

How to tell your Company's Story in Just 15 Slides



What We Will Cover Today

- Quick sense of who's in the room
- Review of The LHS Fifteen Slide Presentation® methodology
 - Sample slides
- Review methodology for elevator pitch
 - Practice your pitch live!

https://www.youtube.com/watch?time_continue=1&v=AclUQu8QgHI

Communicating Respect

Why are you here?

Your goal as a presenter is to suit your audience and be clear on your objectives

Whether small or large company

UCSF Innovation
Ventures



Credibility At Stake


If complex data or information does not coalesce into a few clear ideas, you've promised music but delivered noise.

It is not the chart or graph that they will judge, it's the information itself.



Conventions are the Form of Expectation:

It will be harder to
remember if you
deviate from
convention



Influence of the brain and expectation
are far greater than the raw data

Example Conventions

- Up is good
- Down is bad
- North is up
- South is down
- Red is negative
- Green is positive
- Blue is cold
- Hierarchies move from top down
- Lighter color shades are emptier or lower darker one

Work within Conventions

Story-telling is an Art that Captures Audiences

Transform your data and concepts into memorable stories

Conceptual

Focus Ideas

Goals Simplify, teach



Data Driven

Statistics

Inform, enlighten



What's your story?



Title Slide

WHY?

End with why you're
excited about the
opportunity

Company Name

Tagline

Logo

Speaker Name

Date

Conference Name



Corporate Introduction

March 2018



Conference Title
Presenter
Date



Conference Title
Presenter



October 2018

LEO SCIENCE &
TECH HUB

Moving towards precision medicine in dermatology.

LEO Science & Tech Hub
Cambridge, MA (USA)

22-05-2018

Michael Sierra - Vice President

March 2017 Dermatology Innovation Forum

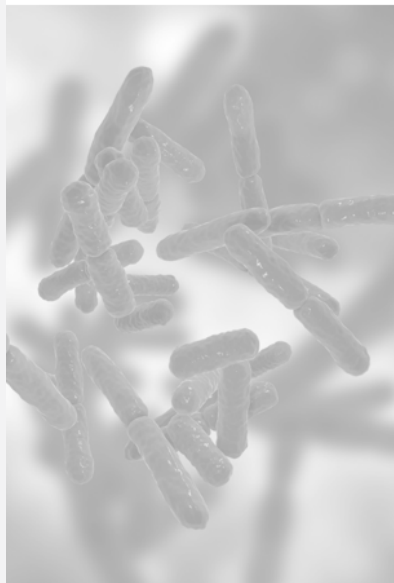


Slide 1: Overview

4-5 high-level
bullets with
key facts about
your company

Answer the question, “why” up
front to garner interest

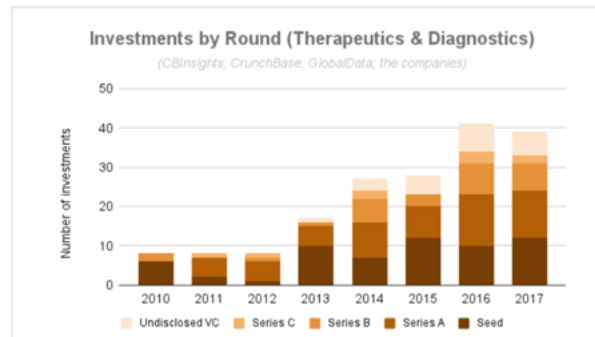
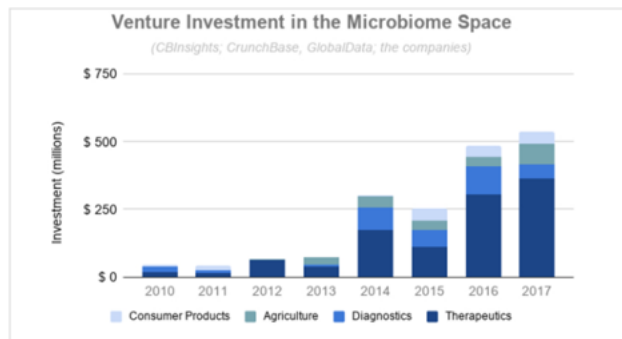
Company Overview



Founded:	May 2017 between Nationwide Children's Hospital (NCH) and <u>Monon Bioventures LLC (MBV)</u>
Technology:	Novel "Activated Bacterial Therapeutic" Delivery Platform (ABT) for Drug Development
Stage:	Phase I Clinical
Focus:	GI Disorders in Pediatrics, Geriatrics & Infectious Disease (Human and Animal Health)
Located:	Indianapolis, IN
IP:	Worldwide Exclusive License from NCH
Prior Funding:	Series A - \$4M; \$380K in Non-Dilutive Funding
Target Raise:	Series B - Up to \$20M; 2H 2019

