



# SPEED VENTURE SUMMIT



Roy Wallen, CEO  
TendoNova Corporation  
[roy.wallen@tendonova.com](mailto:roy.wallen@tendonova.com)

 760 415 3166  
@TendoNova

# Tendinopathy is one of the most common causes of pain worldwide

---



- Over **30 M people** in US with chronic tendon pain
- Orthopedics has moved from open procedures to decreasing invasiveness
- Providers require specialized tools to perform procedures
- **\$1.2 billion** market opportunity

# TendoNova's Ocelot™ system

## Cost-effective, in-office device for ultrasound-guided orthopedic procedures



Procedure-specialized probe

Maximizes efficacy and minimizes procedure time for percutaneous tenotomy



Reusable, rechargeable handle

Integrates seamlessly into the clinical workflow







Provides the first real-time, objective measurement of procedure effect, reducing barriers to adoption

Data-gathering for long-term improvements

# TendoNova's technology meets the needs of physicians, payers, and patients

---

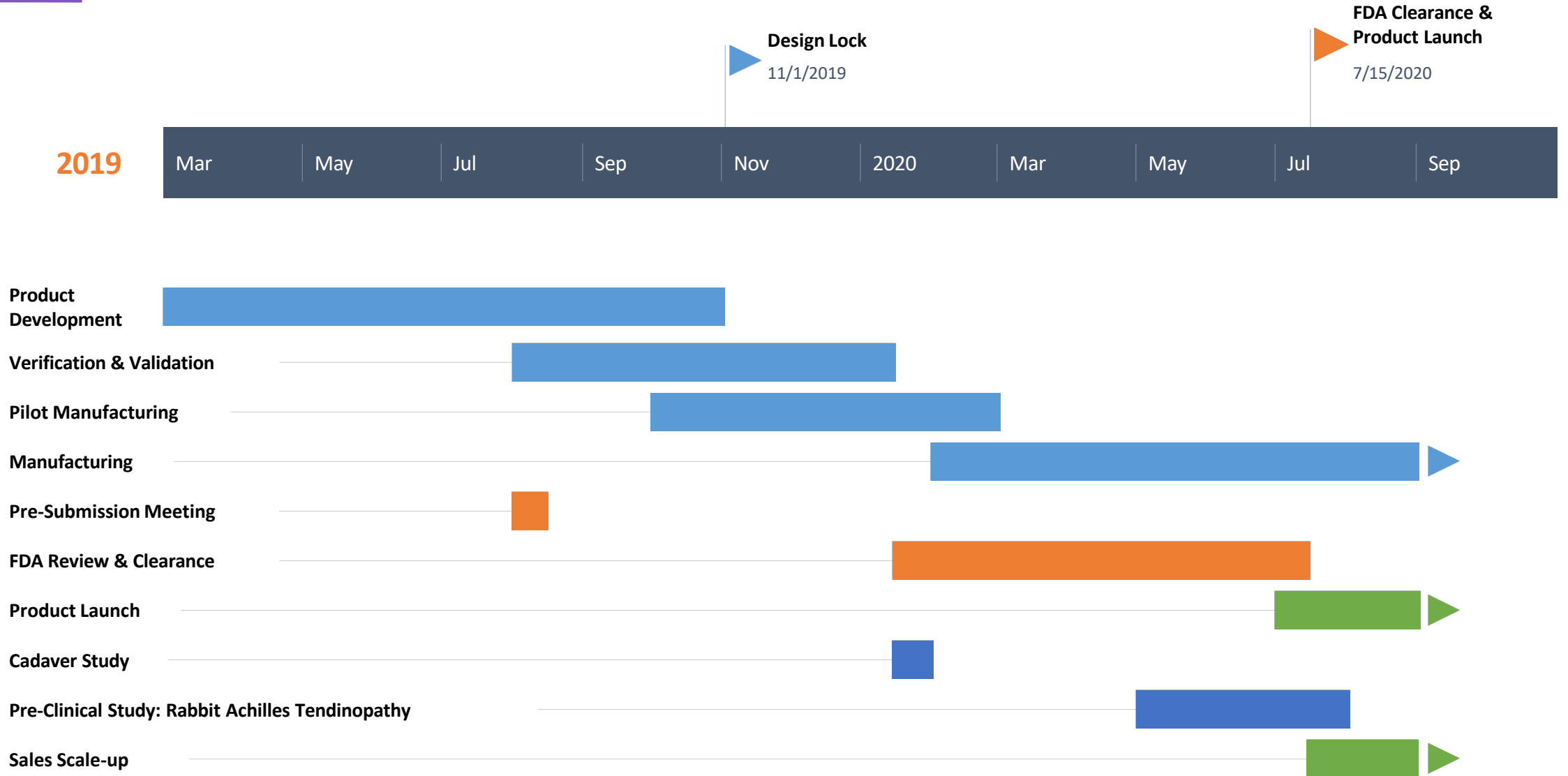
-  **Improved Clinical Outcomes**
  -  **Improved Patient Experience**
    -  **Decreased Cost of Care**
      -  **Improved Physician Experience**

