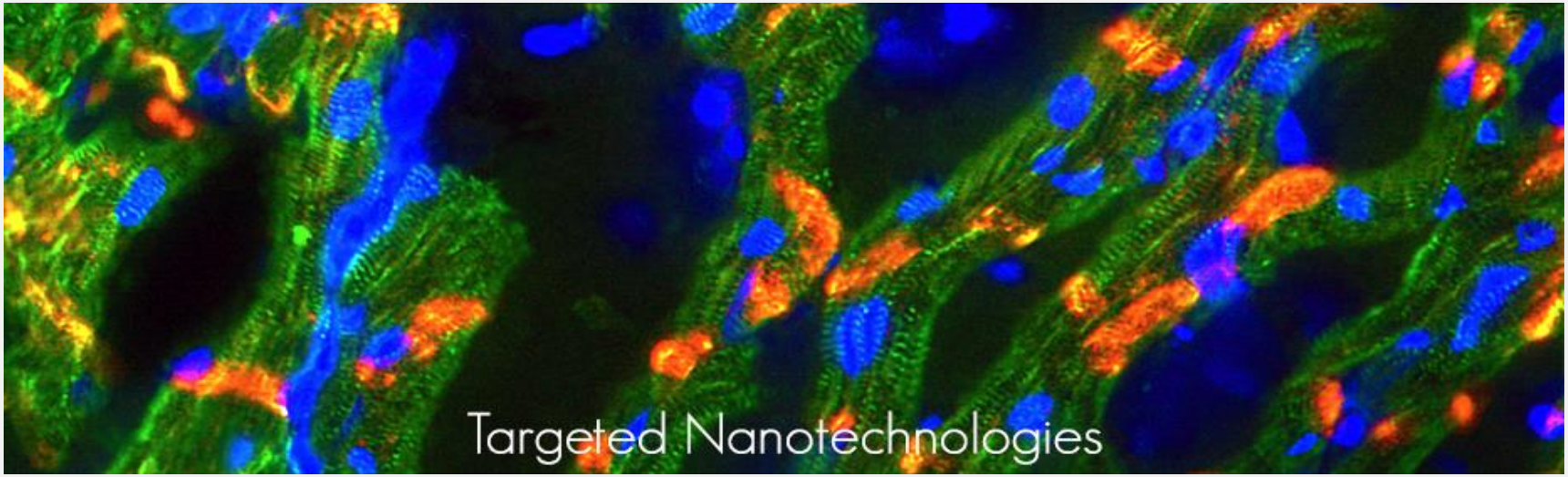
Privo Technologies

UMASS LOWELL

MIT

Privo technologies.



Privo

- Privo is a company that was founded and is led by Manijeh Nazari Goldberg, who took two degrees (engineering and computer science) from UMass Lowell and then one each from Harvard and MIT.
- Privo Technologies was formed to commercialize a discovery made in Robert Langer's laboratory at MIT that allowed the delivery of various drugs through encapsulation using nan-technology
  - Privo was a winner of the MIT 100 K Business Plan Competition
    - Their original idea was Nano delivery of insulin by chewing gum
  - Nano Drug Delivery
- In a very tough area of raising money to commercialize. It can take a billion dollars to bring a new drug to market.
- A later page will show their initial business plan canvas.

Photo by Shawn Henry

Privo Technologies website

The Privo website (www.privo.com) describes the venture this way:

> WELCOME TO PRIVO TECHNOLOGIES, INC.
>
> At Privo Technologies, we are developing an entirely new class of targeted treatments such as chemotherapy drugs, radiation sensitizers and radiation protectors and mitigators. Our proprietary nano-engineered platform is based on innovations in nanotechnology and material science discovered at MIT's Langer laboratory. Privo's platform is designed to create robust treatments for a wide range of indications while reducing or limiting the treatments harmful side effects. We deliver drugs via the mucosa with the initial focus on oral cavity mucosa.
>
> We are excited about building a pipeline of treatments with a range of product candidates in oncology, infectious diseases, and radiation. Our initial product candidate is a treatment for the critically underserved worldwide market of oral cancer.
>
> We are developing our novel targeted treatments for worldwide markets at our facilities in the greater Boston area.