Capital Investment and Clinical Progress in the Microbiome Industry

- Since 2010 approximately \$1.8B of venture investment (Seed round through Series C)
- 60% of the investment (\$1B) in 2016 and 2017 alone
- Since 2014, an increase in Series B and C funding rounds demonstrate clinical progress



*Source – Global Engage (<http://www.global-engage.com/life-science/investing-microbiome-future/>); February 2018

Slide 2:

The Agenda

Six Basic Elements

1. Medical Problem & Your Solution
2. Market Opportunity
3. Product Differentiation
4. Leadership Team, Board, Scientific Advisory Board
5. Development, Regulatory & Manufacturing
6. Commercial Strategy

Slide 3: The Problem

Describe the problem

Layman's terms

Use of infographics

Back up facts

Use of research

Slide 4:

The Solution

Description of products and services

Compelling benefits

Barriers to entry

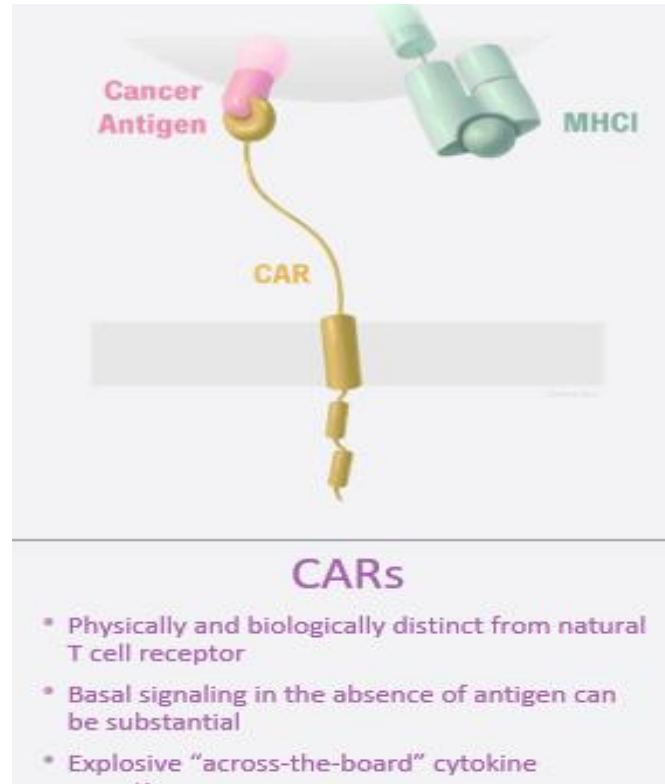
Differentiation

Threats

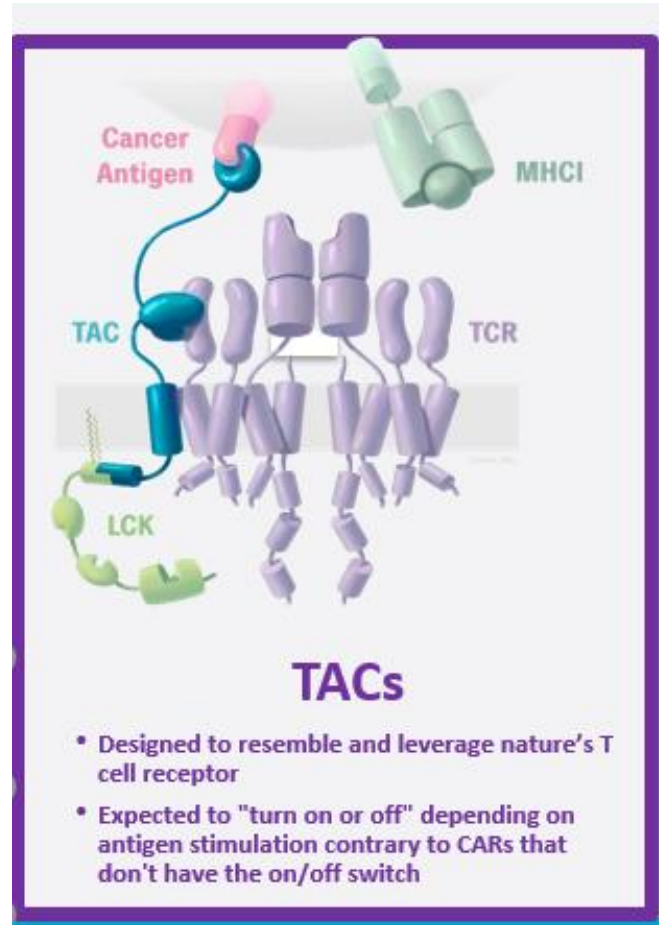
Opportunities

Validation

CARs
 “Distinct from
 natural T cell
 receptor” may
 cause more
 toxicity – no
 on/off switch