# Business model


- Three system components
  - single-use disposable (revenue driver)
  - multiple use driver
  - data display and analytics
- Current technology drives patients to hospitals ⇒ market opportunity in clinics and private practice
- Reimbursement for practices higher than costs to implement



# Go-to-market plan



# Competitive landscape

Technology	Short learning	Easy set-up	Predictable results	Cost effective	Office-oriented
Physical therapy					✓
Manual percutaneous technique		✓		✓	✓
Biological therapeutics	✓				✓
Tenex Health TX™1 MicroTip	✓		✓		
HydroCision TenJet	✓		✓		
 TendoNova™	✓	✓	✓	✓	✓

# Leadership team

## LEADERSHIP



**Roy Wallen, CEO**

- Over 30 years of medical device experience
- Multiple, successful product launches
- Founder of Directional Healthcare Advisors



**Lou Malice, Chair**

- Over 30 years of medical device experience
- CEO, NFANT Labs
- Board Member, Intent Solutions, LLC
- Georgia Tech, INSEAD

## CO-FOUNDERS & MANAGEMENT



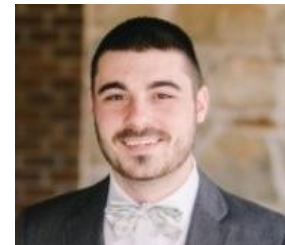
**Shawna Khouri**  
Business Management



**Jonathan Shaw, DPT, OCS**  
Clinical and Market Management



**Luka Grujic**  
Product Management



**Brett Rogers**  
Engineering and Operations  
Management

## MEDICAL ADVISORS



**Kenneth Mautner, MD**

- Assist Prof Orthopaedics, Emory Univ.
- Director, Sports Medicine Physical Medicine & Rehabilitation Fellowship



