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Committee Meeting: 5/11/2016

**Board Meeting:** 5/12/2016 Austin, Texas

Wallace L. Hall, Jr., Chairman Ernest Aliseda Alex M. Cranberg Brenda Pejovich Sara Martinez Tucker

	Committee Meeting	Board Meeting	Page
Convene	2:00 p.m. Chairman Hall		
U. T. System Board of Regents: Discussion and appropriate action regarding Consent Agenda items, if any, assigned for Committee consideration	2:00 p.m. Discussion	Action	178
2. U. T. System: Report on a systematic assessment of how to best advance Offices of Technology Commercialization and the process of commercialization of discovery across the U. T. System	2:01 p.m.  Report/Discussion  Dr. Hurn  Ms. Goonewardene	Not on Agenda	179
3. U. T. System: Report on MicroTransponder, a U. T. Horizon Fund Portfolio Company	2:10 p.m.  Report/Discussion  Ms. Goonewardene  Mr. Frank McEachern,  CEO, MicroTransponder	Not on Agenda	198
4. U. T. System: Report and discussion on the initiatives of the Institute for Transformational Learning	2:20 p.m.  Report/Discussion  Dr. Mintz  Dr. Baker Stein	Not on Agenda	220
Adjourn	2:45 p.m.		

# 1. <u>U. T. System Board of Regents: Discussion and appropriate action regarding Consent Agenda items, if any, assigned for Committee consideration</u>

### **RECOMMENDATION**

No Consent Agenda items are assigned for review by this Committee. The Consent Agenda begins on Page 251.

2. <u>U. T. System: Report on a systematic assessment of how to best advance Offices of Technology Commercialization and the process of commercialization of discovery across the U. T. System</u>

### REPORT

Ms. Julie Goonewardene, Associate Vice Chancellor for Innovation and Strategic Investment and Managing Director of the U. T. Horizon Fund, will report on an assessment conducted on U. T. System institutions' Offices of Technology Commercialization in response to a recommendation from the report titled, "Task Force on Intellectual Property: Disposition, Practices, and Mechanisms of Implementation," issued in August 2014 by the U. T. System Task Force on Intellectual Property (IP) Issues. A PowerPoint presentation is set forth on the following pages.

### BACKGROUND INFORMATION

The IP Task Force, created by Chairman Foster on February 6, 2014, was charged to evaluate the intent, rationale, current language, workability, and requirements of the U. T. System Board of Regents' *Rules and Regulations* related to the disposition and management of research-derived intellectual property at U. T. System institutions and to recommend changes or revisions of the Regents' Rules to the Board of Regents. The Task Force issued a report in August 2014 titled, "*Task Force on Intellectual Property: Disposition, Practices, and Mechanisms of Implementation*." The report was accepted and recommendations approved by the Board of Regents on February 12, 2015.

One of the recommendations from the report was to "carry out a systematic assessment of how to best advance Offices of Technology Commercialization and the process of commercialization of discovery at each U. T. System institution."

In response to the IP Task Force recommendation, an assessment was conducted to:

- 1. Provide information on the approach used for assessing technology commercialization across U. T. System institutions.
- 2. Present findings on "how to best advance offices of technology commercialization and the processes of discovery at each U. T. System institution and across and between U. T. System institutions."
- 3. Recommend the mechanisms by which U. T. System can provide commercialization resources that will incentivize, promote, and support commercialization by U. T. System institutions.

A Systematic Assessment of How to Best Advance
Offices of Technology Commercialization and the Process of
Commercialization of Discovery Across the U. T. System

Ms. Julie Goonewardene
Associate Vice Chancellor for Innovation and Strategic Investment and
Managing Director of the U. T. Horizon Fund

U. T. System Board of Regents' MeetingTechnology Transfer and Research CommitteeMay 2016



# Recommendations from Review

- Recommendation 1: Presidents at each U. T. System institution should clearly articulate the mission and corresponding primary metrics of their commercialization offices
- Recommendation 2: Establish a first-of-its-kind U. T. System
   Commercialization Fund to advance the commercialization missions and
   primary objectives of U. T. System institutions
- Recommendation 3: Launch the U. T. System Proof-of-Concept Fund and the Patent Nationalization Program, as part of the U. T. System Commercialization Fund, and continue to support royalty audits
- **Recommendation 4**: Gather data from the U. T. System Mentor Network pilot program to inform next steps for a U. T. System Entrepreneurship-in-Residence (EIR) program



# How do these Recommendations Strengthen Us?

- Creates a mechanism by which U. T. System can incent commercialization activity across mission critical areas
- Clarifies the role of commercialization offices across U. T. System
- Avoids defining commercialization missions and metrics for institutions
- Builds an innovation pipeline that serves administrators, innovators, and commercialization offices across academic and health center institutions



May 11-12, 2016 Meeting of the U. T. System Board of Regents - Technology Transfer and Research Committee

# Which Data Informed the Recommendations?

- Self-reported performance data to the Association of University Technology Managers (AUTM) from FY 2012 - 2014
- May 2015 July 2015: U. T. System Office of Technology Commercialization (OTC) staff traveled to all U. T. System institutions and met with administrators, commercialization staff, and other stakeholders, such as faculty and entrepreneurs
- October 2015: Follow-on survey was sent to commercialization office directors to gather information on the mission statement, organizational structure, core commercialization areas, and primary challenges and opportunities faced by their offices
- November 2015: Survey was sent to various stakeholders on perceptions of commercialization/entrepreneurship objectives and services offered at U. T. System institutions

Three-Year Average Performance Self-Reported to AUTM for the Top 10 Commercialization Institutions/Systems in the United States, FY 2012 - 2014 (Note – Top 5 shown below)

Measure	Top 5	U. C. Syste	ystem MIT U.T.S		U. T. Syste	System Columbia		а	Stanford		
Overall Rank			1		2		3		4		5
Avg. Licensing Revenues (\$M)	101.4	107.5	3	91.6	5	56.4	8	160.9	2	90.8	6
Avg. Licenses Issued	116.3	214.0	2	75.3	8	117.0	3	76.0	7	99.0	5
Avg. Licenses \$1M+	9.7	15.7	1	11.0	2	9.7	3	7.0	4	5.3	7
Avg. Total Research Expenditures (\$M)	2,232.2	5,410.7	1	1,561.1	3	2,548.6	2	769.0	8	871.7	7
Avg. Federal Research Expenditures (\$M)	1,350.4	2,870.6	1	1,309.7	2	1,265.9	3	646.4	7	659.5	6
Avg. Industry Research Expenditures (\$M)	181.8	360.0	1	109.5	2	257.7	3	N/A	-	71.3	6
Avg. Prov. Patents Filed	387.0	811.3	1	418.3	2	318.3	3	N/A	-	268.7	4
Avg. U.S. Patents Issued	226.1	384.7	1	271.0	2	187.0	4	92.3	7	195.7	3
Avg. Legal Fees (\$M)	17.2	36.3	1	18.2	2	9.7	4	12.7	3	9.3	5
Avg. Legal Fees Reimbursed (\$M)	8.7	21.0	1	10.4	2	4.5	3	3.9	5	3.7	6
Avg. Number of Startups	27.2	65.3	1	16.7	4	22.3	2	15.7	7	16.0	5



