

# Sacral Neuromodulation, **RECHARGED**



**November 2020**  
(Nasdaq: AXNX)

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To be the global leader in sacral neuromodulation by providing customer-centric solutions to treat **urinary and bowel dysfunction** and improve the quality of life for patients and their families



**Clarity of Purpose**



**Thoughtful Innovation**



**Integrity and Quality**

# Axonics Overview



## Large and Significantly Underpenetrated Market

- The sacral neuromodulation (SNM) market is significantly underpenetrated
- Medtronic is the legacy player with estimated global sales of ~\$650 million in 2018
- Implanters expect to grow procedure volume by 15-20% annually, driven by innovation Axonics has brought to SNM

## Innovative Technology

- First rechargeable SNM system. Designed to last at least 15 years with a patient-friendly recharging experience
- Axonics implantable neurostimulator (INS) is 60% smaller than Medtronic's non-rechargeable InterStim II
- First full-body MRI compatible SNM system, with 1.5T and 3T labeling

## Strong Clinical Data

- Completed 24-month clinical data of 129-subject FDA pivotal study
- Completed 24-month clinical data of 51-subject European clinical study

## Regulatory Status and IP

- Currently have U.S. FDA approval for OAB, FI, and UR; additional regulatory approvals in Europe, Canada & Australia
- 25 wholly-owned, 29 licensed from AMF (54 total) issued or licensed U.S. patents covering miniaturization of generators, charging and communication

## Large Commercial Footprint

- U.S. commercial operations launched in November 2019; select E.U. markets and Canada launched in November 2018
- 185+ U.S. field team members; 8 field team members in E.U.

## Early Commercial Success

- Net revenue of \$35.2 million in 3Q20
- 600+ unique accounts (hospitals and ambulatory surgery centers) in the U.S. as of September 30, 2020
- Agreements in place with virtually all national and regional hospital systems in the United States

**Experienced senior management team with >140 years of combined experience in the medical technology industry**

# Strong Management Team with Decades of Medical Technology Experience



Raymond W. Cohen

Chief Executive Officer



Dan Dearen

President & CFO



Rinda Sama

Chief Operating Officer



Karen Noblett, M.D.

Chief Medical Officer



John Woock, Ph.D.

Chief Marketing Officer



Al Ford

Chief Commercial Officer

■ 35+ Years of Experience

■ 30+ Years of Experience

■ 15+ Years of Experience

■ 25 + Years of Clinical Experience

■ 10+ Years of Experience

■ 20+ Years of Experience

# Overactive Bladder and Fecal Incontinence: High Prevalence and Debilitating Impact on Quality of Life



## OAB and FI affect over 60 million adults in the US

### Overactive Bladder (OAB)

Sudden urge to urinate; may result in urinary urgency incontinence (UUI) and/or urinary frequency (UF)

- ❖ OAB affects over **40M adults** and FI affects over **20M adults** in the US<sup>1</sup> (some adults suffer from both UUI and FI)
- ❖ Only **half** of those with severe symptoms seek treatment<sup>2</sup>
- ❖ OAB and FI have a significant **negative impact** on **quality of life**, mental health, sleep, productivity, and social activities<sup>1,3</sup>

### Fecal Incontinence (FI)

Inability to control bowel function, including involuntary loss of solid or liquid feces

- ❖ **80%+** of patients prescribed medications **discontinue use** within 6 months based on unmet treatment expectations, adverse effects, and cost<sup>3</sup>
- ❖ SNM is **broadly reimbursed**<sup>4</sup> with a U.S. market size of \$575+ million

1. Coyne, et al., "The Prevalence of Lower Urinary Tract Symptoms (LUTS) in the USA, the UK and Sweden." BJUI, Nov 2008.  
2. Shaw, et al., "Barriers to Help Seeking in People with Urinary Symptoms." *Fam Pract*, Feb 2001.  
3. Reynolds, et al., "The Burden of Overactive Bladder on US Public Health." *Curr Bladder Dysfunct Rep*, Mar 2016.  
4. CMS National Coverage Determination (NCD) is established for Sacral Nerve Stimulation.