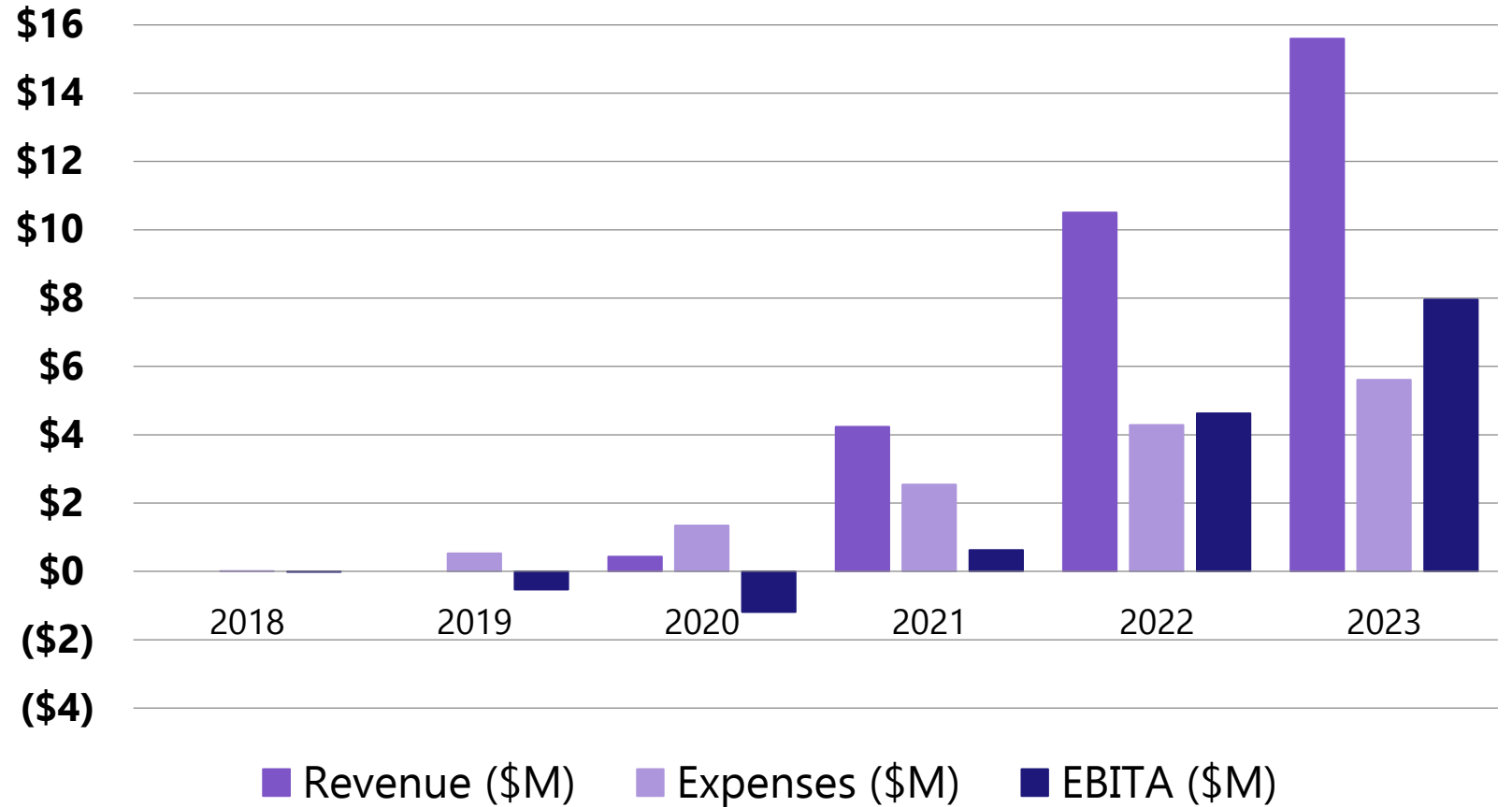
**Gerard Malanga, MD**

- New Jersey Sports Medicine
- New Jersey Regenerative Institute



# Revenue plan

- Gross Margin: 75%
- EBITA average: 40%
- Cash-flow positive in 2021
- Drivers
  - Leverage KOLs
  - Specialized sales
  - White paper
  - Peer-reviewed literature



# Key product milestones

- ✓ Substantial product development progress
  - Proof of concept demonstrated
  - Multiple design iterations complete
  - Beta prototype completed
- ✓ Strong Intellectual Property Portfolio
- ✓ Company formed as Delaware C-corp, Georgia registration, other registration pending
- ✓ Established medical advisory board
- Development execution (\$1.3 million)
  - Final design (MVP), verification, validation, documentation
  - Regulatory clearance to market
  - Pilot-scale manufacturing, market launch



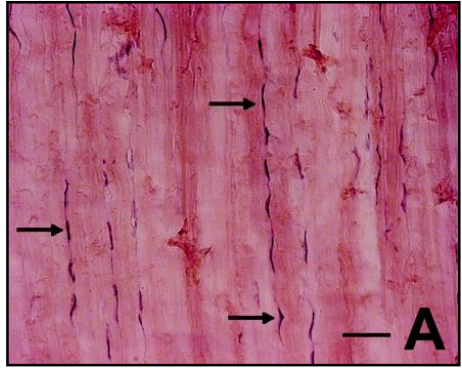
# Appendix



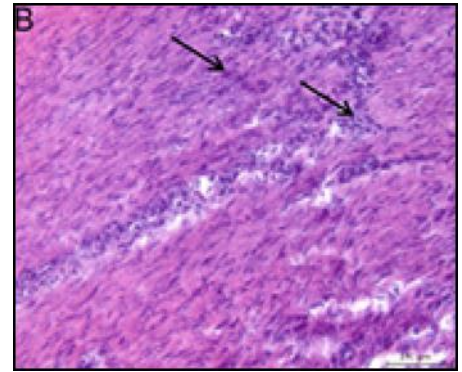
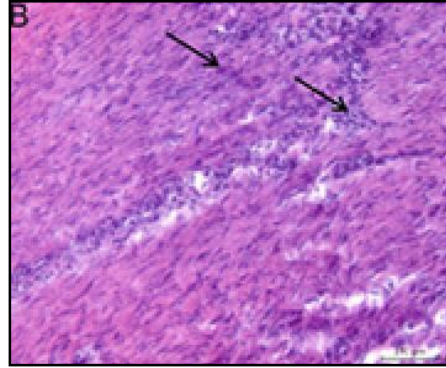
Roy Wallen, CEO  
roy.wallen@tendonova.com  
+1 760 415 3166  
tendonova.com

