

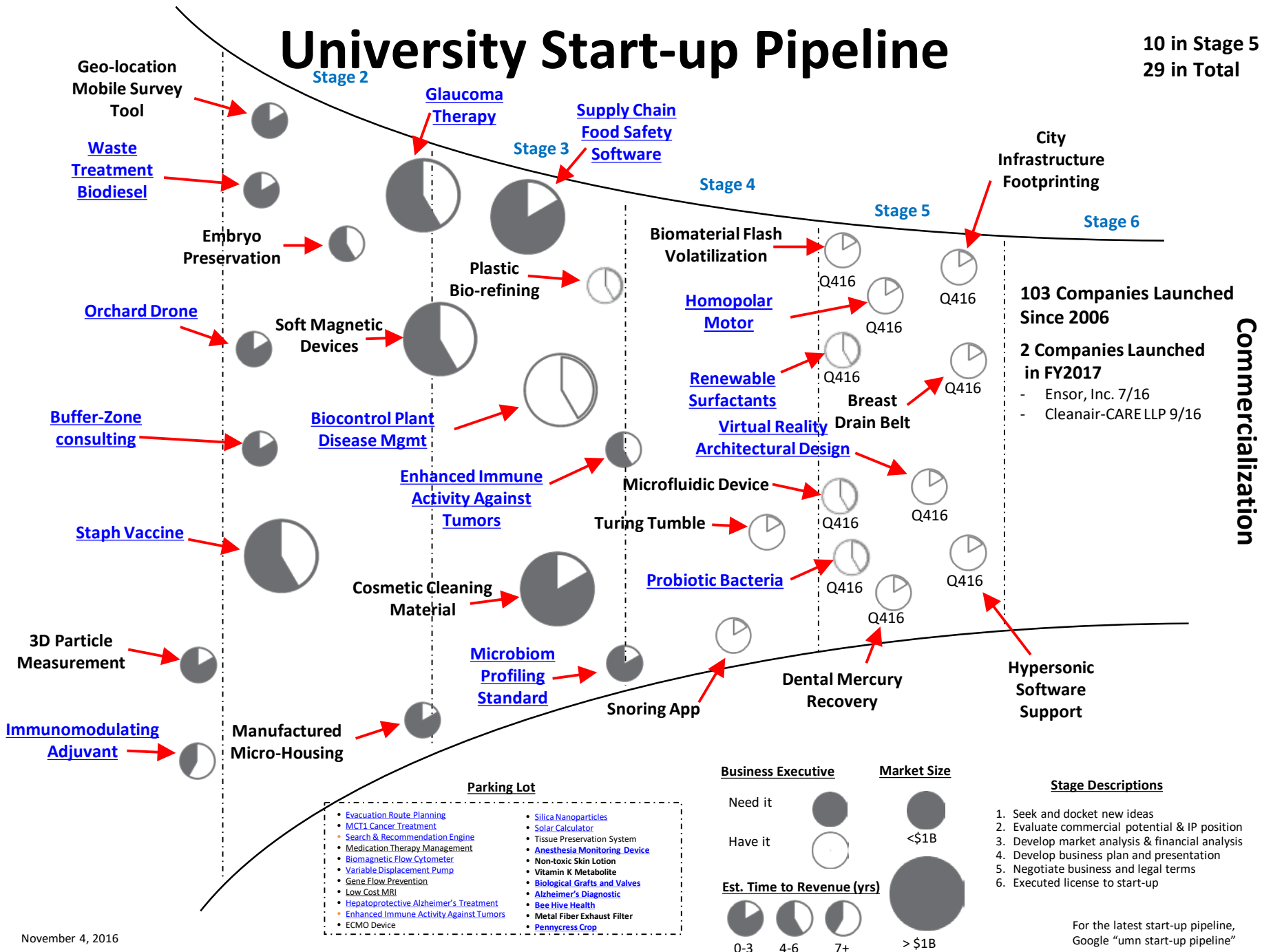
**FPIRC 2016**

**Role of Startups in a Healthy Industry**

Russ Straate  
University of Minnesota

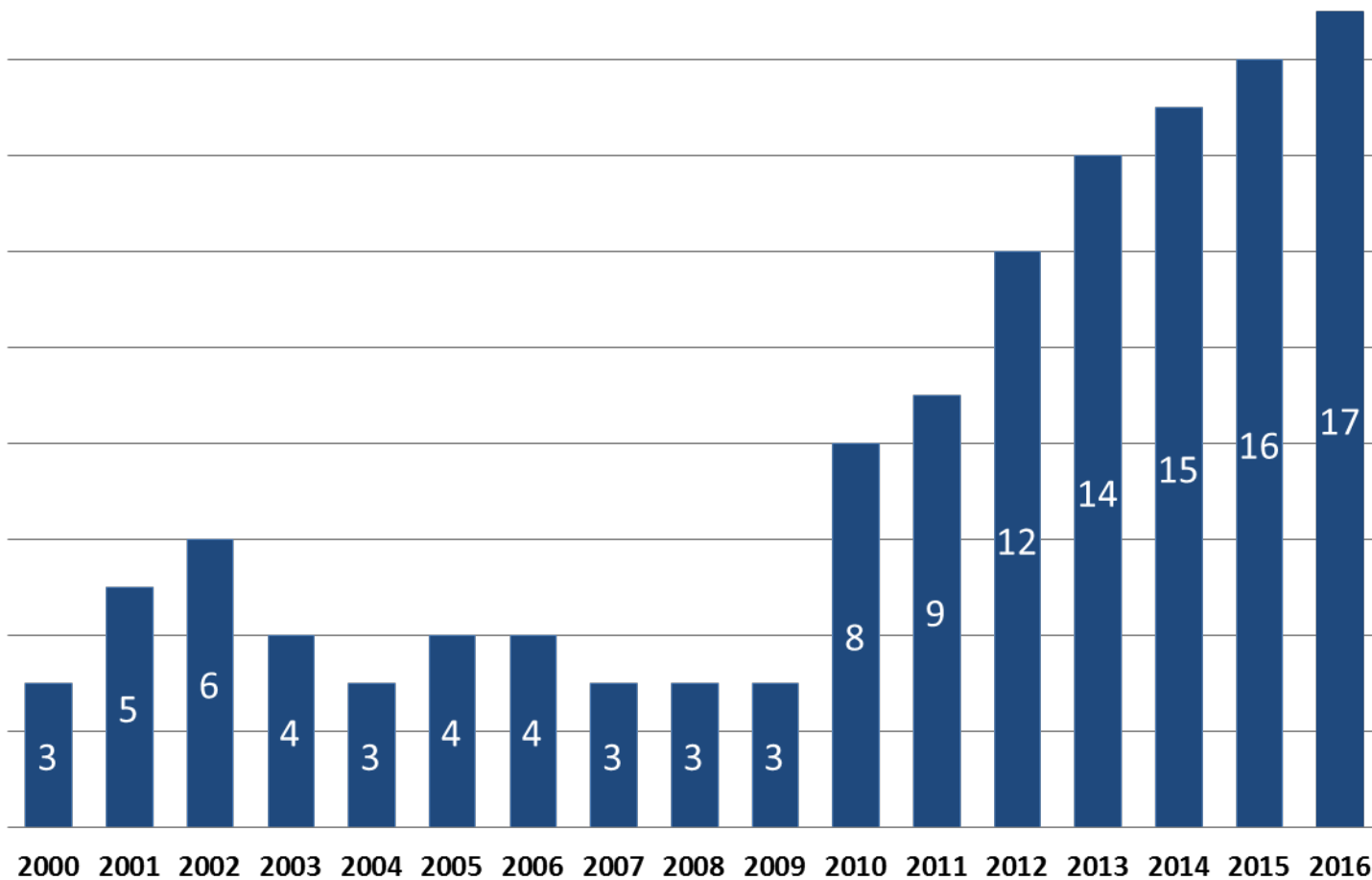
# University Start-up Pipeline

10 in Stage 5  
29 in Total



# FY 2016

## Another Record Year for UMN Start-ups



### FY '16 Stats

- **Multi-sector**

- 2 Med Device
- 7 Bio/Pharma
- 3 Software/IT
- 3 Eng/Phy Sci
- 1 Food/Ag
- 1 Energy & Env