# How Unique Are Each of the Offices?

Institution	UTA	UTAUS	UTD	UTEP	итнясн	UTHSCSA	итнѕст	UТМВ	UTMDA	UTPB	UTRGV	UTSA	UTSWMC	UTT	Totals
Total staff	3.0	23.0	6.5	5.0	6.5	5.0	0.0	6.0	10.0	0.0	2.5	4.0	22.5	1.0	95.0
Total research expenditures (\$M)	71.1	585.3	99.7	74.5	223.4	178.3	11.0	124.8	736.2	1.2	18.9	45.4	398.6	4.6	2,573.0
Total industrial research expenditures (\$M)	5.5	71.3	9.0	2.0	42.6	32.4	0.6	10.1	75.3	0.2	1.0	Not Avail.	25.0	0.0	275.0
Licenses executed	3	21	2	1	27	11	1	7	9	0	3	6	37	0	128
Provisional patents filed	38	102	25	12	15	21	1	11	37	0	3	31	47	0	343
U.S. patents issued	21	50	11	5	23	11	1	24	27	0	3	2	31	0	209
Start-up companies formed	1	7	0	1	2	2	0	2	3	0	1	2	6	0	27
Licensing revenue (\$M)	0.0	17.1	0.1	0.0	3.3	2.8	0.0	2.1	21.5	0.0	0.1	0.1	5.4	0.0	52.5
Legal expenditures (\$M)	0.4	2.4	0.4	0.2	1.0	0.4	0.1	0.7	2.9	0.0	0.1	0.3	1.2	0.0	10.1
Reimbursements for legal expenditures (\$M)	0.0	0.3	0.1	0.0	1.0	0.3	0.0	0.1	2.2	0.0	0.0	0.1	0.6	0.0	4.8



# **Findings: Mission Statements**

Commercialization missions at many U. T. System institutions are unclear to their various stakeholders

3. In terms of defining commercialization success, how would you best summarize your understanding of the top priority of leadership at your institution?

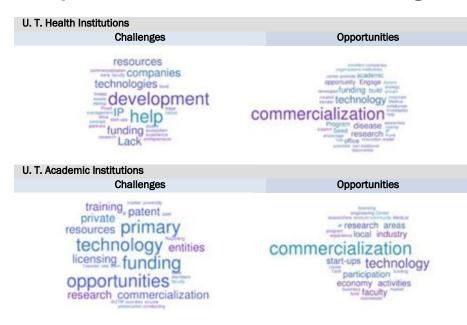
Answer Options	Response Percent
Providing excellent service to faculty, students and staff	37.8%
Generating revenues	18.9%
Positively impacting peoples' lives	25.7%
Other	17.6%
Responses	74



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# Findings: Challenges and Opportunities

Self-Reported Commercialization Challenges and Opportunities (by Institution Type)



- Two main challenges/ opportunities:
  - Resources
  - Funding

# Resources: Proof-of-Concept Fund

- The majority of top-tier institutions across the nation operate a proof-of-concept program, including:
  - University of California System (\$8M in proof-of-concept funding to 55 projects between 2011-2013)
  - State University of New York (\$1.5M in funding has led to \$3.5M in funding from external partners since 2011)
  - University of Illinois (\$1M proof-of-concept funding since 2009 has led to 9 startup companies, \$49M raised in venture and angel funding, and \$1.3M in additional government funding support)
- Compared to peers, U. T. System is behind the curve in providing proof-of-concept resources that can significantly benefit the U. T. System institutions



# Resources: Patent Nationalization Program

# Self-Reported Data to OTC on Patent Budget at the Beginning of FY2014 and Actual Patent Expenditures for FY2014 across U. T. System Institutions

Institution	Patent Budget at Beginning of FY2014 (\$M)	Actual Patent Expenditures for FY2014 (\$M)
U. T. Arlington	0.00	0.45
U. T. Austin	2.00	2.40
U. T. Dallas	0.61	0.39
U. T. El Paso	0.07	0.20
U. T. Health Science Center - Houston	1.18	1.18
U. T. Health Science Center - San Antonio	0.40	0.43
U. T. Health Science Center - Tyler	0.00	0.00
U. T. M. D. Anderson Cancer Center	2.50	2.86
U. T. Medical Branch - Galveston	0.90	0.67
U. T. Permian Basin	0.00	0.00
U. T. Rio Grande Valley	0.09	0.07
U. T. San Antonio	0.25	0.33
U. T. Southwestern Medical Center	1.20	0.65
U. T. Tyler	0.00	0.00

Note – U. T. Rio Grande Valley data is comprised of the aggregated data reported by U. T. Brownsville and U. T. Pan American



# Resources: Royalty Audits

- Commercialization offices are limited in their ability to monitor delinquent licensee
- In larger offices across the nation, a best practice is to regularly audit licensing portfolios to identify licensees who may owe millions of dollars in delinquent royalty payments
- From on-site interviews, a majority of commercialization office directors from the health science centers identified royalty audits as a useful resource that OTC has funded in the past

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# Resources: Entrepreneur-in-Residence Program (EIR)

- A number of the U. T. System institutions stated that they would like assistance in attracting executive talent to work with U. T.-related startups
- MIT, Columbia, Stanford, and UCLA, have accomplished this objective through mentoring and EIR programs
- Startups often attribute their success to top-notch and experienced management teams, as well as well-connected mentors that enable fundraising, hiring, partnerships, customers, etc.
- U. T. System has not yet capitalized on its brand and size to develop and strengthen an integrated mentor network across its institutions

- Presidents at each institution should clearly articulate the mission and corresponding primary metrics of their commercialization programs
  - Establish a common understanding of commercialization measures from those reported in AUTM licensing surveys
  - Directors will select and provide to the OTC primary metrics that will help them to achieve their objectives
  - OTC will generate a Systemwide annual report that will present the most exciting commercialization advances across U. T. System and promote the objectives of the institutions, as well as report on Systemwide performance metrics

- Establish a first-of-its-kind U. T. System Commercialization Fund to advance the commercialization mission and primary objectives of the U. T. System institutions
  - OTC will work together with commercialization office directors to create the structure and a transparent and equitable process for the allocation of resources and funds across institutions
  - OTC is particularly interested in advancing commercialization across mission critical areas
  - Utilizing Available University Funds as a first source of capital, the primary purpose of this fund will be to advance the commercialization missions and improve performance across the metrics provided by U. T. System institutions

- Launch the U. T. System Proof-of-Concept (POC) Fund and the Patent Nationalization Program (PNP), as part of the U. T. System Commercialization Fund, and continue to support royalty audits
  - POC will offer finite, milestone-based awards intended to advance research products/technologies and improve the probability of attracting further extramural funding and market interest
  - PNP will provide funding for the nationalization of patents to commercialization offices, which will increase the value of U. T.-generated intellectual property, as well as improve the marketability of these assets
  - The Commercialization Fund will support third-party royalty audits to identify licensees who are not fulfilling their financial obligations to the commercialization offices

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# Discussion: A Strategic Approach to the POC Fund