Privo's Current mission

Let us look at how the Privo founder and CEO, Manijeh Nazari Goldberg describes the current mission of Privo. Then we will examine how they arrived at that mission after beginning as a treatment for diabetes.

- https://www.youtube.com/watch?v=0iFGBhLoPjQ

Privo Technologies -Company

THE COMPANY

- Company founded in 2010 to develop a novel nanotechnology based drug delivery platform capable of delivering drugs locally and topically through various mucosa (e.g. mouth, cervix, etc.). The research had been conducted at MIT's Langer Lab, which provides access to expertise in the field of nano-encapsulation and drug delivery.

THE TEAM

- Manijeh Goldberg was the founder, and her team is a cross-functional group of scientists, clinical, and business experts and advisors.

THE CORE TECHNOLOGY

- Their treatments are intended for replacing current intravenous drug therapy with local therapy, thereby increasing efficacy (much higher dosing) and significantly reducing the systemic toxicity. The technology involves encapsulating FDA approved drugs in nano-particles which are taken up by cells more efficiently than would be the free form drug.

THE BUSINESS MODEL

- The company is developing a chemotherapy treatment for oral cancer as its initial application of the platform. The company plans to work with a large pharmaceutical partner to support costly clinical trials and to market and distribute the product. Thereafter, the company is planning to develop a pipeline of applications on this platform.

Privo Business Model Canvas –Early Version

Key Partners	Key Activities	Value Proposition	Customer Relationships	Customer Segments
• NSF and NIH • Mass Life Sciences • Universities (MIT, Harvard, UML,etc • Academic Centers • Venture Capital • Philanthropy	• Diabetes Research • Trans-Mucosal Delivery development • Fund raising • Grant Writing	• Oral Mucosal Drug Delivery • Improve patient quality of life. • Improve compliance relative to injections • Minimize side effects • Reduce Hospital Stay • -Reduce overall cost of healthcare.	• Endocrinologists as advisors	Type II diabetic patients who need to inject insulin
	Key Resources Scientists Mass Life Science Center		**Channels** Large Pharma as partners or purchasers	

Cost Structure	Revenue Streams
• Salaries • Lab space • Lab equipment • Materials and supplies • Fund raising • IP license and development • Legal	Commercial Licensing Sale of the company Royalties

In the beginning.

- The initial target was delivery of insulin in chewing gum to treat diabetes.
- They won the MIT 100 K Business Plan Competition with that.
- While the technology worked, they began to realize that is would be difficult to bring this to market in a market crowded with new and existing products.
- They made this discovery through an extensive customer discovery process modeled on the Lean Launchpad approach popularized by Steve Blank.

The Product

- PRV111 is Privo's nano-engineered product. It consists of a topical patch designed to deliver and retain high concentrations of various existing systemic agents within the primary tumor and associated nodal basins. When placed on a tumor, PRV111 releases and retains cisplatin-loaded particles into the tumor, resulting in a dramatic reduction in tumor size, without the accompanying systemic side effects associated with intravenous cisplatin (i.e. nephrotoxicity and neurotoxicity). Local and regional effects of PRV111 are expected to improve tumor resectability, decrease post-operative radiation and chemotherapy, and improve patient survival. This organ-sparing therapy is special because it can preserve oral cavity form and function. Also, it can improve control of the disease loco-regionally, which can result in improving a patient's overall survival rate. In patients with the metastatic disease, PRV111 (when combined with standard of care chemo-radiation regimen) can provide improved locoregional control while maintaining a tolerable side effect profile that ultimately improves quality of life.
  - https://www.newswire.com/news/privo-technologies-receives-a-3m-award-20704923