# Sacral Neuromodulation Overview

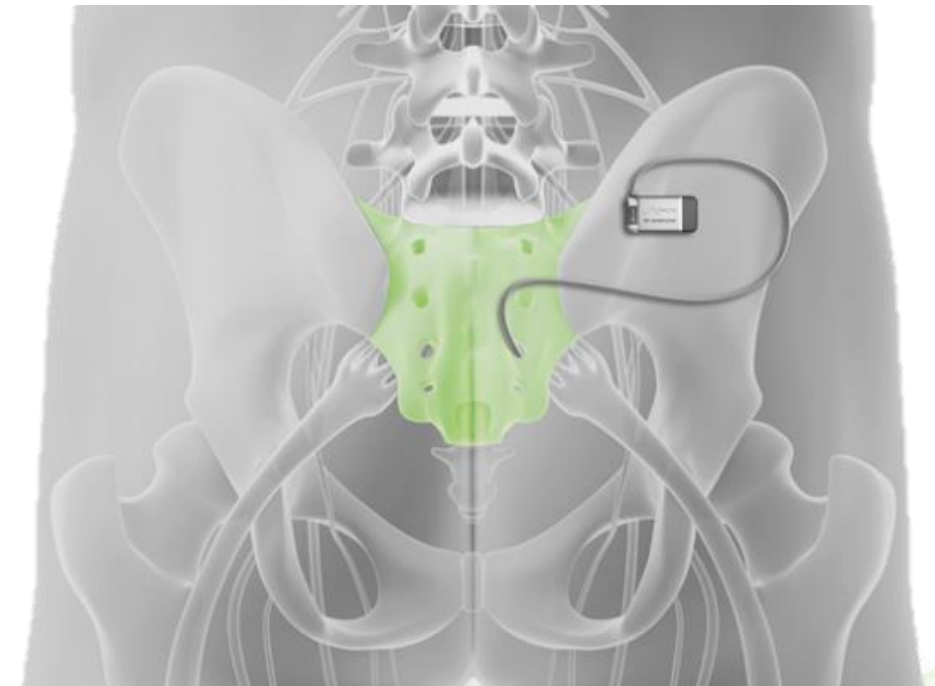
SNM therapy has been commercially available in the United States for **over 20 years** and has been **clinically proven** to provide a safe, effective, durable solution to OAB and FI

## Efficacy of SNM therapy:

- Mild electrical pulses targeting the sacral nerves restore normal communication between the brain and the bladder
- Therapy supported by a large compendium of peer-reviewed publications
- Hundreds of thousands of patients have been implanted worldwide

## Historic shortcomings of legacy SNM technology (Medtronic InterStim II):

- Surgically explanted and replaced every 3-5 years due to battery depletion
- Size of implanted device can result in pain and discomfort
- Patients have unfavorable experience using the therapy
  - Limitation with constant voltage
  - Complicated patient programmer
- Head-only MRI compatibility limited adoption and required explant for a full-body MRI scan



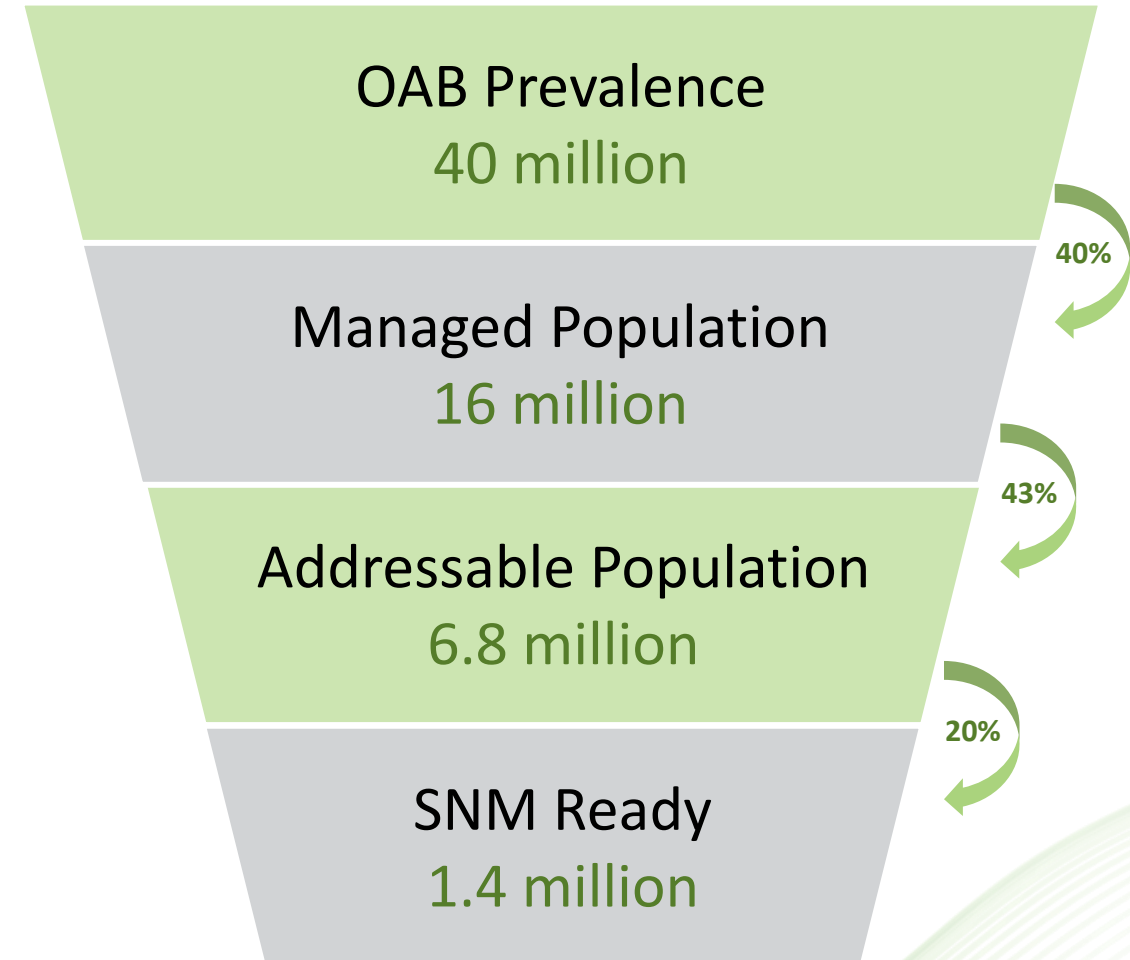
# Sacral Neuromodulation – U.S. Market Opportunity