TAC Advantage: “Designing Safe and More Effective T-Cell Therapy”



Slide 5:

The Market and Target Product Profile

Clear definition

Size, growth, and share

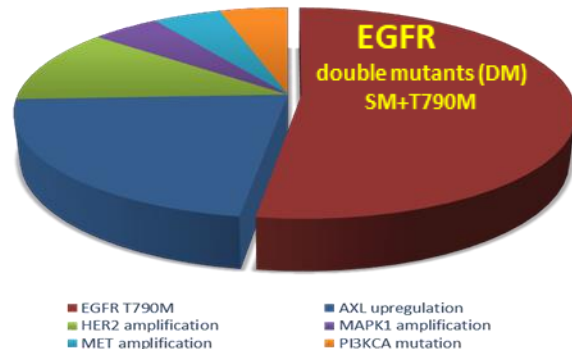
Key players and strategies: differentiation, commoditization, pricing

Payer distribution: private and public, reimbursement issues

EGFR Single/Double Mutant Inhibitor: 3rd Gen EGFR TKI

Proven therapeutic Target

- Only 1 approved third generation drug that targets the activating EGFR mutations including the T790M+ mutation (osimertinib)
 - Tagrisso, AZD9291
- The T790M+ mutation develops in:
 - Asia – ~50 % of all NSCLC patients
 - US – ~30% of all NSCLC patients



We believe that there is a need for a second drug that is potent, shows high activity to this mutation and importantly penetrates the blood brain barrier

Lead Program: SB-121 for Necrotizing Enterocolitis (NEC)

- 10% of infants born under 1500g develop NEC
- Mortality rate 20-30%
- NEC is the leading cause of death from GI disease in premature infants
- Cost associated with NEC is \$500M-\$1B in the U.S.

Scioto Opportunity:
Standard of Preventative Care

Preemie health disparities may be wider than thought, study says

Research had indicated disparities were minimal

By: JACQUELINE HOWARD, CNN

Posted: Sep 10, 2018 11:14 AM CDT Updated: Sep 10, 2018 11:14 AM CDT



Nationwide Children's spinoff fighting infection in premature babies raises \$1.8M

May 22, 2018, 6:00am EDT

A Nationwide Children's Hospital spinoff that's developing a probiotic treatment for the leading cause of death from gastrointestinal disease in premature infants has raised \$1.8 million from a group of funds including Rev1 Ventures.

Indianapolis-based Scioto Biosciences Inc. raised the round with Indiana-based BioCrossroads and Elevate Ventures, along with Columbus-based Rev1. It previously had \$380,000 in grants from the National

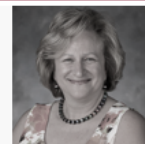
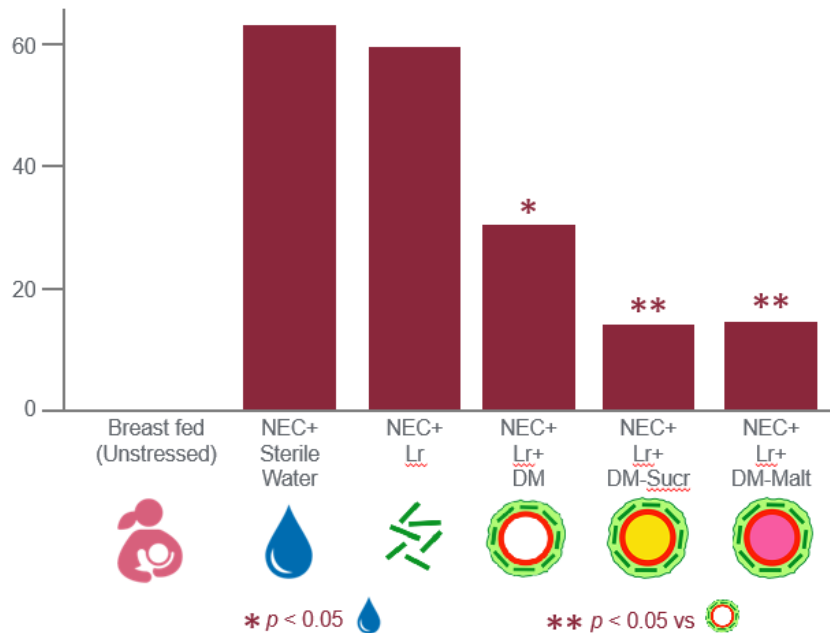


Slide 6: Competitive Positioning

(within limitations
of data)