Privo: Learn and Pivot

- As they moved forward they learned both from their successes and their mistakes –and got lots of advice along the way.
- They Interviewed
  - 20 Physicians
  - 40 Scientists
  - 12 Attorneys
  - 6 Multinational Pharmaceutical Co.
- They wrote many Grants (that were peer reviewed) for
  - NCI (National Cancer Institute)
  - NIH (National Institute of Health
  - MLSC (Mass Life Science Center)
  - NSF (National Science Foundation)
  - Next (Rare Disease services)
  - NCL (Nano Characterization)
  - Deshpande –MIT
- They met with the governments of 7 other countries
- This is all part of the Customer Discovery Process.
- The things that they learned led to a new Business Model Canvas

Privo Business Model Canvas –2014 Version

Key Partners

- NSF and NIH **and NCI**
- Mass Life Sciences
- Universities (MIT, Harvard, UML,etc
- Academic Centers
- Venture Capital
- Philanthropy
- **New England Hospitals**
- **Global Hospitals**
- **Chief Research Officers (CRO) for manufacturing and pre-clinical.**

Key Activities

- ~~Diabetes Research~~
- ~~Trans-Mucosal Delivery development~~
- Fund raising
- Grant Writing
- **Optimize Formulation**
- **Build partnerships**
- **Manufacturing nanoparticles (NP's)**
- **Pre-clinical trials**
- **Phase 1 clinical trials**

Value Proposition

- Oral Mucosal Drug Delivery **for oral cancer chemotherapy**
- Improve patient quality of life.
- ~~Improve compliance relative to injection~~s
- Minimize side effects
- **Vastly lower toxicity**
- **Ease of use**
- ~~Reduce Hospital Stay~~
- Reduce overall cost of healthcare.

Customer Relationships

- ~~Endocrinologists as advisors~~
- **Oncologists as advisors**
- **Pharma as advisors/mentors**
- **Oncology radiologists**

Customer Segments

- ~~Type II diabetic patients who need to inject insulin~~
- **Chemo-wafer cancer patients**
- **Age 62+ at diagnosis**
- **Early stage oral cancer (OC) patients.**
- **Later stage OC patients.**
- **HPV patients (male 40-59)**
- **Oncology surgery patients**
- **Head and neck oncologists and surgeons**
- **Maxillofacial and oral surgeons**
- **General oncology surgeons**
- **Larger pharma –licensing**

Key Resources

Scientists
Mass Life Science Center

- **other applications**
- **Deliver other drugs through buccal tissue using NP permeation**
- **Using NP loaded chemo-wafer to deliver drugs to other targets.**

Channels

Large Pharma as partners or purchasers for **Global Marketing Sales and Distribution**

Cost Structure

- Salaries
- Lab space
- Lab equipment
- Materials and supplies
- Fund raising
- IP license and development
- Legal

Revenue Streams

Commercial Licensing
Sale of the company
Royalties

Now THAT is quite a pivot!

- After learning that diabetes was too difficult a target due to all of the alternatives in the market place, they turned to oral cancer as a primary target and other kinds of chemotherapy as an additional target.
- This changed things like their key partners, key activities, value propositions, customer relationships, and customer segments.

- You can now see why effectual entrepreneurship focuses on the iterative relationship between means, goals, interactions, and commitments.
- You can also see how the Lean Launchpad model emphasizes customer discovery and pivoting after learning new information.

- EE is far less goal oriented and far more interested in how one can use the resources at hand to create something of value.
- The Lean Launchpad encourages one to iterate and pivot.