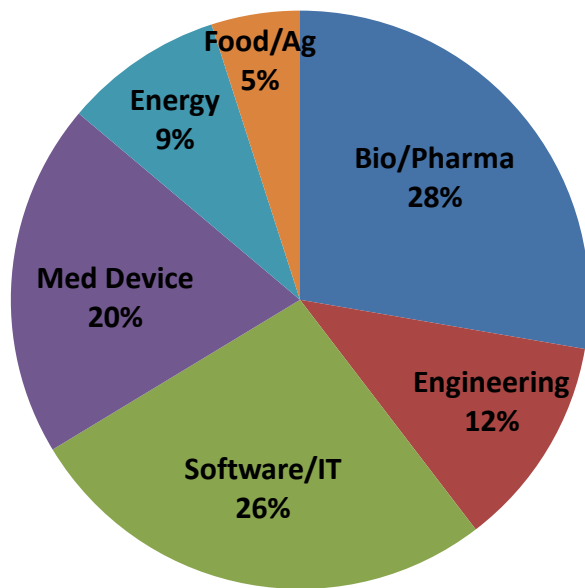
- **Location**

- 14 in Minnesota
- 3 Outside Minnesota

UMN fiscal year

# UMN Start-up Demographics

**Start-ups Created by Sector  
FY06 – FY16**



Start-ups by Sector	YTD FY16	FY06 – FY16
Bio/Pharma	7	28
Engineering & Phy Sci	3	12
Software/IT	3	27
Med Device	2	20
Energy & Env	1	9
Food/Agriculture	1	5
Startups by Location		
Reside in Minnesota	14	78
Reside out of Minnesota	3	23
<b>Total</b>	<b>17</b>	<b>101</b>