# Tendinopathy: an injury that failed to heal

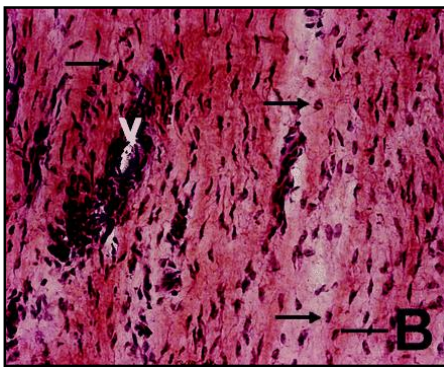
1. Healthy Tendon



2. Acute Injury



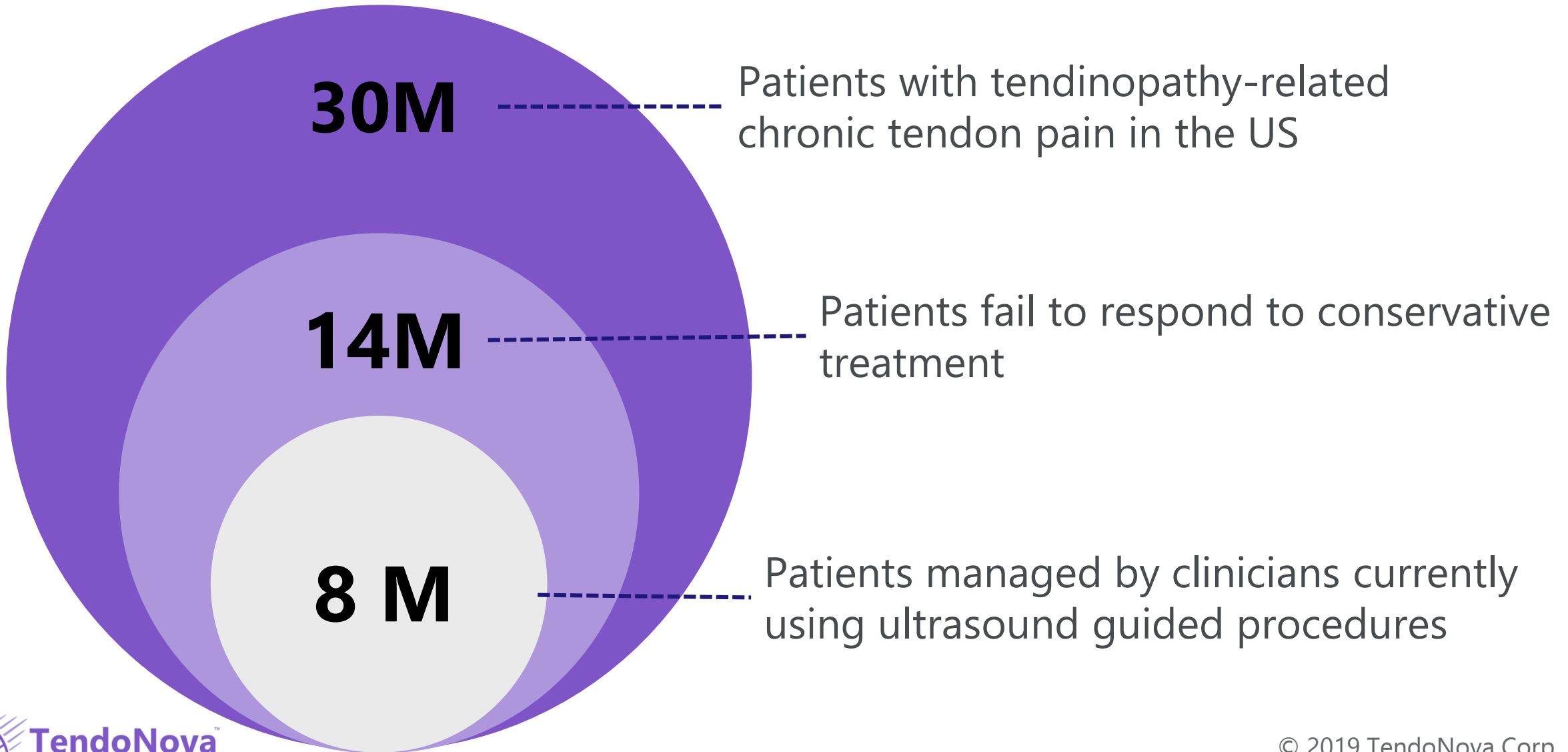
4. Controlled injury



3. Chronic Injury

1. Normal healthy tendon resembles a rope with well organized fibers ensuring strength
2. Newly injured tissue contains inflammatory components that *facilitate* healing
3. Interruption of the healing cycle through repeated reinjury leads to living tissue in a static state
  - Nerves and arteries are present and result in persistent pain
  - Fibers become linked making natural breakdown unlikely
4. Controlled physical disruption of the pathologic tendon allows the healing cycle to restart and healthy tendon remodeling

# Tendinopathy: Large unmet need and a sizable market opportunity



# Established treatment methodology:

## Mechanical disruption of soft tissue promotes new healing

### THE TREATMENT OF "TENNIS ELBOW."

BY

G. PERCIVAL MILLS, F.R.C.S.,

SURGEON, ROYAL ORTHOPAEDIC AND SPINAL HOSPITAL, BIRMINGHAM.

THERE is probably nothing which brings the surgical profession into greater discredit at the present time than its inability to cure a "tennis elbow" extremely common, and so helpless a treatment that most sufferers now resort to a medical man at all. For a long time I have been gravely considering what may be done in this condition the osteopaths and manipulators have been curing the patients in hundreds. Let us neglect pathology and consider what can be done about it clinically.

In the first place it is almost confined to tennis players, golfers, and workers in certain trades which involve the

1928

- Benefits of mechanical intervention for tendinopathy reported in BJM

1980s

- Perioperative tendon scraping commonly adopted

2000s

- Rise of minimally invasive techniques for orthopedic procedures

Today

- Ultrasound-guided procedures gain traction in-office

# Current in-office treatment options for tendinopathy are ineffective and inconsistent



## Medication & Physical Therapy

The vast majority of patients with tendinopathy are referred to physical therapy

40-80% symptoms do not resolve



## Percutaneous Needle Tenotomy

A controlled re-injury using a standard syringe needle to restart the healing cycle