Recent News of Privo

- 11/12/2018 Privo Technologies Receives a $3M Award: Privo has been selected for the prestigious Phase IIB Bridge Award from the **National Cancer Institute (NCI)**. The NCI SBIR Bridge Award supports Privo's clinical trial for its nanotechnology-based treatment of oral cancer. This award was given to only 4 companies in the United States.
  - https://www.newswire.com/news/privo-technologies-receives-a-3m-award-20704923
- 01/10/2017 - Privo Technologies receives the 2016 **National Tibbetts Award** for outstanding contributions to the Small Business Innovation Research (SBIR) program. The SBIR program stated "We are proud to recognize your company's outstanding work that has contributed so greatly to the success of the SBIR program." Privo would like to congratulate it's team for their hard work and dedication to the company. On January 10, 2017, Privo's CEO and Founder, Dr. Manijeh Goldberg, received the honor at the White House during a special awards ceremony. News Article
- 12/10/2016 - Privo Technologies receives **2015 TechConnect Innovation Award** -Privo Technologies received the "2015 National Innovation Award" from the TechConnect World Innovation Conference. Privo's ChemoThin Wafer project was rated in the top 5% of all award applicants. News Article
- 09/13/2016 - Privo receives **Commercialization Award from the National Cancer Institute**. -Privo Technologies is proud to serve as both an exhibitor and selected speaker at the RESI conference in Boston, and would like to thank the National Cancer Institute for funding Privo's inclusion as part of this conference.
- 12/10/2015 - Privo Technologies opens **new lab** facility in Peabody, Ma. -Privo Technologies expands to a new 3000 square foot facility just outside of Boston, MA. Located at 200 Corporate Place, Suite 6B in Peabody, Massachusetts, the new facility consists of two separate research labs that will be used in it's continued pursuit of excellence in the field of cancer research. Privo's new location provides office space and conference rooms to accommodate the company's continued growth moving forward.
- 11/03/2015 - **Privo receives Orphan Designation from the Food and Drug Administration** for anatomically accessible oral cancers. Receipt of this designation entitles Privo's current and future oral cancer treatments to additional patent protection, 7 years of drug exclusivity, and tax credits equal to 50% of research and development costs. Orphan Designation will enable Privo to accelerate the drug development timeline for oral cancer treatment.
- 2012 and 2013 - Our Oral Cancer treatment receives **MIT's Innovation Award two years in a row**. -The project was awarded over $300,000 in funding from MIT's Deshpande Innovation Center in 2012 and 2013 to support the company's drug development activities. We are proud to receive these very competitive awards and honored to be amongst some of the best innovations coming out of Massachusetts Institute of Technology (MIT). 2012 Grant Announcement 2013 Grant Announcement
- Boston's WomenPreneurs to Watch -*The harder I network, the luckier I get*
- Privo's CEO speaks at IDEASTREAM, MIT Deshpande Center Symposium 2014 -*Tougher on Cancer, Easier on the Patient*
- Privo's CEO speaks at IDEASTREAM, MIT Deshpande Center Symposium 2013 -*Buccal Delivery of Chemotherapy to treat Oral Cancer*
- *From night-vision cameras to insulin chewing gum* ...-News from MIT Sloan Fellows
- Source: http://www.privotechnologies.com/news.html

Leveraging Strengths

- Notice how Privo has used each award and honor to leverage their next steps.
- It all started with the MIT 100K Business Plan Competition in 2010.
- They leveraged that award into many more.
- They obtained government grants for their basic research.
- They obtained government grants under the SBIR program to enable their commercialization process.
- They used the Lean Launchpad model to do customer discover and to pivot form a target of diabetes to a target of oral cancer.
- The business plan in 2018 is vastly different than the one that won the MIT 100 K competition.
- The business model canvas shows this pivot very clearly.
- In the fall of 2018, Privo began a clinical trial in 8 hospitals around the US: Baylor College of Medicine (6 hospitals), University of Texas (1 hospital), University of Cincinnati Cancer center (1 hospital)
  - https://www.newswire.com/news/clinical-trial-expected-to-yield-promising-results-for-oral-cancer-20677770