- Potential funding sources: Philanthropic (unrestricted)/AUF (restricted)
- **Objective:** Provide gap funding to accelerate the research/development and commercialization of mission-critical areas
- **Structure:** Centrally administered through U. T. System OTC and in collaboration with U. T. System institutions
- Selection: External review committee
- Impact: Increase likelihood of follow-on research funding; decrease time to commercialize research; increase deal flow for U. T. System OTCs and the U. T. Horizon Fund
- Sustainability: Implement mechanisms to return POC capital invested (i.e., investment rights, equity options, or reimbursement through royalty payments received by OTCs)



- Gather data from the U. T. System Mentor Network pilot program to inform next steps for a U. T. System EIR program
  - OTC will seek to build a strong mentor and executive network as the basis for informing the structure and goals of a potential EIR program
  - The OTC is already in the process of launching a U. T. System Mentor Network, which will be organized in the first half of 2016 and piloted in August 2016
  - One key objective of the pilot is to establish a baseline on the potential benefits and associated costs with a formal EIR program
  - Analysis will be completed at the end of 2016 and presented to the Intellectual Property Task Force at that time



# Follow-up Actions

- Task the presidents of all U. T. System institutions to work with their commercialization offices to clearly articulate a commercialization mission and corresponding metrics
- Task U. T. System institutions to communicate their commercialization mission and objectives in all relevant internal and external marketing materials
- Task the OTC to work with commercialization office directors across U. T. System to create the structure and process for the U. T. System Commercialization Fund
- Recommend to the Board of Regents the authorization of funding towards the U. T. System Commercialization Fund, which will include a U. T. System POC Fund, Patent Nationalization Program, and support for royalty audits
- Task the OTC to gather data from the U. T. System Mentor Network pilot program and provide a report on the benefits and costs related to a Systemwide EIR program



# 3. <u>U. T. System: Report on MicroTransponder, a U. T. Horizon Fund Portfolio Company</u>

### **REPORT**

Ms. Julie Goonewardene, Associate Vice Chancellor for Innovation and Strategic Investment and Managing Director of the U. T. Horizon Fund, will introduce Mr. Frank McEachern, J.D., Chief Executive Officer of MicroTransponder, a U. T. Horizon Fund portfolio company. Mr. McEachern will report on the activities and progress of MicroTransponder. A PowerPoint presentation is set forth on the following pages.

### BACKGROUND INFORMATION

The dual-purpose mission of the U. T. Horizon Fund is to 1) help move novel technologies to the marketplace to impact the world, and 2) create a positive financial return. To achieve its dual-purpose mission, the U. T. Horizon Fund invests both (i) in companies utilizing U. T. System innovations, and (ii) in companies in which U. T. System holds an existing equity interest, but which may not necessarily be utilizing U. T. System innovations.

MicroTransponder is a U. T. Horizon Fund portfolio company that embodies the Fund's dual-purpose mission. The clinical-stage company is leveraging decades of neuroscience research to develop treatments for two separate neurological conditions: chronic tinnitus and post-stroke upper limb mobility issues. Chronic tinnitus is the persistent presence of noise in a person's ears or head and, according to the NIH, is a primary condition reported by veterans who served in Iraq and Afghanistan. Also as reported by the NIH, stroke is the leading cause of long-term disability in the U.S., affecting nearly four million stroke victims directly and tens of millions more whose lives are interconnected. In pursuit of its therapies, MicroTransponder has completed numerous scientific collaborations with researchers from U. T. Dallas and other leading universities and is currently completing pivotal trial-enabling studies at multiple clinical trial sites in Texas and throughout the U.S.

Mr. McEachern has worked as a corporate securities attorney at Baker Botts, LLP, where he represented Advanced Neuromodulation Systems (ANS) in their merger with St. Jude Medical, the largest neurostimulation merger to date. He has nearly a decade of executive leadership experience in the implantable neurostimulation field and serves on the Board of the Texas Biomedical Device Center at U. T. Dallas. Mr. McEachern received a B.B.A. from U. T. Austin Business Honors Program and completed a J.D. from U. T. Austin.



Frank McEachern - CEO

Corporate Presentation

U. T. System Board of Regents' Meeting
Technology Transfer and Research Committee
May 2016

# **Paired Stroke Rehab**

695,000

Annual incidence of ischemic stroke ~1 person every 45 seconds

### 320,000

Patients who still suffer from upper arm deficits 3 months post their stroke

\$140,000

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Direct Medical Cost of care for an ischemic stroke survivor

### \$73.7 BLN

How much the US spent on stroke-related costs and disability; patients require daily assistance from family members or paid healthcare workers.



### **Tinnitus**

3.9 Million

People in the U.S. with severe, tonal tinnitus

No drugs approved in the U.S. or EU for tinnitus.

#1 disability among recent U.S. Veterans \$1.6B in annual VA disability payments

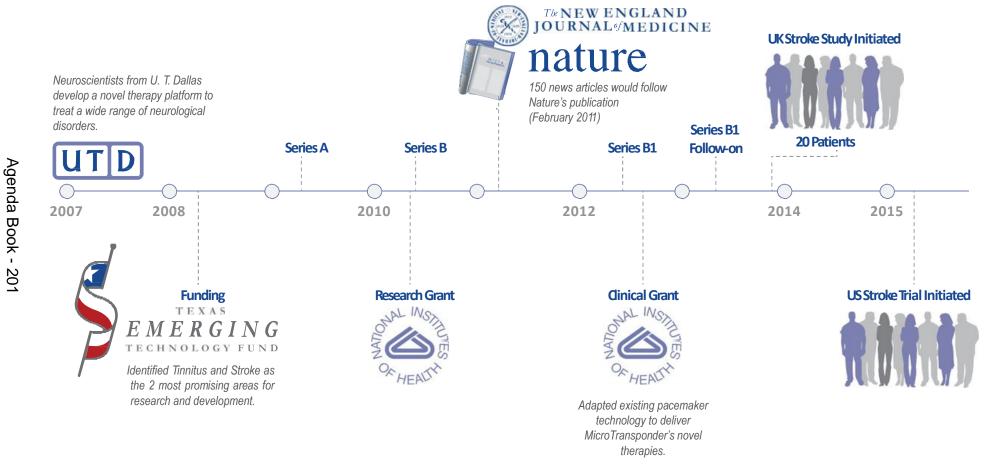
Currently, no effective treatment.



Note: Cyberonics (NASDAQ: CYBX, \$1.6BLN Market Cap) is the largest neurostimulation company focused solely on VNS. Annually it sells 14,520 Devices. (9,850 in U.S., 4,670 OUS)

**Our Markets** 

### How MicroTransponder Found the Product: A Visual Chronology



# Why MicroTransponder Pursued the Indication: Stroke Rehab



Harnessing Plasticity to Reset Dysfunctional Neurons

## nature

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Reversing Pathological Neural Activity Using Targeted Plasticity

### **22 Academic Publications**

Nature
New England Journal of Medicine
Neuromodulation
Neuroscience
Cerebral Cortex
Hearing Research
Biologicial Psychiatry
Stroke
Brain Stimulation

The pre-clinical data showed that Vagus Nerve Stimulation (VNS) therapy paired with rehab was effective over a wide range of brain damage suffered by stroke subjects.