## Significant Clinical Need, Low Penetration

- **OAB prevalence:** 40 million (16% or one in 6 adults) have symptoms of OAB
  - Only 40% of this group seeks medical attention (**managed population**) due to embarrassment, misconception that leaking is part of aging, etc.
- **Addressable population:** 6.8 million have underlying cause of OAB that is treatable with SNM
  - Over 90% of the addressable population are women
  - Over 3 million Americans are on second-line drug therapy and working their way through the care pathway
  - *Based on published literature, only 3-9% of second line patients have historically advanced to third line therapy*
    - Primarily due to lack of awareness of SNM therapy and drawbacks of third line therapies (Botox and InterStim)
- **SNM ready population:** 1.4 million are SNM eligible, representing a multibillion-dollar U.S. market opportunity.
  - *An additional ~5 million patients are either active in the care pathway or are currently "lost" (stopped taking meds and suffering in silence)*
  - *In 2019, there were approximately 40,000 SNM procedures in the United States, implying a penetration rate of ~1%*

## U.S. SNM Market Opportunity





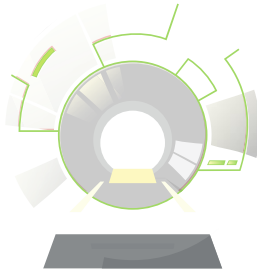
# Axonics r-SNM<sup>®</sup> System



**Approved in U.S., Europe,  
Canada and Australia**



**Rechargeable miniaturized INS  
with 15+ year life**



**Approved for full-body  
1.5/3.0T MRI scans**



**Simplified programmer,  
wireless charging system and  
easy-to-use remote control**

# Axonics Therapy is Long-lived and Fuss-free



Axonics is approved for 15+ year life in the body



\* Botox treats OAB only.

Axonics Therapy significantly reduces the need for frequent treatments or device replacement surgeries

(1) BOTOX injections are typically required every six months to maintain reduction of OAB symptoms.  
(2) Patients with the Interstim typically require replacement surgery every three to five years.

Botox<sup>®</sup> is a registered trademark of Allergan, Inc. All rights reserved.  
InterStim<sup>®</sup> is a registered trademark of Medtronic, Inc. All rights reserved.

# Axonics Therapy Has Significant and Distinct Advantages Compared to Legacy SNM Technology



**Titanium-ceramic INS construction allows for miniaturization and highly efficient charging with minimal heating**

- **Size:** 60% smaller and half the weight compared to InterStim II
- **Implant Life:** at least 15 years; 3-4x longer life than InterStim II
- **Constant Current Stimulation:** consistent and reliable therapy by adjusting output automatically
- **Modern, Convenient and Durable:** efficient and safe charging, wireless communication
- **Full-Body MRI Compatible**

# Patients Prefer the Axonics System Over InterStim II



Axonics surveyed 137 patients **being treated with Axonics Therapy** who had previously been implanted with a Medtronic InterStim II™ device. The survey asked patients about their experience with Axonics Therapy and **to make comparisons to their InterStim experience.**