Most successful charts show a single salient point so clearly that we feel we understand the charts meaning without trying

Effect On Incidence of NEC



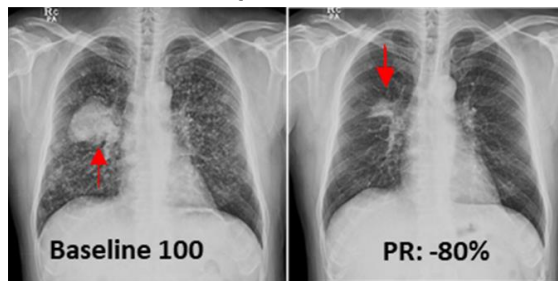
“The live bacterial therapeutic platform delivery system provided the best protection against NEC that I have seen in all of my years doing this type of research.”

~ Dr. Gail Besner,
Chief of Pediatric Surgery

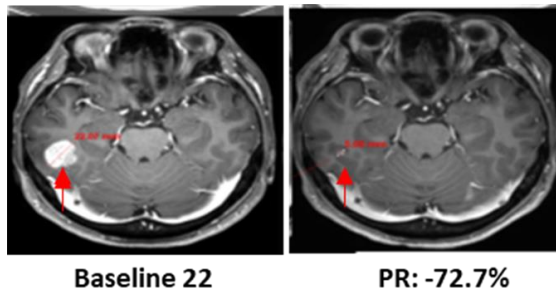


ASCO Abstract 9033: Results from Phase 1/2 Study of Lazertinib (YH25448/GNS-1480), a 3rd-Generation EGFR-TKI, in Advanced NSCLC

Case Study 1: subject with extracranial tumor of del19/T790M mutation dosed with YH25448 40mg



Case Study 2: subject with intracranial brain tumor of del19/T790M(-) mutation dosed with 40mg



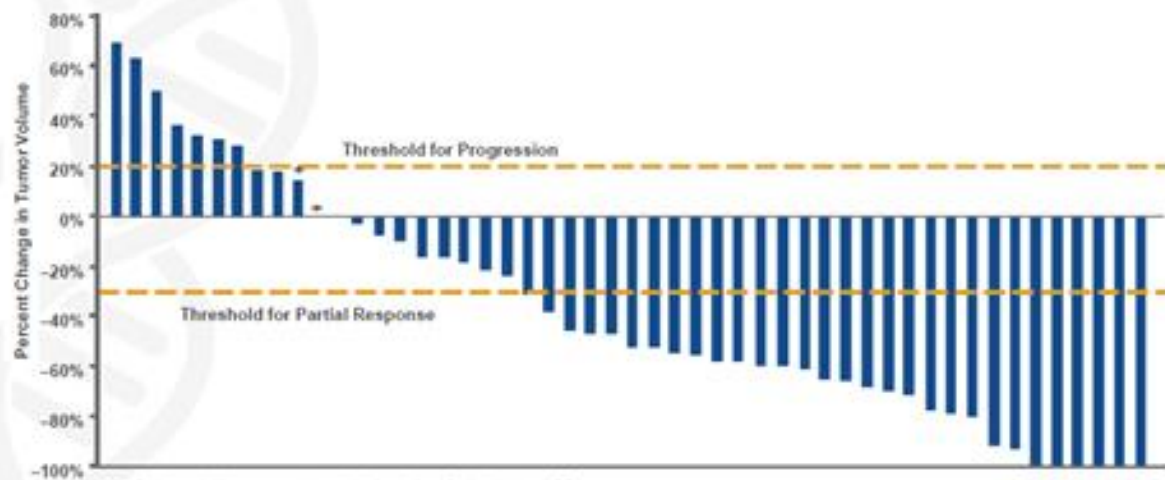
- Shows anti-tumor activity by reducing tumor size in the lung and the brain
- At lowest dose tested
- Highly selective against mutant forms of NSCLC

Advanced/ Metastatic Melanoma



Indoximod plus Pembrolizumab (PD-1)

Impressive Clinical Benefit and Disease Control Rate



*SD of primary lesion; new non-target lesions classified patients as PD. *Based RECIST guidelines version 1.1. *Non-ocular and cutaneous patients