The pre-clinical data also showed that the therapy worked across disabilities common to the target populations:

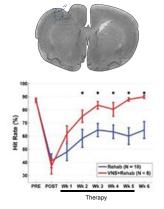


### **Chronic Stroke**

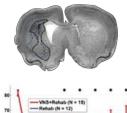
Patients whose stroke events occured a long time ago and still have disabilities.

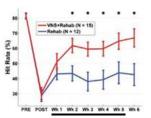




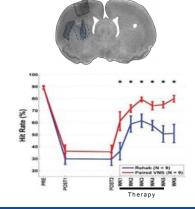




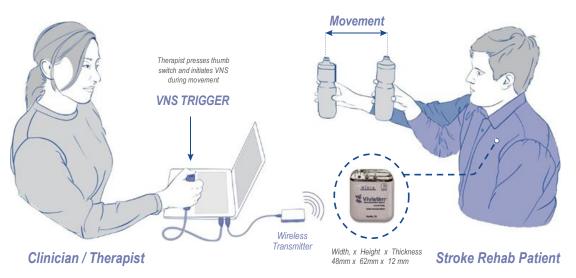








# What is the Product: Stroke Rehabilitation



# **Paired** Vagus Nerve Stimulation (VNS)

### with Physical Therapy

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Therapist uses thumb switch to trigger VNS during physical movements by the patient.

Stimulation of the vagus nerve releases important brain chemicals involved in learning and plasticity.

These chemicals strengthen brain circuits that are responsible for arm movement. Therefore, pairing movements with VNS is important.

### **Safety Well Established**

VNS medical implants started in 1997

### **100,000** patients

Use implanted VNS for Epilepsy Implant is placed in left pectoral region

### **75 Minutes**

Duration of implanting procedure

### 90 Minutes

Duration of treatment

### 3

Treatments per week

### 6 weeks

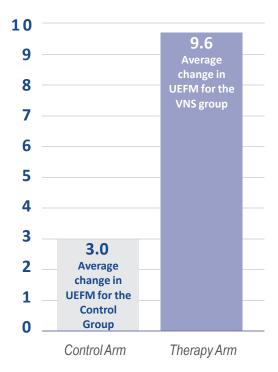
Duration of treatment cycle

### Cyberonics

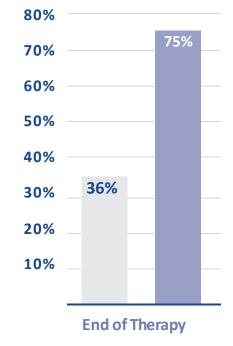
2014 VNS sales \$292M



## How We Know It Works: Stroke Rehabilitation



Average UEFM S core Change on Trial



UEFM – Upper Extremity Fugl-Meyer, the gold standard of measuring movement. A change in score ≥ 6 is considered clinicinally meaningful (responder)

- 75% of Patients Responded to the Therapy
- The 9.6 Change in UEFM Score is Statistically Significant Compared to Control (p= .038)
- Chronic Patient Population Average of 1.8 Years Post-Stroke
- "These results are impressive. This therapy has the potential to improve the lives of my patients."

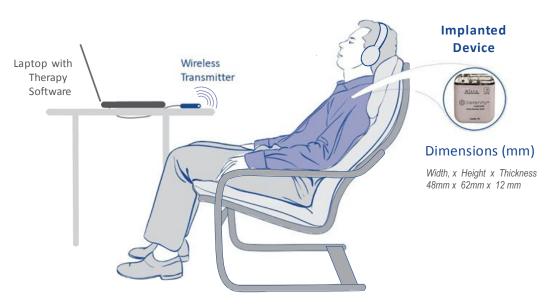
### Stephen Cramer, M.D.

Director, Clinical Translational Science at UC Irvine



# What is the Product: Tinnitus

For Tinnitus, we pair stimulation with tones



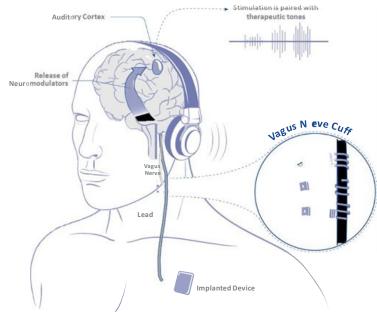
### At-Home Therapy Patient Begins Sound Therapy

Patients administer the therapy from the comfort of their own home. No therapist required.

Therapeutic tones are played outside of patient's tinnitus frequency.

### **Neuroplasticity**

Pairing tones with VNS increases the brain's ability to repair brain circuits and reduce the perception of tinnitus.



# Why MicroTransponder Pursued the Indication: Tinnitus



Harnessing Plasticity to Reset Dysfunctional Neurons

## nature

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Reversing Pathological Neural Activity Using Targeted Plasticity

### 22 Academic Publications

Nature
New England Journal of Medicine
Neuromodulation
Neuroscience
Cerebral Cortex
Hearing Research
Biologicial Psychiatry
Stroke
Brain Stimulation

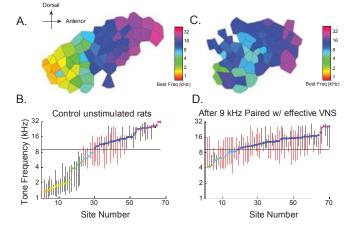
After trauma that damages a person's hearing, there is lack of auditory input to one or more regions of the auditory cortex in the brain. A region in the auditory cortex not receiving its normal input will seek input from neighboring

regions and this interference causes a malfunctioning circuit. The auditory neurons start firing spontaneously and in unison - this is perceived as tinnitus.

LETTER Nature 470, 101–104 (03 February 2011)

# Reversing pathological neural activity using targeted plasticity

Navzer D. Engineer<sup>1,2</sup>, Jonathan R. Riley<sup>4</sup>, Jonathan D. Seale<sup>4</sup>, Will A. Vrana<sup>4</sup>, Jai A. Shetake<sup>4</sup>, Sindhu P. Sudanagunta<sup>4</sup>, Michael S. Borland<sup>4</sup> & Michael P. Kileard<sup>4</sup>

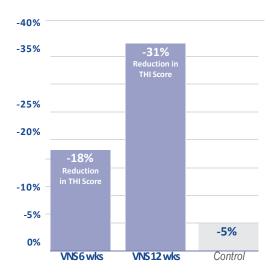




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# **How MicroTransponder Knows It Works: Tinnitus**

### **Primary Efficacy**



Median THI (%) Change During Trial

### **THI Responder Rate**



THI – Tinnitus Handicap Inventory, the gold standard of measuring the severity of a patient's tinnitus. 20% or greater change is considered clinically meaningful (responders)

- 56% of Patients Responded to the Therapy
- Highly Motivated Patients
   96% Compliance with Therapy (n=30)
- Difficult to Treat
   Average patient had tried 4 other
   treatments and had tinnitus for 18 years
- "We have patients reporting big changes in their lives as the result of this therapy."