**83% of patients would recommend Axonics Therapy to a friend, while only 5% would recommend the InterStim™ II System**

**Patients said the most beneficial features of their Axonics System are:**

**① Long Life (15 years)**

**② MRI Conditional Safety**

**③ Easy Remote Control**

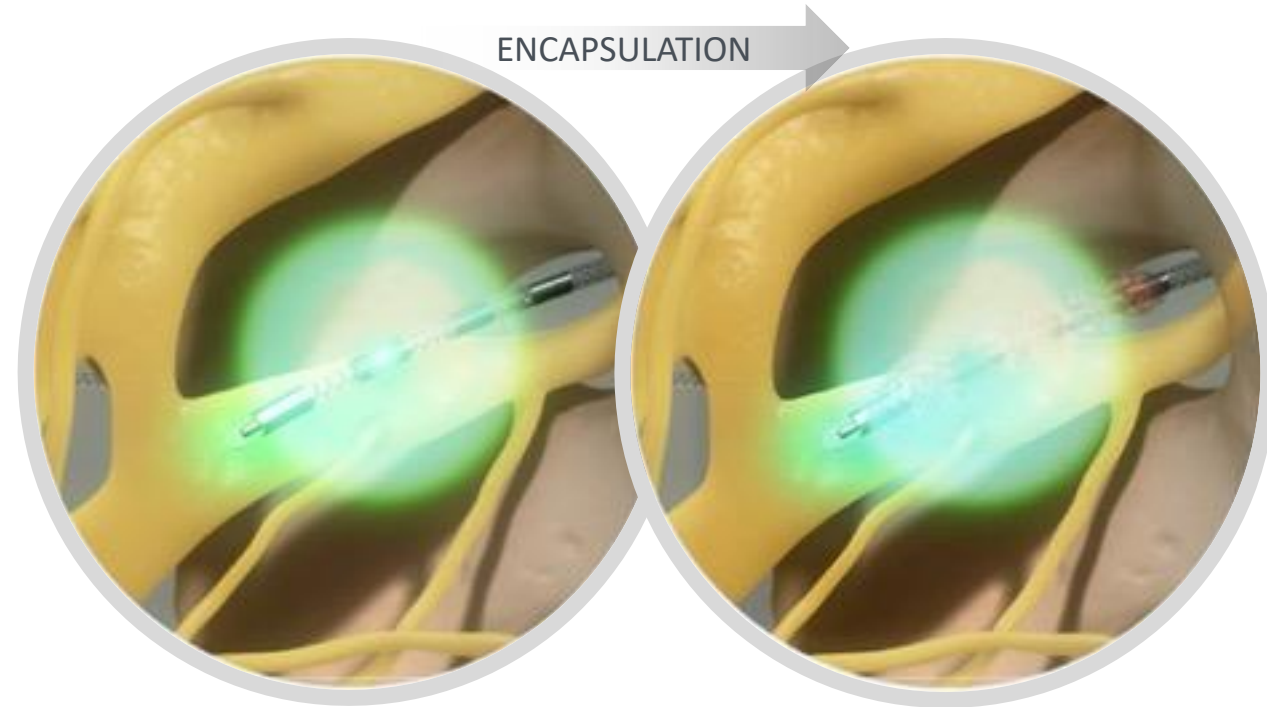


# Axonics Employs Constant Current Stimulation

Scar tissue encapsulates foreign objects placed in the body, which causes tissue impedance to increase and creates resistance to the flow of current. The legacy standard of care, InterStim II, employs constant voltage.