Interim data support decision to initiate Pivotal Phase 3 vs single agent PD-1

Encouraging Early Data in DIPG

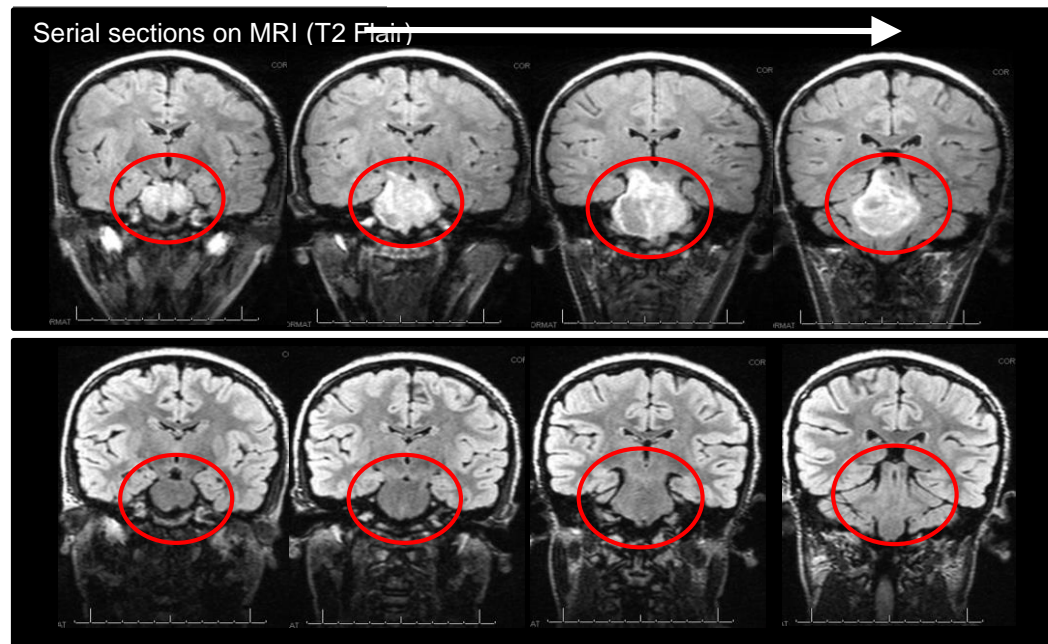
Response for 9.4-Year-Old Male with Newly Diagnosed DIPG

Baseline
(pretreatment)

DIPG scans reviewed by
Tina Young-Poussaint, M.D.,
Boston Children's Hospital

Patient 037 classified as:
"Significant response"

After 6 weeks of
indoximod +
radiation (54 Gy)



Patient remains neurologically normal at 6 months from initial treatment

Slide 7: Team

Photographs and
background on key
members

Establish company's
pedigree

Tell a story about the
company's culture

EXPERIENCED LEADERSHIP TEAM



Michael Almstetter
CEO

chemistry studies
at TU Munich

Chemical synthesis,
automation, and MedChem
optimization



Thomas Loeser
CFO

economic studies
at LMU Munich and HBS

Strategic alliances,
US market entry strategy,
Fundraising/Exits



Michael Thormann
CSO

biochemistry studies
at Leipzig and Barcelona

Computer-Aided Drug
Design, data and molecular
modeling



Andreas Tremel
COO

biology studies
at University Regensburg

Assay technologies, biological
screening, and compound
profiling

Management team collaborates since late 90's

Proven track record in deal making, milestone delivery, M&A, and exits

Specialist team (20 FTE's) in drug design, compound synthesis, and characterization

origenIS

Experienced Executive Team

Executive Team

Joseph Trebley, PhD
Chief Executive Officer

Jim Schulz
Chief Financial Officer

Mark Heiman, PhD
Chief Science Officer

Kevin Meyer
Chief Operating Officer



Board of Directors

Graeme Martin, PhD
former CEO, Takeda Ventures

Micah Mackison
SVP, Corp. Development, Assembly
BioSciences

Brian Stemme
Project Director, BioCrossroads



Scientific Team

Scientific Advisors

Jaswant Gidda, PhD

Preclinical

Sam Corvelevn

CMC Drug Development

CALIBRIUM

 anagin

Lilly

INTREXON®

Galápagos

Nationwide Children's Hospital: Scientific Team

Steven Goodman, PhD

Principle Investigator, Center for Microbial Pathogenesis

Gail Besner, MD

Chief of Pediatric Surgery

Michael Bailey, PhD

Principle Investigator, Center for Microbial Pathogenesis

Lauren Bakaletz, PhD

VP for Basic Science Research



Slide 8/9: Pre-clinical and Clinical Pipeline

Names and descriptions of preclinical compounds, indications, platforms, programs behind the lead compounds