### Richard Tyler, Ph.D.

Professor, Otolaryngology at the University of Iowa

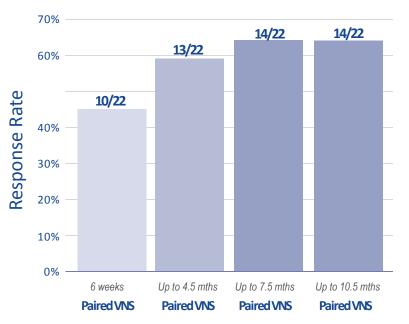


# **Tinnitus Study**

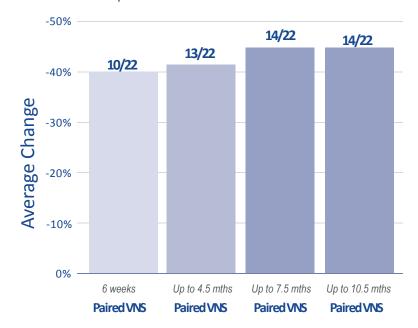
### Long-Term Efficacy for more severe patients (>38% in THI)

22/30 patients had moderate or greater tinnitus at baseline (10 moderate, 8 severe, 4 catastrophic)





# THI % Average Change for moderate or greater tinnitus responders

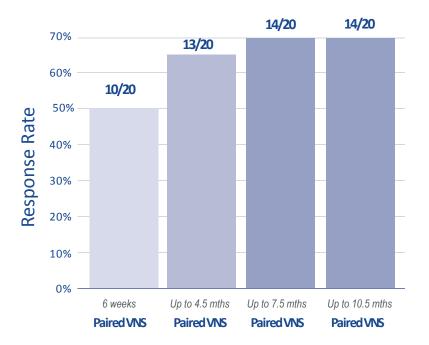


### **Target Population**

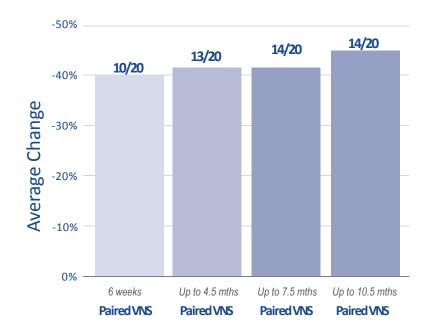
### Long-Term Efficacy for more severe patients ( $\geq$ 38% and $\leq$ 90% in THI)

20/30 patients were in this THI range (10 moderate, 8 severe, 2 catastrophic)

THI Responders Rate 20% or greater change for > 38% and < 90% in THI



THI % Average Change for >38% and <90% in THI responders



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# **Why This Matters**



**Case Study Patient** 



# Status

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- 6 issued U.S. patents, 21 pending or allowed, with 267 unique claims.
- System development complete.
- 2nd stroke trial completes enrollment in Q2 2016 with a CE mark expected in Q1 2017.
- CE mark in Q3 2016 for tinnitus.
- Favorable reimbursement codes exist. (EU \$14,500 / U.S. \$27,500).
   The cost of the system will be ~ \$5,000 (82% U.S. Profit Margin).
- U.S. pivotal trials for both tinnitus and stroke planned for Q4 2016.
- FDA has approved the Investigational Device Extension (IDE) for a 120 patient pivotal study in tinnitus.

### 267 Unique Claims





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# **European Sales Launch Strategy**



VP of Sales and Marketing - EU

Jean-Philippe Allar

- Led Cyberonic's European VNS Sales for 10 years
- VP of Sales for Neurotech, selling VNS devices for another 2 years, ending in 2012
- 25 years of medical device sales in Europe, great clinical contacts and reimbursement expertise

### Germany



Established Reimbursement

Initial Launch Market

# **Management Team**



Frank McEachern, J.D. CEO

Agenda Book -

- Attorney at BakerBotts LLP, including St. Jude / ANS merger
- Business and Law degrees from the University of Texas at Austin
- Significant experience with medical device regulation, reimbursement, outsourcing arrangements, and IP matters



Jordan Curnes, M.B.A. President and COO

- Co-founder, prior health care consulting expertise
- · M.B.A. from Duke University,
- Finance degree from Notre
  Dame
- · Co-founder, prior health care



Navzer Engineer, M.D., Ph.D. CSO and VP of Medical Affairs

 Expert in neurostimulation procedures and published papers in Nature



Brent Tarver VP of Clinical Affairs

- Clinical Director at CYBX for 15 years
- Supervised 17 device trials in 8 countries
- Specific previous experience with VNS therapy for treatment of epilepsy and depression



Ravi Jain, M.S. Director of Engineering

- Experience at St. Jude on both implantable pulse generator (IPG) and lead development
- Responsible for the vagus nerve cuff lead design and production



Jean-Philippe Allar VP of Sales & Marketing Europe

- European General Manager at Cyberonics for 10 years
- Previous experience at Neurotech and Apnex Medical, both neuromodulation startups

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# Valuation Framework: Initial Public Offerings (IPOs)

rket data as of April 1, 2015

	Indication	Dev. Stage @IPO	IPO Pricing	IPO Date	Market Cap
	Back Pain Neurostim	Post CE Mark Pre FDA Approval	Raised \$145 M IPO @ \$523 M	Nov 2 0 1 4	\$1.72 BLN
MAINSTAY  MEDICAL	Back Pain Neurostim	26 patients PreFDA Approval	Raised \$25 M IPO @\$108 M	Apr 2014	\$72.4 M
Second Slght	<b>Vision Restoration</b> Neurostim	Humanitarian Device Exemption	Raised \$32M IPO @\$326 M	Nov 2 0 1 4	\$170.5 M
(CAurisMedical	<b>Tinnitus</b> Drug	248 patients, Phase II	Raised \$56.4M IPO @\$140 M	Aug 2 0 1 4	\$130.5 M
ОТОНОМУ	<b>Tinnitus</b> <i>Drug</i>	532 patients, Phase III	Raised \$115 M IPO @\$888 M	Aug 2014	\$450.7 M

# **Valuation Framework: Transactions**

		Valuation	Amount Raised		
Micro <b>Transponder</b>	2015	\$	\$	20 stroke patients EU 40 tinnitus patients US/EU	Stroke
S saluda MEDICAL	2015	N/A	\$10M	80 patients US	Backpain
IMTHERA	2011	\$60M	\$16M	14 patients EU	S leep Apnea
NEUROPACE	2011	\$100M	\$50M	30 patients EU and US	Epilepsy

# **Neurostimulation: Valuation Framework**

		Valuation	Amount Raised			
Micro <b>Transponder</b>	2015	\$	\$	20 stroke patients EU 40 tinnitus patients US/EU		Stroke
AUTONOMIC TECHNOLOGIES	2015	\$130M	\$32M Raised	100 headache patients US		Headache
:• Axonics	2014	N/A	\$33 M Raised	0 patients US		Urinary Incontinence
SetPoint MEDICAL	2013	N/A	\$27M Raised	8 patients US		Rheumatoid Arthritis
	2011	\$120M	\$58M	24 patients US 70 patients EU	A STATE OF THE STA	Backpain
Spinal Modulation	2009	\$70M	\$30M	10 patients US	SA SEL	Backpain