Management Team

- **Manijeh Goldberg, Ph.D., M.B.A., M.S. -- Chief Executive Officer** -Manijeh is the Founder and CEO of Privo. She has over 20 years of experience in the biomedical industry, in large companies and five startups (one was acquired for $275M). She holds a PhD in Biomedical Engineering, an MS in Biomedical Enterprise from Harvard Medical School, an MBA from MIT, and an MS in Computer Science and Mathematics.
- **Ellen Milano -- VP of Regulatory** -Ellen Milano is President of Milano Regulatory Solutions, Inc. She brings more than 40 years of extensive experience in both Regulatory Affairs as well as pharmaceutical technical issues. Her broad knowledge of the FDA-regulated industry spans the drug sector, and includes both pre- and post-approval stages of development. She has expertise in product development, regulatory affairs, analytical development, QA/QC and compliance, QSR and PAI and diverse FDA submissions (CMC sections of INDs and NDAs; ANDAs; DMFs, Supplements and Amendments).
- **Michael H. Silverman -- Chief Medical Officer** -Michael H. Silverman, MD, FACP, is a board-certified internist with over 3 decades of experience in biopharmaceutical industry clinical research, product development, and strategic planning. His pharmaceutical industry career has included positions of increasing responsibility at both global and start-up companies, where he has managed multiple pharmaceutical and biotechnology projects across a broad scope of therapeutic areas. Dr. Silverman received his MD from the University of Chicago and is doubly certified by the American Board of Internal Medicine, and was awarded Fellowship by the American College of Physicians in 1983.
- **Steven Goldberg, M.B.A. -- Chief Financial Officer** -Steven serves as the Chief Financial Officer to Privo. He has worked as an executive in multiple industries with over 30 years of successful fundraising experience with expertise in modeling financial scenarios. He holds an MBA from Colombia University and BA from Tufts University.
- **Bill Riffert, B.S. -- Vice President of Business Development** -Bill Riffert is a leading industry executive with in depth experience in building long term mutually beneficial strategic partnerships. With over 20 years of international success working in high value sales, technology, and business development, Bill has proven his skills in bringing together technology and client needs to produce expert solutions.
  - Source: http://www.privotechnologies.com/management.html

Scientific and Medical Advisors

- **Robert Langer, Ph.D**. -David H. Koch Institute Professor at MIT and the father of drug delivery and tissue engineering with over 800 patents with over 25 successful biotech startup companies.
- **Nishant Agrawal, M.D**. -Nishant Agrawal, MD, is the director of Head and Neck Surgical Oncology at the University of Chicago Medicine. Dr. Agrawal specializes in the management of patients with benign and malignant tumors of the head and neck. His work has achieved international recognition in the field of head and neck surgical oncology, and head and neck cancer genetics. Prior to joining the University of Chicago, Dr. Agrawal was an associate professor at Johns Hopkins University.
- **James L. Demetroulakos MD FACS** -Dr. James Demetroulakos is Chief of Otolaryngology/ Head and Neck Surgery at the North Shore Medical Center and Attending Staff at Mass General Hospital/Mass Eye and Ear Infirmary. He received his medical degree from Brown University and has been in practice for more than 20 years.
- **Jack Wilson, Ph.D**. -Distinguished Professor of Emerging Technologies and Innovation. President Emeritus of The University of Massachusetts system. Chair of the Riverhawk Venture Fund. Chair of the Commonwealth of Massachusetts John Adams Innovation Fund Advisory Council. Past-Chair of MA Defense Technology Initiative.
- **Maria Alonso, Ph.D**.-Professor of Biopharmaceutics and Pharmaceutical Technology, University of Santiago de Compostela (USC). Widely respected for her contributions to vaccine/drug delivery nanocarriers. University of Santiago de Compostela (USC).
- **John Ripple** -John Ripple is the owner of Ripple Biotech, which advises early stage biomedical companies on strategy, business development, and fundraising. His other business experiences include medical device marketing and management consulting. He additionally serves as an advisor to the MIT Deshpande Center for Technological Innovation and the MIT Venture Mentoring Service. He received a B.S. in Mechanical Engineering from Bucknell University and an M.B.A. from Harvard Business School.

  - Source: http://www.privotechnologies.com/advisors.html

Questions

- What were the key changes in the business plan and business model?
- What drove those changes?

- She has created an advisory board of a diverse group of individuals. Why do you think she did that?

- It is estimated that it takes an investment of several billion dollars to bring a drug to market through all the clinical trials and government approvals. Clearly Dr. Goldberg has been quite successful in raising millions of dollars to support the company thus far. How would you advise her to bring the potential product the rest of the way to the market?