Shawn Wilhelm  
Enfield Technologies

Pat Dillon  
MN-SBIR

# SBIR/STTR FUNDING

- **NON-DILUTIVE** Seed money to fund high risk, high payoff projects with commercial/military potential - **NOT A LOAN**
- Small business program (1-500 employees)
- 11 federal agencies = ~\$2.5 billion each fiscal year
- Intellectual property rights are retained by the small business
- Recognition, verification and visibility by large companies, investors, etc.
- Maintain control of the company
- Potential leveraging tool to attract other investments (state funding, angel, early stage and venture capital)
- Potential for sole-source federal government contracts with any federal buying office
- **MN-SBIR, your local resource, free, confidential one-on-one assistance from pre-proposal to pre-award to post award.**





FIND FUNDING

Search Open Funding Topics

Search

SUCCESS STORIES

GET THE 411



LEARN ABOUT



I'M A(AN)...



I WANT TO...

# CONTACT MN-SBIR

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**Facebook: [MHTA](https://www.facebook.com/MHTA)**

**Linked In: [minnesota-high-tech-association](https://www.linkedin.com/company/minnesota-high-tech-association)**

*MN-SBIR is funded in part through a Cooperative Agreement with the U.S. Small Business Administration, a grant from the Minnesota Department of Employment and Economic Development and in-kind support from MHTA.*

# Doug Johnson

## Lite Run



# A story of starting a pneumatic medical device company

Improved body weight support for rehabilitation gait training

Pressurized lower body suit (pneumatic) and device (pneumatic counterforce and controls) provides body weight support

Safe, comfortable gait training can improve outcomes, increase safety, reduce therapist's burden, and reduce costs

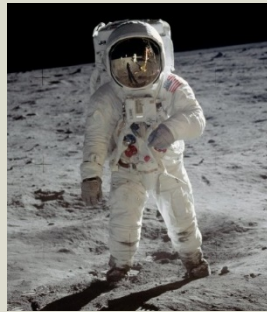
Lite Run's mission is to help people regain their ability to stand and walk following an injury or disability, such as a stroke.



## Unweighting Runners



## Invention!



## Medical Applications

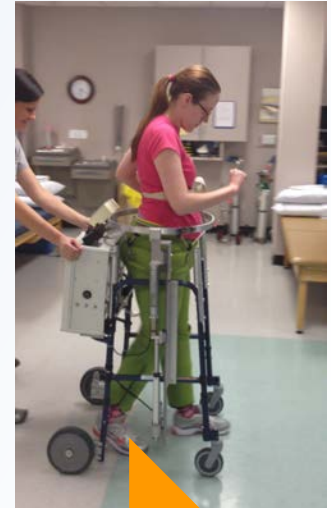


- SBIR Phase I Proposal Specified Mobile System
- SBIR Phase I Proposal Rejected
- Patent Applications Filed
- Patent Application Rejected "it wont work"

## Prototype



## First Feasibility Trial



Early Work

2009

Differential Pressure Space Suit  
 Developed Treadmill System  
 Patent Application

2010

Founded Lite Run as LLC  
 Patent Applications

2012

Self Funded Prototype  
 Focus Group  
 Business Plan

2013

First Feasibility Trial with Prototype



*Eunice Kennedy Shriver* National Institute of Child Health and Human Development  
Health research throughout the lifespan



**NEPDC**  
New England  
Pediatric Device Consortium



## NEPDC and TREAT Awards to Medical Device Innovators

### 2014

- First Patent Issued
- Series A Funding
- Begin Product Development
- With sit to stand

### 2015

- Complete Product Development
- Clinical Feasibility Study
- 22 Patients Stroke, Paraplegia, Multiple Sclerosis, Spinal Injuries

First Patent Allowed

### 2016

- Applied for NIH Phase II Direct
- NIH Conference Poster
- Design of Medical Devices Conference
- Awarded TREAT Grant
- NIH Proposal Rejected
- Won NEPDC Pediatrics Grant
- Space in University Enterprise Laboratories
- Five Patent Allowances
- Bridge Loans
- Building Commercial Systems

### 2017

- Clinical Trials
- FDA Registration
- Market Launch
- Commercialization
- Series B Funding