# **Potential Acquirers**



### Cochlear Implant (CI) Leader

2013 CI Revenue was \$646M Great relationships with key opinion leaders in space

# **Expertise in Hearing**

Same physician call points, MicroTransponder (MTI) would be a tuck-in acquisition

# sonova

# **Cochlear Implant - Emerging Competitor**

2013 Cochlear Implant Revenue was \$218M, 33% increase
Trying to grow their neurostim presence

### **Dedicated Hearing Aid Player**

Committed to broader hearing issues MTI would be a tuck-in acquisition



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### **Dominant Neurostim Leader**

Estimated \$8B in Cash, \$1.8B rev. Leaders in Pain, Urinary Incontinence, DBS space

### Same Call Points

Needs growth, and VNS lead Sales force understands IPGs, Already sells to Ear, Nose, and Throat (ENT) specialists



### Ischemic Stroke, Interest in Neurostim

Already bought BSX Neurovascular, Concentric Medical Long held interest in neurostimulation space

# Stroke Experience

Call points with stroke docs Great device sales force



### Large Neurostim with VNS Research

\$550M in revenues
Previous VNS research for cardiac

### **VNS** Research

Sales Reps familiar with IPG Expanding indications



### Largest VNS Company

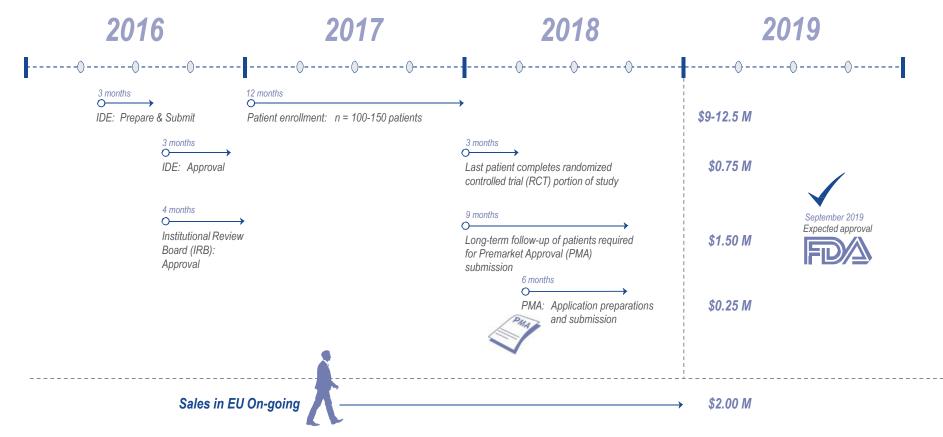
\$292M in revenues Recently expanded focus beyond epilepsy

## **VNS** Expertise

Easy tuck-in acquisition
Sales force fully understands surgery

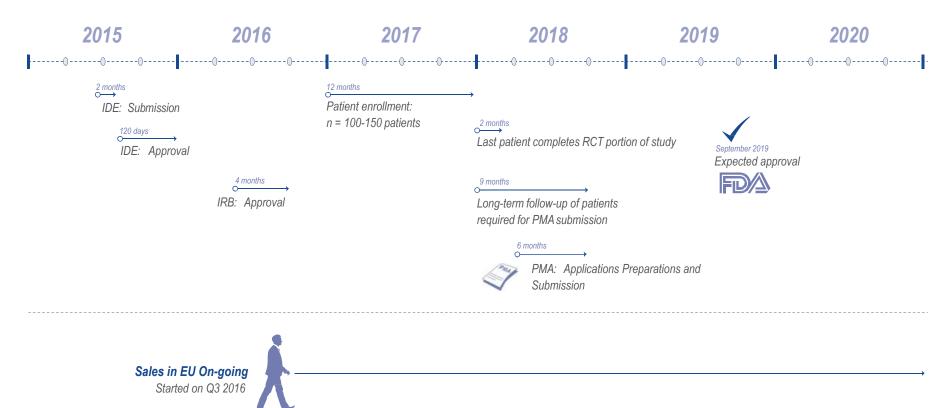


# Pivotal Trial Timelines: Stroke (\$13.5 - \$17.0 M)





# Tinnitus: Path to the U.S. Market





# 4. <u>U. T. System: Report and discussion on the initiatives of the Institute for Transformational Learning</u>

# **REPORT**

Dr. Steven Mintz, Executive Director of the U. T. System Institute for Transformational Learning (ITL), and Dr. Marni Baker Stein, Chief Innovation Officer, will provide a report on the initiatives of the ITL.

A PowerPoint presentation is set forth on the following pages.



Dr. Marni Baker Stein, Chief Innovation Officer

Dr. Steven Mintz, Executive Director

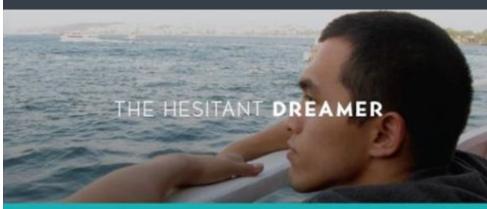
Institute for Transformational Learning (ITL)

U. T. SYSTEM BOARD OF REGENTS' MEETING
TECHNOLOGY TRANSFER AND RESEARCH COMMITTEE | MAY 2016



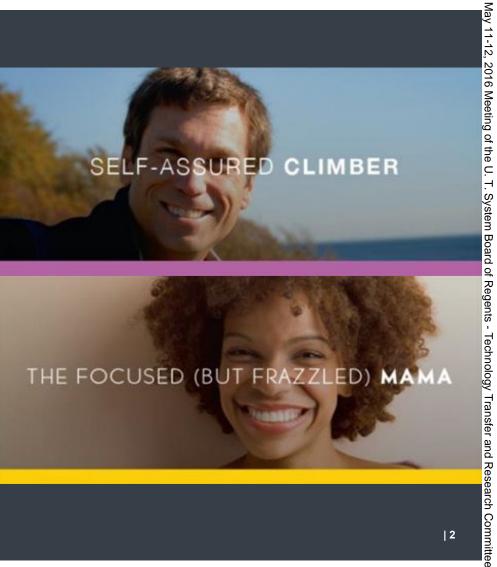
May 11-12, 2016 Meeting of the U. T. System Board of Regents - Technology Transfer and Research Committee

# THE NEW STUDENT PROFILE









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# IT'S A VUCA WORLD

Volatile Uncertain Complex Ambiguous







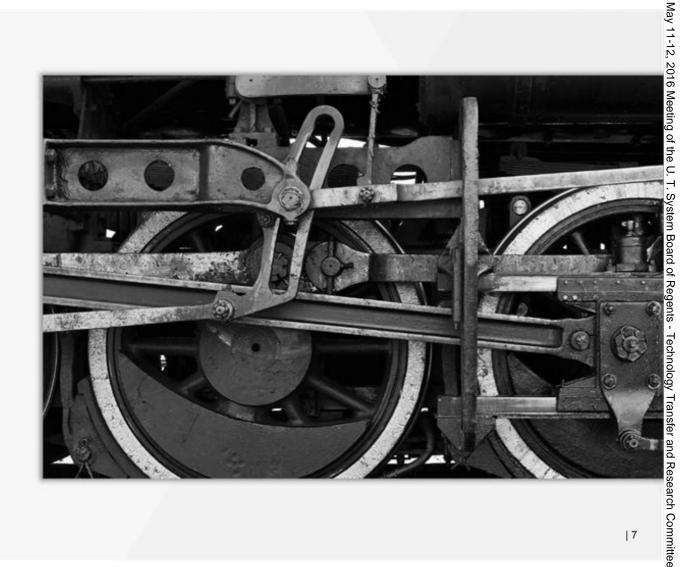
# Why can't we get more learners to this bright future?