Procedure endpoint is determined by tactile feedback resulting in a long learning process

Minimally invasive, but inconsistent results



## Biologics

Highly variable outcomes

Clinician-dependent product formulation

Not currently reimbursed

# Next-generation orthopedic procedures will be in-office

---

## Bringing surgical-level care to the office



- Orthopedics has moved from open procedures to decreasing levels of invasiveness
- Ultrasound has become sufficiently inexpensive and sophisticated that many soft-tissue pathologies can be identified & targeted in-office
- Providers require specialized tools to perform these percutaneous procedures



# Strong Intellectual Property Portfolio

- Exclusive license in all fields
  - Emory University
  - Georgia Institute of Technology (GTRC)
- 2 patents pending (PCT)

(19) <b>United States</b>	(10) <b>Pub. No.: US 2017/0049468 A1</b>
(12) <b>Patent Application Publication</b>	(43) <b>Pub. Date: Feb. 23, 2017</b>
<b>Mautner et al.</b>	
<hr/>	
(54) <b>SYSTEMS AND METHODS FOR TISSUE TREATMENT</b>	<b>Publication Classification</b>
(71) Applicant: <b>Emory University</b> , Atlanta, GA (US)	(51) <b>Int. Cl.</b>
(72) Inventors: <b>Kenneth R. Mautner</b> , Atlanta, GA (US); <b>Luka Grujic</b> , Boston, MA (US); <b>Shawna M. Hagen</b> , Atlanta, GA (US); <b>Brett Rogers</b> , Macon, GA (US); <b>Jonathan Shaw</b> , Atlanta, GA (US)	<i>A61B 17/32</i> (2006.01)
	<i>A61B 17/34</i> (2006.01)
	<i>A61B 17/16</i> (2006.01)
	(52) <b>U.S. Cl.</b>
	CPC ..... <i>A61B 17/32002</i> (2013.01); <i>A61B 17/1624</i> (2013.01); <i>A61B 17/3478</i> (2013.01); <i>A61B 2017/00734</i> (2013.01)
(21) Appl. No.: <b>15/307,070</b>	(57) <b>ABSTRACT</b>
(22) PCT Filed: <b>Apr. 28, 2015</b>	Systems and methods are configured to treat a tissue by automatically linearly oscillating an instrument into a target site. A system may include a body having a length and configured to receive a portion of the instrument guide member having an exposed end and/or an instrument. The system may further include an actuator member disposed within the body and configured to linearly oscillate the
(86) PCT No.: <b>PCT/US2015/027909</b>	
§ 371 (c)(1), (2) Date: <b>Oct. 27, 2016</b>	