Differentiating features of each

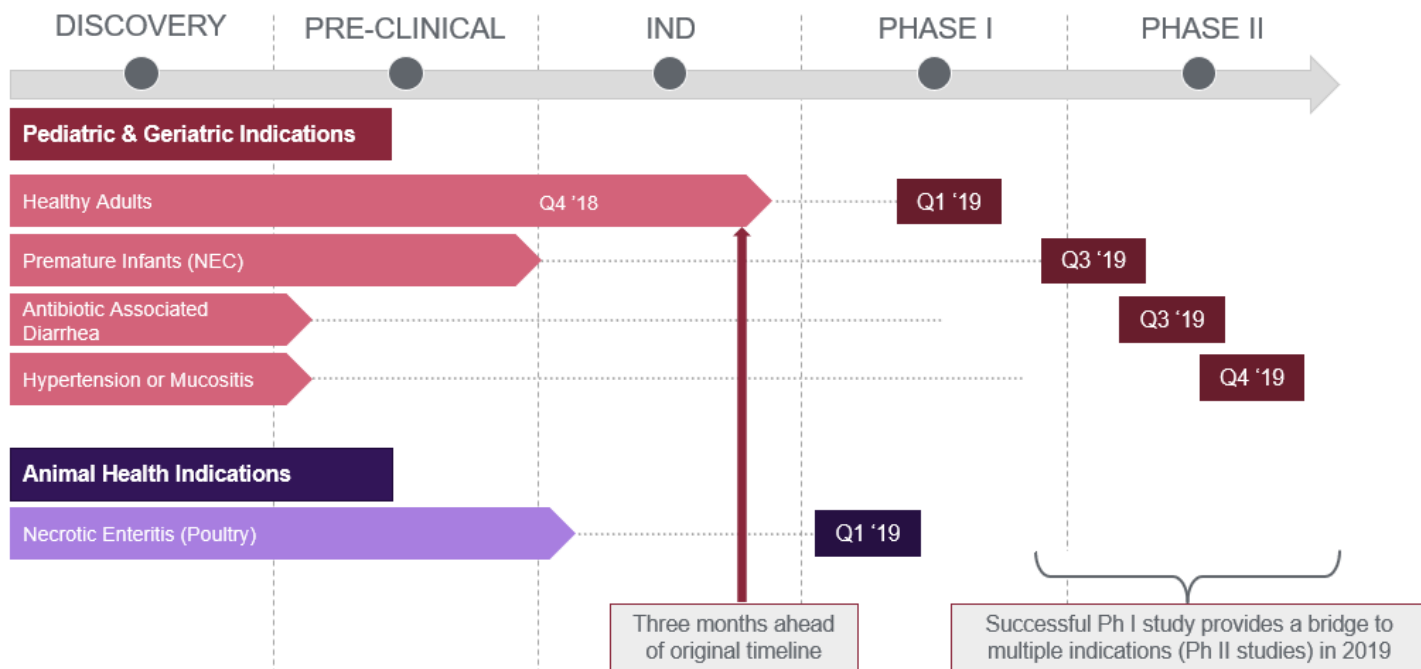
Synergies between programs

Goals

Safety and efficacy

Estimated data timeline

Product Pipeline: SB-121



Promising & Diversified Pipeline

	Target	Profile	Tumors	Clinic Ready
Solid Tumors	ROR1 (Tyrosine-protein kinase transmembrane receptor)	Promise in multiple large solid tumor markets	Lung, breast, colon, gastric, pancreatic, and CNS tumors	H2 – 2019
	HER2 (human epidermal growth factor receptor 2; Receptor tyrosine-protein kinase erbB-2)	Much improved animal efficacy & safety compared to CAR-Ts	Glioblastoma; osteosarcomas; other HER2 over-expressing tumors	H2 – 2019
	Undisclosed	Promise in solid tumors	Solid tumors, high unmet need	2020 – 2021
B-Cell Malignancies	BCMA (B-Cell Maturation Antigen)	Best-in-class potential (autologous and/or allogeneic)	Multiple Myeloma	2019 – 2020
	CD19 (B-Cell Antigen)	Best-in-class safety and efficacy potential	DLBCL	Early 2019
Discovery	Platform Development	Off-the-shelf TAC T-cells, complementary chimeric receptors to enhance TAC T-cells, CMC improvements, etc.		

- **Successful pre-CTA** meeting with Health Canada in December 2016: Agreement on key preclinical, clinical and manufacturing requirements; Next **Pre-CTA update** meeting with Health Canada planned for **Early Q2-2018**

Slide 10: Regulatory Strategy

Discuss geographic strategy

Highlight milestones
achieved to date

Provide overview: BLA, SPA,
Orphan status, Pediatric
voucher, Fast track

Xadago® (Safinamide) Approved and Launched in Europe for the Treatment of Parkinson's Disease



EU MARKETING AUTHORIZATION (RECEIVED FEBRUARY 2015)

- Both dopaminergic and non-dopaminergic mechanisms
- Sustained efficacy for 2 years for ON Time, OFF Time and UPDRS III
- "Very much/much improved" in Clinical Global Impression
- Significant improvement in activities of daily living (UPDRS III)
- Well tolerated
- No drug interactions; no age, gender or race restrictions
- No dietary restrictions
- No requirement for laboratory tests, ECG, or any other examination