## CONSTANT CURRENT

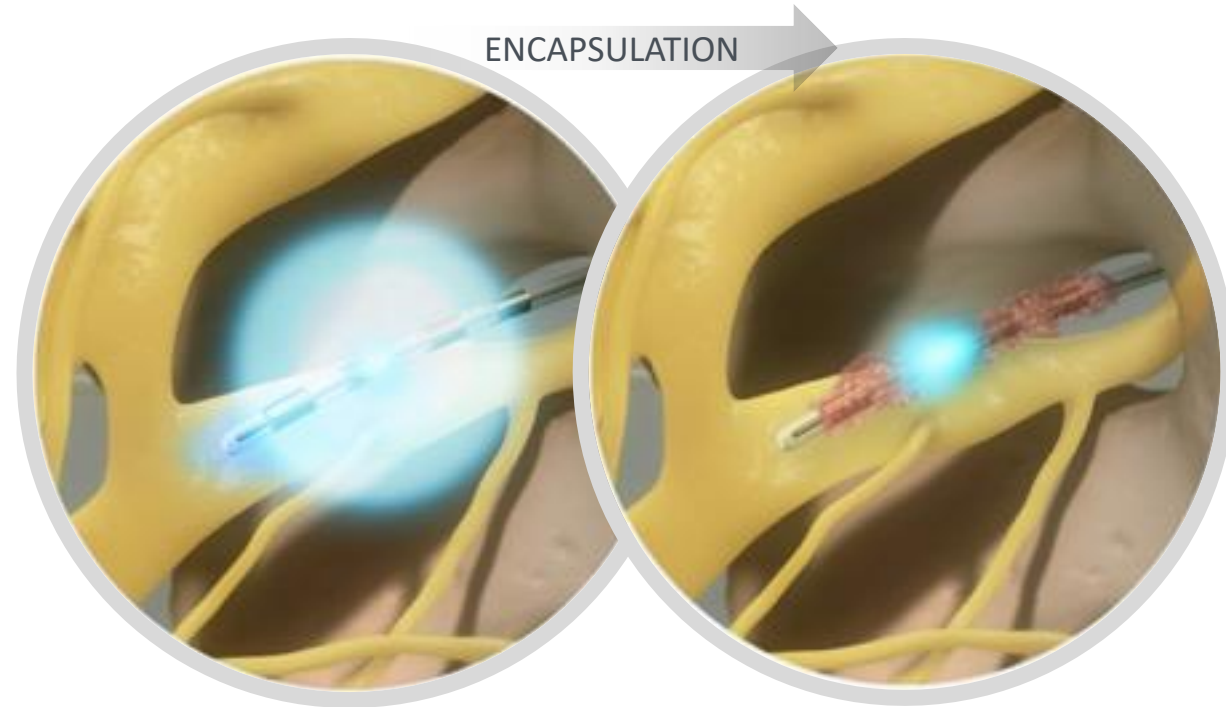
ENCAPSULATION →



Current delivery stays the same,  
providing more consistent therapy

## CONSTANT VOLTAGE

ENCAPSULATION →



Current delivery decreases resulting  
in smaller stimulation field

# Axonics System is Efficient and Easy to Recharge





**CHARGE ONCE  
A MONTH**



**ONE HOUR  
CHARGE TIME**

# Axonics Labeling Provides the Best MRI Conditions in Sacral Neuromodulation



MRI Conditions	 Axonics		 InterStim II and InterStim Micro	
	1.5T	3T	1.5T	3T
Full Body MR scanners				
B1+rms Limit (uT)	No Limit	1.7	3.0	1.3
SAR Limit (W/kg)	2.0	1.2	0.5	0.5
Allowed Scan Time / Wait Time	30 min / 5 min		30 min / 60 min	
Max Spatial Field Gradient (Gauss/cm)	2500		2000	
MRI Readiness/Eligibility Check	Uses Patient Remote Control		Uses Patient Programmer and Communicator	

MDT Source: MRI Guidelines for InterStim™ systems 97810 3058 3023 2020-07-15 (M980291A015 Rev A)  
AXNX Source: 110-0092-001rL MRI Guidelines Full Body United States

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# Overview of Axonics' Clinical Studies



## ARTISAN-SNM

## RELAX-OAB

### PURPOSE

To gain U.S. FDA approval

Post CE-Mark study

### POPULATION

- Urinary Urgency Incontinence
- 14 sites in U.S. and 5 in Western Europe

- Urinary Urgency Incontinence and Urinary Urgency Frequency
- 7 sites in Western Europe

### SIZE

- **129** subjects implanted

- **51** subjects implanted

### STATUS

- 6-month results published in *Journal of Urology*
- 1-year results published in *Neurourology and Urodynamics*<sup>1</sup>
- 2-year results submitted for publication

- 1-year results published in *Neurourology and Urodynamics*
- 2-year results published in the *Neurourology and Urodynamics*<sup>2</sup>

<sup>1</sup> Artisan 1Y manuscript : <https://onlinelibrary.wiley.com/doi/full/10.1002/nau.24376>

<sup>2</sup> Relax 2Y manuscript : <https://onlinelibrary.wiley.com/doi/10.1002/nau.24317>



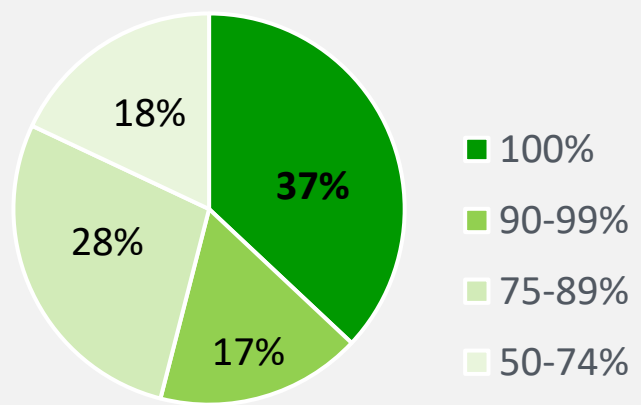
# ARTISAN-SNM: 2-year Responder Rate Highest Ever Reported in SNM Clinical Literature



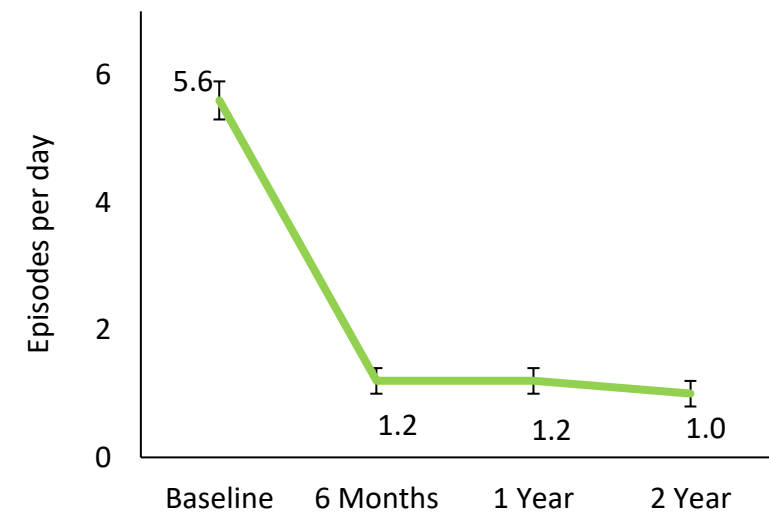
88%

of all implanted patients were therapy responders at 2-years post-implant

Magnitude of Urge Leak Reduction in Therapy Responders  
(% of subjects)



