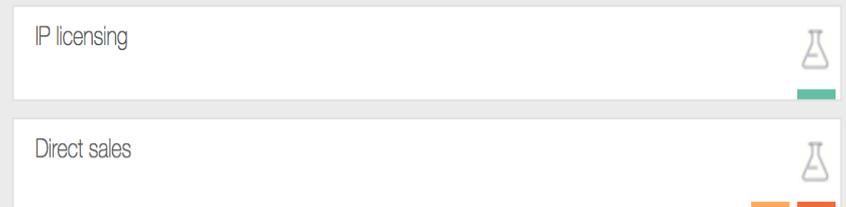
CURRENT BUSINESS MODEL CANVAS #8



Cost Structure



Revenue Streams



LaunchPad Central

Key Partners



Suppliers: ex. PNABio, Lean Chemical co.



Strategic Alliances: U of R, U.Pitt, UCSF, Southern Research



Joint Bus.: Gilead, Merck



Contract Lab: LabCorp, Quest



NGO: Gates Foundation, amfAR, WHO



Key Activities



Grant writing



KOL



Preclinical testing



Clinical validation



FDA approval



Key Resources



Clinical trials consultant



Regulatory consultant



IP



Suppliers: ex. PNABio, Lean Chemical co.



Advisory Board





Q&A

sbir.cancer.gov/icorps

Submit your questions through the Q&A chat box