# Straightforward regulatory & reimbursement



## US regulatory

510(k) with well-established predicates

No clinical trial



## EU regulatory

ISO 13485

MDR 17/745



## Reimbursement

8 in-office codes at launch

Procedure margins \$146 to \$645

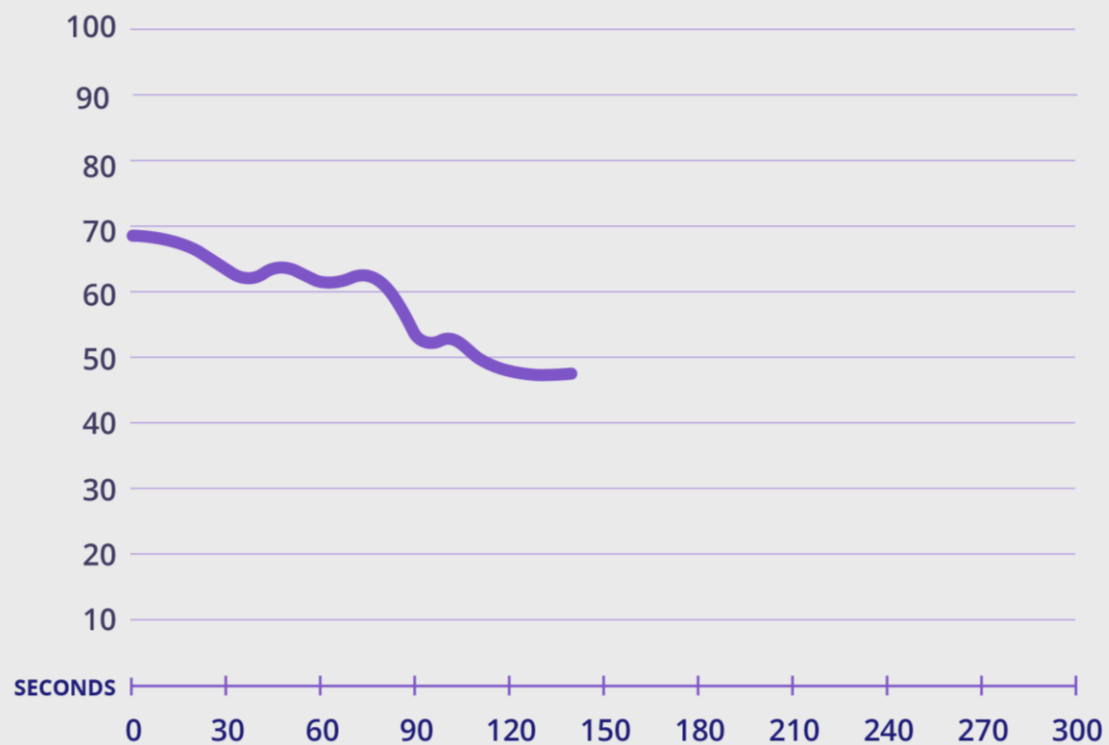


PATIENT ID #  
74361B

NAME  
Susan Parker-Smith

DOB Jan 23, 1994  
GENDER Female

## LOCATION Patellar Tendon



### TREATMENT INFORMATION

TOTAL TIME 2 MIN 28 SEC

INITIAL VARIANCE 68.3%

FINAL VARIANCE 49.3%

VARIANCE **19%**



END TREATMENT

# Investment

## Convertible debt note

- Conversion Price at 80%
- 5% interest
- 2-year maturity
- \$5 million valuation cap

## Use of funds

- Final product development & design for manufacturing
- Regulatory strategy and execution
- Validation testing
- Patent portfolio expansion
- Pilot manufacturing
- Market launch

ROY WALLEN

CEO

ROY.WALLEN@TENDONOVA.COM

+1 760 415 3166