LEAKS



## Safety at 2-Years

- Strong safety profile
- No serious device-related adverse events
- No unanticipated adverse events

# Axonics System Has Significant Advantages Compared to Competitor's Rechargeable System





## THE AXONICS ADVANTAGE

<b>Implant Life</b>	15 years		15 years		Innovative SmartCase™ technology: the titanium-ceramic neurostimulator design enables safe and durable long-term performance <sup>1</sup>
<b>Stimulation Delivery</b>	Constant Current		Constant Current		<ul style="list-style-type: none"> <li>• A proven waveform: 89% therapy success at 1-year with limited need to adjust therapy</li> <li>• A simple patient Remote Control, leveraging the benefit of Constant Current stimulation</li> </ul>
<b>Full-Body MRI</b>	1.5	3T	1.5	3T	Driven by SmartMRI™ technology, the Axonics System was designed for an easy MRI experience – and was the first SNM System with 3T MRI
<b>MRI Conditions</b> B1+rms SAR Limit (W/kg) Wait Time (minutes)	3.0 0.5 60	1.3 0.5 60	No limit 2.0 5	1.7 1.2 5	Better parameters allow for better image quality, faster scans, and less wait time for patients
<b>Typical Recharging</b> Expected Interval Expected Duration	2 weeks 1 hour		1 Month 1 hour		<ul style="list-style-type: none"> <li>• Over double the recharge interval offering patients the most flexibility in recharging</li> <li>• Patients will save over 250 hours of charging time compared to Interstim Micro patients</li> <li>• Proven safe and satisfactory charging: 96% satisfaction at 1-year and 100% at 3-years</li> </ul>
<b>Programming Approach</b>	Provide patient default programming options; patient “finds” best program		Utilize programming algorithm to find best program; minimize patient burden		Proprietary algorithm based on intraoperative placement and responses simplifying the programming process for clinicians and patients
<b>Clinical Studies validating patient experience</b>	No studies completed		2 prospective studies with 2-year and 4-year results		Proven results backed by clinical evidence and patient satisfaction data

# Axonics Has Validated the Patient Experience With Strong Clinical Data (ARTISAN 2-year Data)



Clinical data on patient experience	 Axonics	 Medtronic InterStim™ Micro
Therapy success rate	93%	No clinical data
Patient satisfaction with therapy	94%	No clinical data
Patients would undergo therapy again	93%	No clinical data
Acceptability of charging experience	94%	No clinical data
Charging is “EASY”	91%	No clinical data

# Partnership and Support Are Critical to How Axonics Works with Customers

Axonics is committed to partnering with clinicians to advance patient care by providing support that includes:

- Expert clinical support
- Marketing materials to raise patient awareness
- End to end staff/patient education and training
- Patient Care Manager system to streamline and coordinate patient support



Axonics aims to empower clinical teams to help educate their community and to implement the most innovative technology in sacral neuromodulation therapy.



# Sales and Marketing Strategy

We have targeted the top 1,000 implanting centers – urologists, urogynecologists and colorectal surgeons that are trained and have experience performing SNM procedures

## *Marketing Strategy*

- Target high volume U.S. SNM implanters
  - ~90% of historical SNM sales are in the U.S.
  - ~80% of U.S. implant volume is generated by the top 1,000 implanting centers
- Promote broader awareness of SNM therapy with patients and providers
- Focus on building long-lasting physician relationships

## *Commercialization Strategy*

### United States

- Initial hiring and training completed in June 2019
- Highly trained commercial team with significant urology and/or neurostimulation experience
- Over 100 sales representatives and regional sales managers in U.S.
- Clinical support staff of ~100

### International

- Selectively pursue attractive ex-U.S. markets
- Canada, England, Germany, Netherlands, Norway and Switzerland
- Currently 6 sales reps and 2 clinical support staff in EU