FDA APPROVAL

- FDA agrees no additional evaluation of abuse liability or dependence / withdrawal effects in humans is required
- NDA re-submitted Sept 2016: Class II re-submission – 6 month review
- FDA approval date: March 21, 2017

Regulatory Strategy

- **Timing:**
 - Pre-IND to be filed by end of Q1 2018
 - Single dose (nasal gavage) - prophylactic treatment given immediately after birth (likely within 48 hrs)
 - Dr. Jaswant Gidda: Supporting
- **Focus of registration:**
 - Propose a Phase II interventional trial to investigate the role of a Lr biofilm on GI maturity and immune response of premature infants
- **Indications:**
 - Time to establish full enteral feeds
 - Reduction of time/days in the NICU
 - Incidence of necrotizing enterocolitis
 - Time until full term birth weight
- **Inclusion Criteria:**
 - Gestational age 30 - 32 weeks
 - Very Low Birth Weight - 1,500g or less (~60,000 patients per year)

Slide 11:

Manufacturing Strategy

In-house or contract manufacture
(and why)

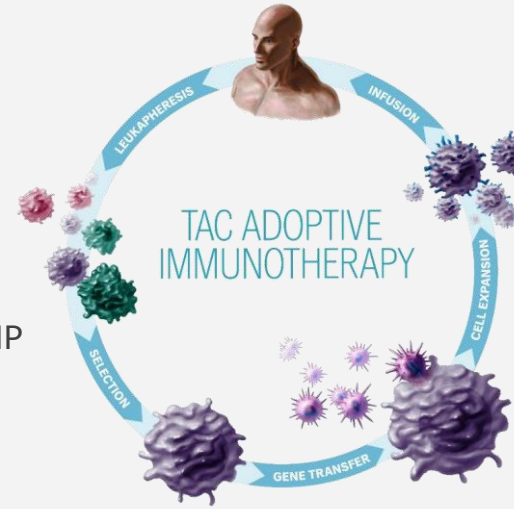
Timing of production

Inventory levels

Special issues

Manufacturing Plans

- Current process uses **lentivirus** and is similar to CAR-T process
- Conducting **scale-up** of manufacturing process in our lab
- Manufacturing at the **Centre of Excellence for Cellular Therapy (CETC)** in Montreal for first-in-man studies
 - The CETC facility 37,000 ft² and is compliant with US, EU and Canadian GMP
 - Tech transfer initiated April 2017 after optimization and scale-up



Slide 12: Commercial Strategy

Out-license or commercialize

Domestic or international partners

Marketing & PR plan

Advocacy Relations

Medical Comms Strategy
KOL Development
Publication and medical meeting strategy

Significant Commercial Opportunity in Safinamide (Xadago®)



- » Milestone and royalty revenues to Newron since 2012
- » Long period of market exclusivity
(patent life: 2029 in EU, 2031 in the US)
- » Peak sales potential \$450m - \$700m+ (analyst estimates)

7 TO 10
million
world wide

20 to 30 percent in early stage
70 to 80 percent in mid to late stage
>\$4 Billion worldwide market



Slide 13: Financial Position

Summary financials

- Balance sheet
- Income statement as appropriate
- Put numbers in context
- Current financial guidance as appropriate

Market position

- Shares outstanding
- Insider holdings
- Market capitalization

Financing

- Current Financing to Date

- NCH – Active RO1
- Scioto - \$380,000 NIH STTR Award Phase I
- Series A Preferred Stock – Led by BioCrossroads
 - Up to \$4 million (>\$1.7M committed and scheduled to close April 23, 2018)
- Animal health venture - Signed option for poultry rights
 - \$50,000 payment (100+ chicken study planned)

- Future Potential Financing

- NIH - Therapeutic for Rare and Neglected Disease Division (Finalist)
- April 2018 – Submission of New Phase I SBIR ~ \$350,000
- September 2018
 - Follow on submission of Phase II STTR ~ \$2.5 million
 - Submission of new Phase I SBIR ~\$350,000

Financial Position

Q1 2018 End Cash and Equivalents	\$143.9 million
YE 2018 Cash Projected	To be updated on Q2 call
Shares Outstanding as of March 31, 2018	37.2 Million

Resources sufficient to support focused clinical development of indoximod

Slide 14:

Upcoming Milestones

Management View of milestone creating value

- Summarize company's upcoming milestones

Upcoming news flow

- Clinical
- Regulatory
- Clinical/medical
- Commercial
- Manufacturing
- Transactions
- Operational
- Management