# "

# We are in a new world, using old tools

- Thomas Friedman, "The World is Flat"





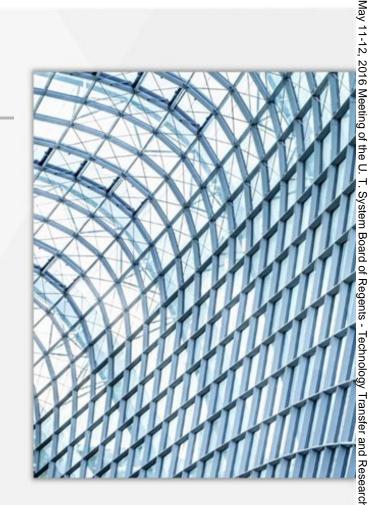
# Design Requirements PART 1

**CONTINUOUS** | Programming pathways that begin as early as middle school and continue throughout a career

**TRANSDISCIPLINARY** | Programming pathways that encourage learners to move beyond disciplinary-specific approaches as they address critical problems and opportunities

**INDUSTRY-ALIGNED** | Programming pathways that are laser focused on the future of work and assume (by design) multiple entry and exit points across a life time

Hi-FIDELITY CONTENT | Curate and develop compelling content that delivers high impact pedagogical approaches (has to look good and work)





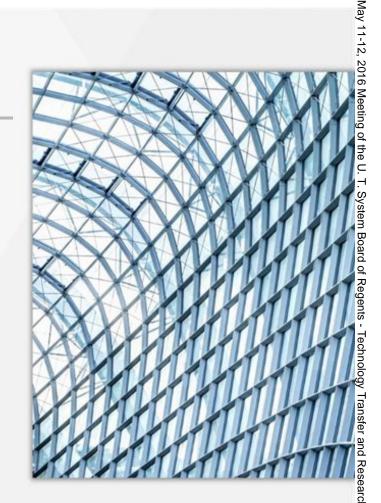
# Design Requirements PART 2

**STUDENT-CENTERED and PERSONALIZED** | Provide students persistent and progressive lifecycle management, learning, career, and content services

**GAMIFIED** | Offer learning activities designed for high engagement and tangible progression

**SOCIAL** | Encourage knowledge networking experiences that are contextualized and designed to drive value

**ATOMIC** | Modularized, stackable learning experiences that tag to a wide range of accomplishments from badge to competency to credit to certificate or degree (potentially across multiple institutions or kiosks)





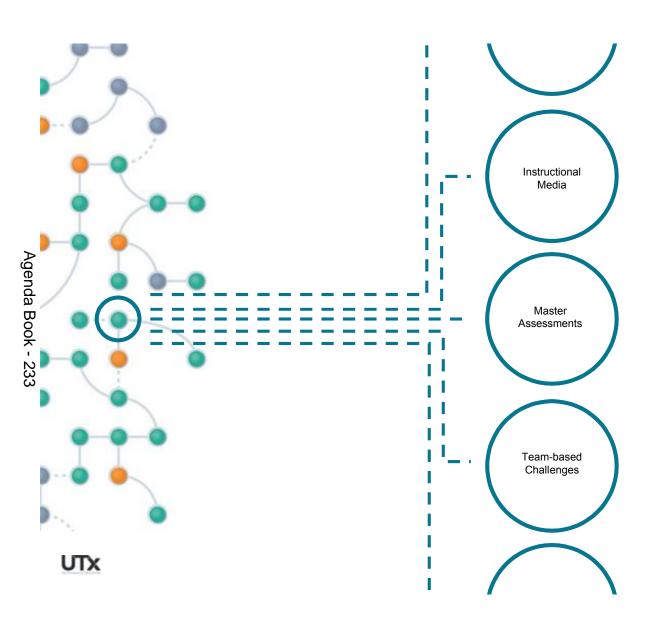




A Persistent
Progressive Profile
and Universal
Transcript

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# The Knowledge Graph



# The Learning Environment



# The Marketplace







THE PROTOTYPE

# **BS** in Biomedical **Sciences**





# High fidelity content and learning experiences that engage students and compete for attention in a complex world:

Mobile-first approach

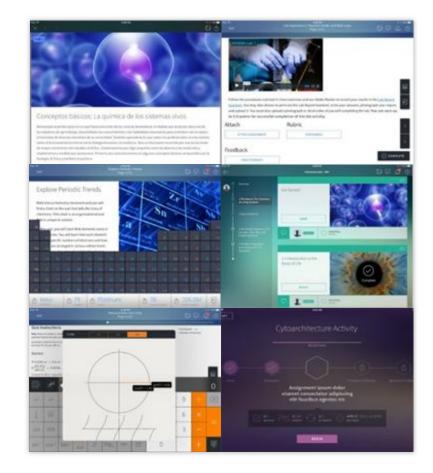
Pre-loaded content

Bilingual content and Offline content

High impact pedagogies and authentic assessment

Distributed activity framework (atomic design)

Points-driven progress indicators



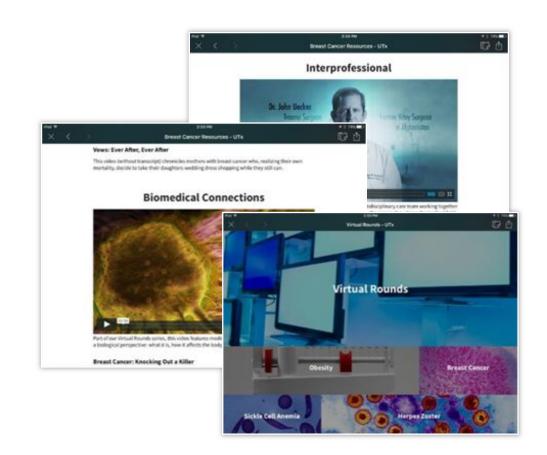


# Transdisciplinary insights and windows into the health professions:

Design across all 120 credit requirements

Synergistic learning pathways across each term

Virtual rounds as red thread across disciplinary domains





THE PROTOTYPE: BS IN BIOMEDICAL SCIENCES

# A level of personalization to support a diverse audience of learners:

Personalization of pace (bounded)

**Block scheduling** 

Pre-set pathways

and...





# A community of care acting on real time engagement and performance data (2.3 million events in term one):

Faculty

Longitudinal Instructional Facilitators

Student Lifecycle Management Coaching (proactive and reactive)

**Dedicated Student Success Coach** 

**Tutoring Services** 





# A commitment to evidence-driven continuous improvement:

Profile

Engagement

Self-efficacy

Endurance

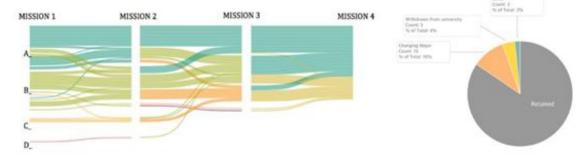
Learning decay

Intervention impacts

Outcomes

Gender and Pace composition by retention category plotted along student ACT score.