# SNM Market is Poised to Double in 3-5 Years



## Key Drivers Accelerating SNM Market Growth

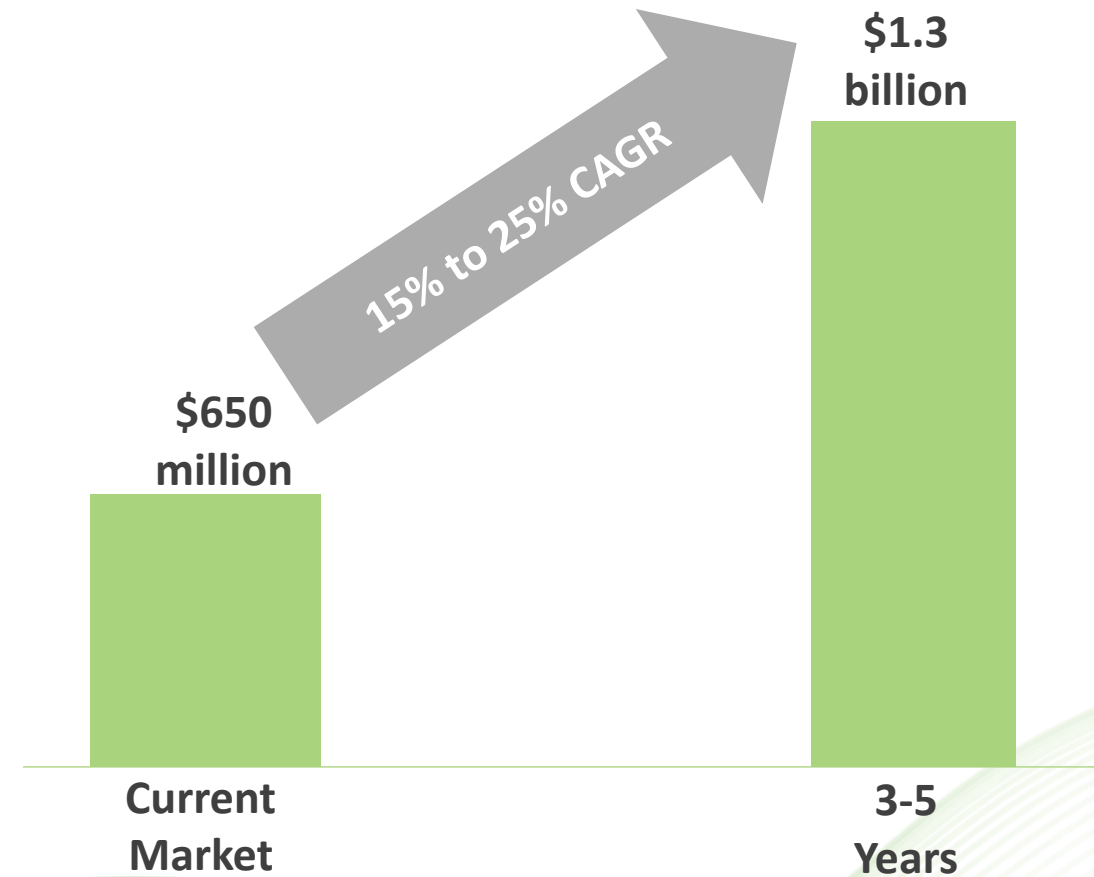
### Innovation by Axonics driving more patients to say “Yes” to SNM

- ✓ Long-lived device: 15+ year life is more attractive to patients
- ✓ Full-body MRI compatibility vs. InterStim II required device explant
- ✓ Higher efficacy and patient satisfaction rates than InterStim II
- ✓ Axonics device is 60% smaller than InterStim II
- ✓ Simple, easy to use patient accessories vs. fussy InterStim II
- ✓ Innovation driving market expansion – SCS analogue

### Increasing patient awareness

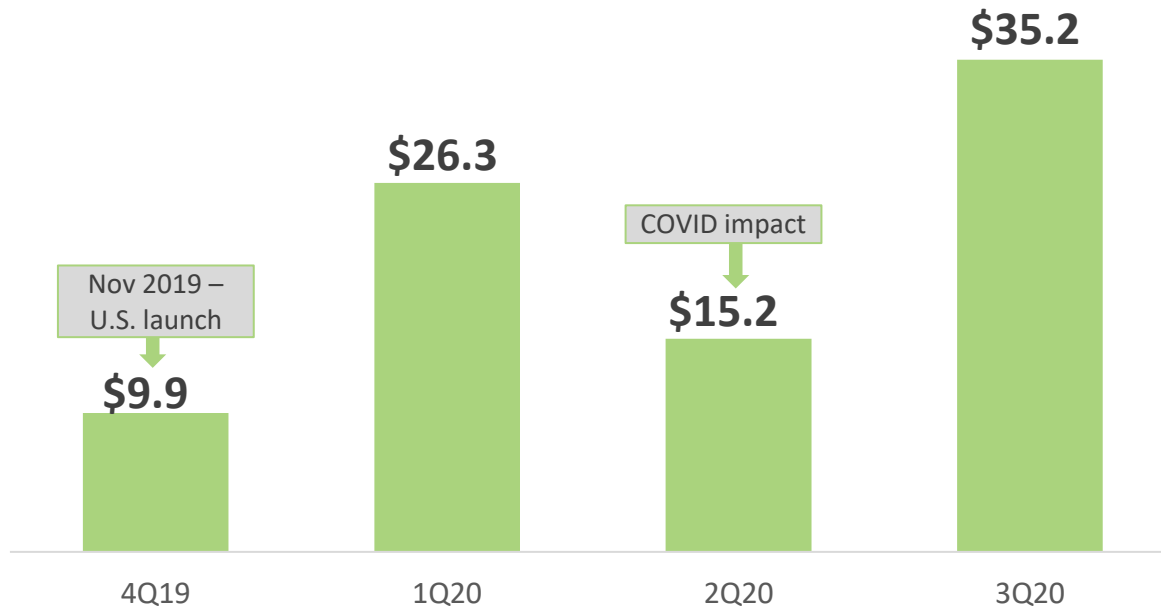
- ✓ SNM historically a “secret therapy” due to incumbent’s monopoly and lack of investment in patient awareness
- ✓ Axonics committed to raising awareness in partnership with implanting physicians
- ✓ Investing in direct to patient marketing programs to help educate patients about their condition and therapy options