Future Milestones – 12 to 24 months

Clinical and Regulatory

- Submit Pre-IND meeting request to FDA
- Complete IND efforts and submit to FDA
- Initiate clinical study (Q2/3 2019)

CMC and Preclinical Efforts for IND

- Finalize contracts for master stocks, manufacturing, analysis and stability
- Formulation and clinical manufacturing process development

Financing - Partnering

- Complete initial partner trials in Q1 2018
- Aggressively seek non-dilutive funding
- Prepare for Series B and/or partner technology
- Identify potential partners for acquisition and licensing opportunities

NewLink Genetics – Key Takeaways

- **Indoximod has a differentiated mechanism of action (MOA)**
 - Reverses the effects of low tryptophan by increasing proliferation of effector T cells
 - Drives differentiation into T helper cells vs regulatory T cells
 - Downregulates IDO expression in dendritic cells
- **Promising clinical activity of indoximod in combination with**
 - Chemotherapy in AML
 - Checkpoint blockade in melanoma
 - Radiation and chemotherapy in DIPG
- **Additional indoximod data to be presented at upcoming medical conferences**
 - Melanoma & Pancreatic Cancer: Final Phase 2 results at ASCO, June 2018
 - DIPG: Updated Phase 1b data at ISPNO, July 2018
 - AML: Updated Phase 1b data intended 2H 2018

Differentiated MOA demonstrating clinical activity for multiple combinations and indications

Slide 15: Conclusion

Use the company's brand statement for the title

Use the company's elevator speech for the text

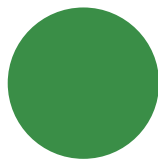
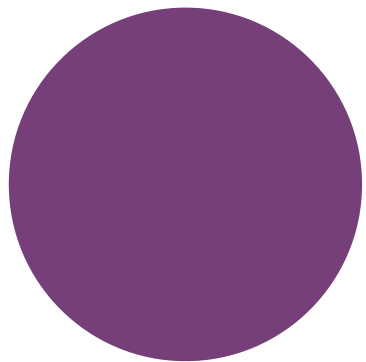
Capture the essence of the preceding 14 slides

Include a contact name, email address and company website address on the final slide

End with a call to action

Investment Highlights

- Major progress has been made in microbiome clinical development
 - Significant public and private investment
- Major opportunity based on delivering and sustaining live therapeutic bacteria
- Scioto's novel ABT platform ensures safe and effective delivery of live therapeutic bacteria
- ABT platform can be used to address multiple indications in human and animal health
- Lead program: SB-121 ready for clinical development in 2019
 - First indication for Necrotizing Enterocolitis (NEC) in premature babies
 - NEC mortality rate of 20-30%
- Current partnership with the Research Institute at Nationwide Children's Hospital (RINCH)
 - Seeking additional platform partnerships for other indications

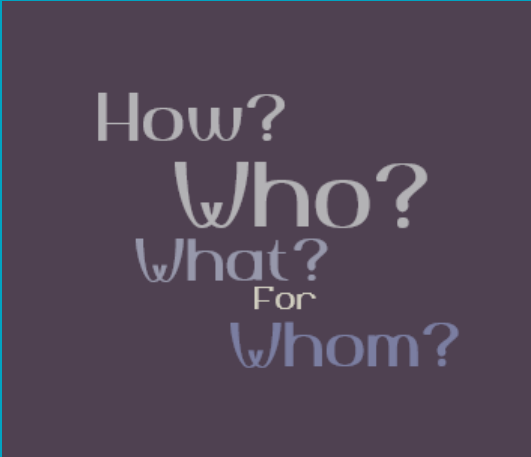


Elevator Pitch



A Great Elevator Pitch Answers:

- Who are we?
- What do we do?
- How do we do it?
- Whom do we do it for?



How?
Who?
What?
For
Whom?

The Process of Creating a Great Elevator Pitch

- Identify answers to the four key questions – write down your answers
- Link them to create a paragraph
- Read the paragraph aloud
- Adapt it to your natural way of speaking
- Shorten it to fewer than 100 words or less than one minute
- Practice it with friends and take their advice seriously
- Memorize key messages so you can adapt and use it anywhere
- Keep your delivery fresh and natural
- Use it often
- Refine it as needed

Example of an Elevator Pitch

Who are we?

- LaVoieHealthScience is an integrated strategic communications agency

What do we do?

- We help health and science companies engage key audiences to build value for their innovations

How do we do it?

- Through integrated communications covering public relations & investor relations

Whom do we do it for?

- Emerging and established health and science companies throughout the globe

If you have any questions, please contact:

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Boston, MA 02129

617-372-8800 ext. 107

info@lavoiehealthscience.com