The Gates Foundation
The Teagle Foundation
The Department of Education
Apple
Salesforce
PBS
Dell Corporate Giving





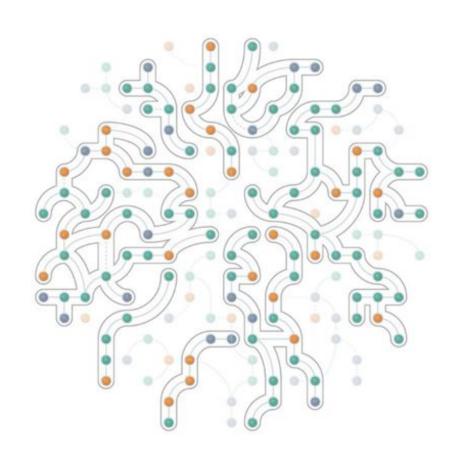
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# Is this model sustainable – and can we get it to scale?

May 11-12, 2016 Meeting of the U. T. System Board of Regents - Technology Transfer and Research Committee

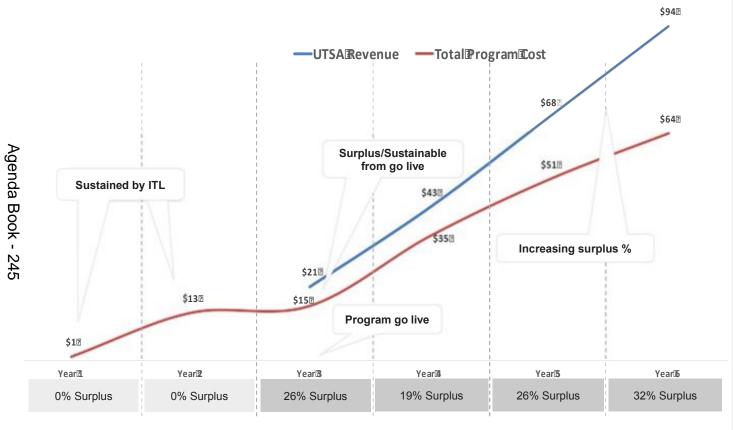
# **UTSA CYBER PORTFOLIO**

- BA in Computer Science
- BBA in Information Systems and Cyber Security
- Multiple Academic Certificates
- Multiple professional/non-credit Certificates
- Credit by exam



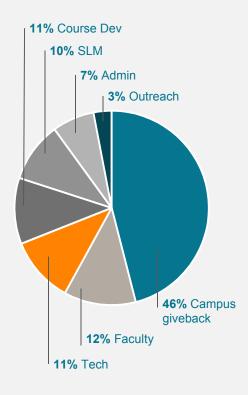


# Total UTSA Program Revenue and Cost (\$m)



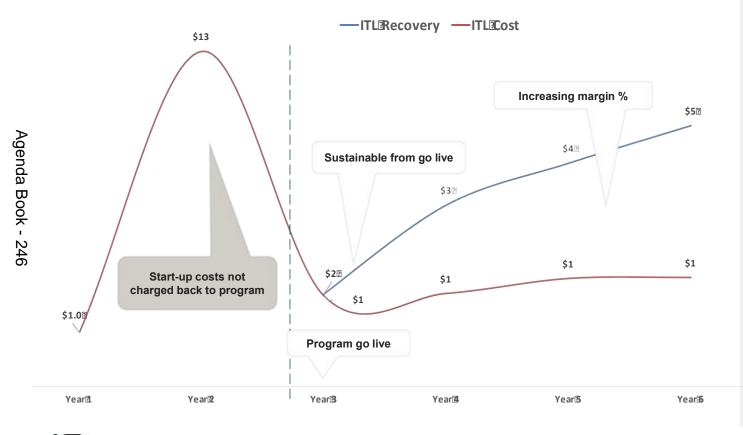
\* Assumes no recovery for initial start-up funds incurred by ITL

# Average Cost Breakdown by Type for Program





# ITL Support for UTSA Program - Recovery and Cost (\$m)



- Assumes ITL will not chargeback any initial program creation costs
- Some recovery can be built into these surplus programs
- ITL costs relate to program are for headcount and program management
- All ITL related costs are recovered at go live



### **ITL PORTFOLIO**

# **BUSINESS**

- U. T. San Antonio BBA Cyber Security and Early Business Core (Fall 2017)
- U. T. Tyler BS Marketing (concept stage)

# **HEALTH PROFESSIONS**

- U. T. Rio Grande Valley BS in Biomedical Sciences (Live Fall 2015)
- U. T. Health Science Center Houston Biostatistics Pathway (Fall 2016)
- TIME Initiative Early Health Sciences Core (concept stage)
- U. T. M. D. Anderson Cancer Center -Cross Institutional UTxHealth Continuing and Professional Education Portfolio (Fall 2017)

# **COMPUTER SCIENCE**

U. T. San Antonio - BA Cyber Security and Early Computer Science Core (Fall 2017)

# **ENGINEERING**

- U. T. El Paso BS Electrical (concept stage)
- U. T. Permian Basin BS Petroleum and Energy Technology (concept stage)
- U. T. Austin Early Engineering (Fall 2017)

# **MEDICAL SCHOOL**

- U. T. Rio Grande Valley Competency Based Degree Mapping (complete Fall 2015)
- U. T. Austin Competency Based Degree Mapping (complete Spring 2015)
- U. T. Austin Value Based Care Metrics (Spring 2016)



# What is the real measure of success?



May 11-12, 2016 Meeting of the U. T. System Board of Regents - Technology Transfer and Research Committee

# **Value Metrics**

# STUDENT ACCESS



# CROSS-INSTITUTIONAL IMPACT

Programs in Development

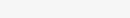
Programs Live

### STAKEHOLDER SATISFACTION

Campus Leadership

Faculty

Students



Retention

Optimized Pace Completion

STUDENT SUCCESS

Annual Earnings to Partners

STAKEHOLDER VALUE

Annual Earnings to ITL





# **Value Metrics**

# Program 2015 2006 Growth Partner Partner Affiliate 2015 2006 Partner Partner Purtner Partner Partner Purtner Partner Partner

Publications

	Requests	for New P	Program Development
	Requests	for Consu	Itation
	Proliferat	ion of Mo	dels Beyond ITL
EPUT	ATIONAL CAF	PITAL	4
REPUT	Foundation	2015	20%
REPUT			2016 Partier Partier Partier
REPUT	Foundation Partners	2015 Factor	Partner Partner
REPUT	Foundation	2015 Factors Partner 2015 Dectors Partner	Partner Partner Partner 2016 Partner Partner
EPUT	Foundation Partners	2015 Factories Partner	Partier Partier Partier 20% Partier
REPUT	Foundation Partners	2015 Factors Partner 2015 Dectors Partner	Partner Partner Partner  2006 Partner Partner Partner