## SNM Market Expansion



# Financial Overview

## Net Revenue



## Gross Margins and Balance Sheet

### Gross Margins

- 3Q20 gross margin: 61.9%
- Longer-term gross margin outlook: low to mid 70% range

### Balance Sheet

- 3Q20 net cash: \$249 million

# Product Development Pipeline



Next-generation implantable neurostimulator that extends the time between **recharging sessions to once a month** was approved by the FDA in April 2020.

**Began shipping to U.S. customers in August 2020.**

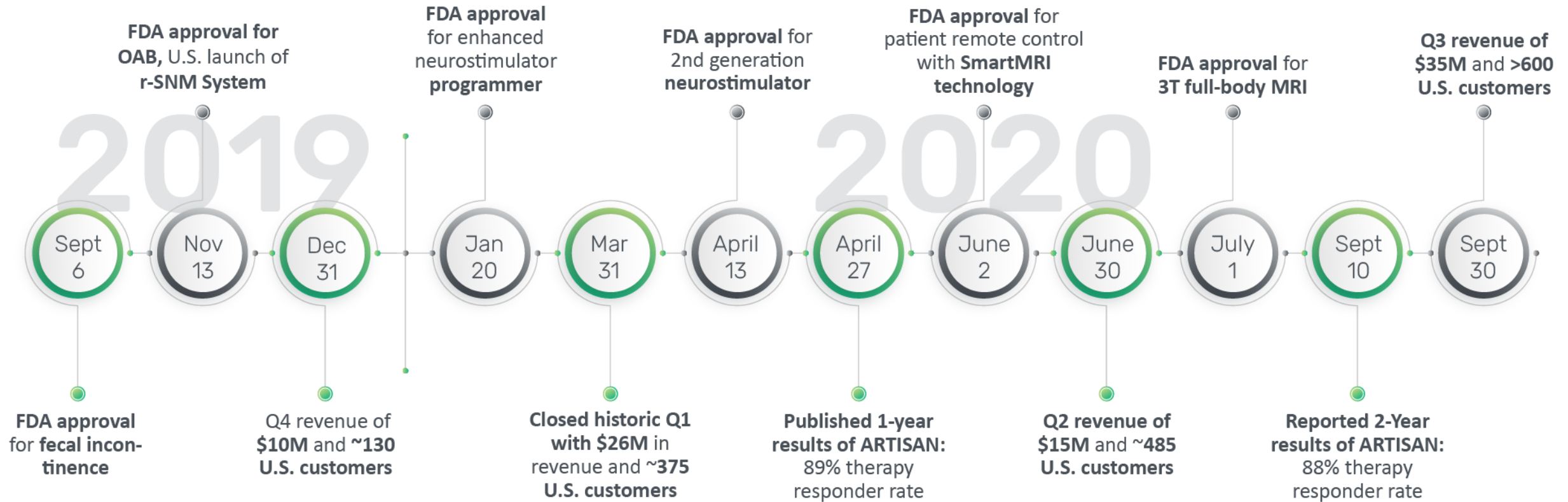
Developed a non-rechargeable device that utilizes a primary cell battery.

**Anticipated FDA filing in early 2021.**





# Key Regulatory and Business Milestones



# Axonics Investment Thesis



**SNM is highly underpenetrated and poised for significant market expansion**

**Long-lived innovative technology with high rates of physician and patient satisfaction**

**Exceptional clinical data with ~90% efficacy in FDA pivotal study**

**Strong commercial team with significant experience in urology and neurostimulation**

**Significant new customer acquisition driving attractive organic growth profile**