Jesse Litwak  
Medtronic

# JESSE LITWAK

## *DIRECTOR – STRATEGY & BUSINESS DEVELOPMENT* **MEDTRONIC CORONARY & STRUCTURAL HEART**

### Background

- Primarily Finance and Strategy (i.e. – failed engineer)
- Last ~11 years in MedTech (Guidant/Boston Scientific, ATS Medical, Medtronic)
- Prior experience in finance and technology with Honeywell

### Current Focus with Medtronic

- External partnerships, investments, acquisitions and divestitures
- Technology assessment and management of external relationships with Innovators, Entrepreneurs, MedTech start-ups and Venture Capital firms
- Strategic Planning
- Market assessments for adjacent applications of technologies and “white-spaces”



# MEDTRONIC: A BROAD \$29B PORTFOLIO BUILT THROUGH A COMBINATION OF ORGANIC AND INORGANIC INVESTMENT

## SUPPORT PRODUCTS AND SERVICES

- Diagnostic Tools
- Medical Supplies
- Surgical Navigation
- Surgical Products
- Patient Monitoring
- Remote Monitoring
- Service Solutions

### Cardiac Rhythm

- Asymptomatic heart rhythms
- Atrial fibrillation
- Fast heart rates (tachycardia)
- Heart failure
- Slow heart rates (bradycardia)

### Coronary

- Coronary artery disease

### Diabetes

- Type 1
- Type 2

### Ear, Nose, and Throat

- Hearing loss and single-sided deafness
- Otologic diseases
- Sinus diseases
- Sleep-disordered breathing
- Thyroid disorders

### Endovascular

- Aortic aneurysms
- Deep vein thrombosis (DVT)
- Peripheral vascular disease
- Venous insufficiency

### Gastroenterological, Urogynecological, and Urological

- Acid reflux
- Appendicitis
- Barrett's esophagus
- Crohn's disease
- Chronic benign liver disease
- Chronic fecal incontinence
- Chronic nausea and vomiting associated with gastroparesis\*

- Colon tumors
- Digestive disorders
- Gallstones
- Gastrointestinal bleeding
- Gastrointestinal functional disorders
- Hemorrhoids
- Hernias
- Nutrition insufficiency
- Obesity
- Ovarian tumors and ruptured ectopic pregnancies
- Overactive bladder and non-obstructive urinary retention
- Pancreatic cancer
- Polyps
- Uterine tumors and fibroids

### Neurological

- Acute ischemic stroke
- Blood clots
- Brain aneurysms
- Brain tumors and lesions
- Chronic cancer pain
- Chronic leg and back pain
- Cranial trauma
- Dystonia\*
- Essential tremor
- Hydrocephalus
- Obsessive-compulsive disorder\*
- Parkinson's disease
- Severe spasticity
- Subdural hematomas

### Pulmonary

- Acute respiratory distress syndrome (ARDS)
- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Lung cancer
- Pulmonary embolisms
- Respiratory compromise
- Sleep apnea

### Spine and Orthopedic

- Cervical degenerative disc disease
- Degenerative disc disease
- Lumbar spinal stenosis
- Orthopedic trauma
- Scoliosis
- Spinal fractures
- Tibial fractures

### Structural Heart

- Congenital heart disease
- Heart valve disease



# MEDTRONIC ORGANIZATION STRATEGIC ALIGNMENT

## Medtronic

\$10.2B

\$1.9B

\$7.2B

\$9.6B

Cardiac and Vascular Group	Diabetes Group	Restorative Therapies Group	Minimally Invasive Therapies Group
<p>Aortic &amp; Peripheral Vascular</p> <p>Cardiac Rhythm and Heart Failure</p> <p><b>Coronary and Structural Heart</b></p>	<p>Intensive Insulin Management</p> <p>Non-Intensive Diabetes Therapies</p> <p>Diabetes Services and Solutions</p>	<p>Brain Therapies</p> <p>Pain Therapies</p> <p>Spine/Orthopedics</p> <p>Specialty Therapies</p>	<p>Early Technologies</p> <p>Advanced Surgical Technologies &amp; General Surgical Products</p> <p>Medical Supplies, Respiratory &amp; Monitoring Solutions, &amp; Venous Solutions</p>

Revenue reflects Medtronic Fiscal 2016 ended April 29, 2016

# NEW TECHNOLOGY ASSESSMENT & INVESTMENT

## MEDTECH PERSPECTIVE

### TECHNOLOGY ASSESSMENT

- Is the idea novel?
- How is the IP?
- What is the market attractiveness?
  - Address unmet customer needs
  - Economic viability
- What are the risks and are they stacked?
  - Technical
  - Clinical
  - Regulatory
  - Market Development

### FUNDING SOURCES

- Private/Angel Investors
- Public/Private Research Grants
- Loans/Debt financing
  - Private/Bank
  - Gov't or Development Org.
- Venture Capital
- Industry/Strategic (timing...is influenced by the left side of this slide)