STARTING FOR SUCCESS

UTSA Entrepreneurship Bootcamp

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Bianca Cerqueira, Co-Founder COO
• PhD Biomedical Engineering
  UTSA/UT Health SA, 2017
• Certificate in Translational Science
  UT Health SA, 2017
• BS Neurobiology and Physiology
  University of Maryland, 2008

Lauren Cornell, Co-Founder CEO
• PhD Translational Science
  UTSA/UT Health SA/UT Austin, 2019
• MS Biomedical Engineering
  UTSA/UT Health SA, 2012
• BS Genetics
  Texas A&M University, 2009
**PROBLEM:** INADEQUATE NIPPLE RECONSTRUCTION

- **Silicone prosthesis**
  - Non-invasive
  - Daily application

- **Tattoo**
  - Lacks projection
  - Fades over time

- **Surgical flap**
  - Additional surgery
  - Flattens within 2 years

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*NOVOTHELIUM*
SOLUTION: TISSUE-ENGINEERED NIPPLE

Nipple areolar tissue → Remove cells and DNA → Acellular nipple areolar matrix

Regenerated nipple in a single procedure that maintains shape & projection, has natural pigmentation, and the potential for improved sensation.
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THE PAST 18 MONTHS:

$193,700 non-dilutive funding
$46,000 + in kind services
TIMELINE:

- **2015**: Company founded Oct 2015
- **2016**: Customer exploration
- **2017**: In-vitro product development
- **2018**: Secure $3M Funding
- **2017**: Business plan competitions
- **2018**: Animal model with USAISR
- **2019**: Sales launch through contract manufacturing
- **2019**: Clinical cohort study
- **2020**: Patent filing/review
WHERE WE BEGAN:

• Started with an idea, no better time than now!
• No lab, no money, no business experience
REGIONAL I-CORP:

- Summer 2015 – MD Anderson in Houston
- Customer discovery
- Product-market fit
BUSINESS MODEL CANVAS:

- **Who will help you?** (Key Partners)
- **How do you do it?** (Key Activities)
- **What do you do?** (Value Proposition)
- **How do you interact?** (Customer Relationships)
- **Who do you help?** (Customer Segment)
- **What do you need?** (Key Resources)
- **How do you reach them?** (Distribution Channels)

**What will it cost?** (Cost Structure)

**How much will you make?** (Revenue Stream)

https://www.launchpadcentral.com
WHO ARE YOUR CUSTOMERS:

• Who is end user?
• Who pays for it?
• Who decides to purchase?
WHO IS YOUR COMPETITION:

- What are people doing now to solve the problem?
- What new technologies are being developed?
  - Research articles/abstracts
  - Patent search
  - Freedom to operate analysis
- Cost
PROTECTING INTELLECTUAL PROPERTY:

• Patent
  • Exclusive right to prevent or stop others from commercially exploiting the patented invention.
  • The invention cannot be commercially made, used, distributed, imported or sold by others without the patent owner's consent.

• Trademark
  • A sign capable of distinguishing the goods or services of one enterprise from those of other enterprises.

• Copyright
  • Rights that creators have over their literary and artistic works including books, music, paintings, sculpture, and films, to computer programs, databases, advertisements, maps, and technical drawings.
  • Copyright protection is obtained automatically without the need for registration or other formalities in majority of countries

http://www.wipo.int/about-ip/en/
PATENTS:

• Public Disclosure (journal articles, conference abstracts, etc)
  • In US: Must file patent within 12 months, otherwise rights lost
  • International: No disclosure allows prior to patent filing

• Provisional application – 12 months

• Conversion to Non-Provisional or PCT (International)

• Essential to have good patent attorney

• Cost $30k+, process can take 3+ years

• University-based research technologies
  • Disclose invention to tech transfer office
  • Inventor retains 50% revenue from licensing fees
  • University pays for patent

http://research.utsa.edu/research-funding/commercialization/intellectual-property-process/
https://www.uspto.gov/patents-getting-started/patent-process-overview#step8
REGULATORY ENVIRONMENT:

• Medical
  • FDA – drug or device or combination?
    • De Novo/510K/PMA/HDE/
    • IND/NDA/ANDA/OTC/BLA
  • Can request feedback from FDA – official vs unofficial correspondence

• Professional or trade organizations

• Federal/state/city regulations

• International
WHAT ABOUT FUNDING?:

• Bootstrapping
• Business Plan/Pitch Competitions
• Incubator/Accelerator programs
• Grants
• Crowdfunding
• Loans
• Investment
BOOTSTRAPPING:

• Self financed
  • Savings
  • Personal income (keeping your day job)
  • Lowest possible operating costs
  • Sweat equity
  • Good for businesses that have low capital requirement
BUSINESS PLAN/PITCH COMPETITIONS:

- Non-dilutive or dilutive funding
- Provide free guidance on how to improve your pitch
Incubator/Accelerator Programs:

**Incubators:** early stage, funding, collaboration, mentorship, networking

**Accelerators:** MVP established, set time frame, provide funding/investment, goal to scale business

http://seedrankings.com/
GRANTS:

- Non-dilutive funding
- Small Business Innovation Research (SBIR)
- Small Business Technology Transfer (STTR)
  - Private (business) public (university) partnership
- Multiple funding agencies
- Phases:
  - 1 – Proof of concept, <$250k, 6-12 months
  - 2 – Continue research, <$1M, 2 years
  - 3 – Commercialization
- SBDC Technology Commercialization Center can provide help: https://txsbdc.org/techcomm/

https://www.sbir.gov/
CROWD FUNDING:

- Many platform options
  - Investment vs non-investment
  - Fees (percentage of funds raised)
  - Time duration
  - Support
- Can help demonstrate market need/interest
LOANS:

• Traditional Bank Loan
  • Small Business Administration – provides guarantee to banks/lenders to pay part of loan if business owner defaults

• Non profits (LiftFund)
INVESTMENT:

• Dilutive funding, investors now own/control part of your company
• Typically high growth high capital businesses
• Angel: Seed funding <$1-2M, high net worth individuals
• Venture Capital: Larger funding <$1-2M, manage fund, usually have board seat, primary interest return on investment
LOCAL RESOURCES:

- CITE
- Institute for Economic Development
- LiftFund
- LAUNCHSA
- geekdom
- MAESTRO
- Bunker Labs SATX
- VELOCITY-TX
- Capital Factory
- Novothelium
OTHER RESOURCES:

https://helloalice.com

https://venturewell.org/
ADVICE:

Success is an iceberg

- Persistence
- Failure
- Sacrifice

WHAT PEOPLE SEE
- SUCCESS!

WHAT PEOPLE DON'T SEE
- Dedication
- Hard work
- Good habits
- Disappointment

@silviaduckworth
ADVICE:

"YOU DON'T HAVE TO SEE THE WHOLE STAIRCASE, JUST TAKE THE FIRST STEP."
- MARTIN LUTHER KING

IF NOT NOW THEN WHEN