

Experience the Difference.  
**EXPERIENCE AXONICS.**



# Investor Presentation

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November 2023 | Nasdaq: AXNX



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This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation are forward-looking statements. Any statements contained in this presentation that are not statements of historical facts may be deemed to be forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, or other comparable terms intended to identify statements about the future. Forward-looking statements include, but are not limited to, statements about unanticipated safety concerns related to the use of our r-SNM System; FDA or other U.S. or foreign regulatory or legal actions or changes affecting us or our industry; intellectual property, product liability or other litigation against us, our third-party manufacturers or other parties on which we rely or litigation against our general industry; any termination or loss of intellectual property rights; any voluntary or regulatory mandated product recalls; adverse developments concerning our manufacturers or suppliers or any future strategic partnerships; introductions and announcements of new technologies by us, any commercialization partners or our competitors, and the timing of these introductions and announcements; announcements of regulatory approval or disapproval of our r-SNM and any future enhancements to our r-SNM System; adverse results from or delays in clinical studies of our r-SNM System; variations in our financial results or those of companies that are perceived to be similar to us; success or failure of competitive products or therapies in the SNM market; changes in the structure of healthcare payment of our r-SNM System; announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments; market conditions in the medical technology industry and issuance of securities analysts' reports or recommendations; rumors and market speculation involving us or other companies in our industry; sales of substantial amounts of our stock by directors, officers or significant stockholders, or the expectation that such sales might occur; general economic, industry and market conditions, including the size and growth, if any, of the market; the expected or potential impact of the novel coronavirus (COVID-19) pandemic, and the related responses of the government, consumers, and the Company, on our business, financial condition and results of operations; additions or departures of key personnel; changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; the results of any future legal proceedings; and the volatility of the trading price of our common stock. Other important factors that could cause actual results, performance or achievements to differ materially from those contemplated in this presentation can be found in Part I, Item 1. Business, "Part I, Item 1A. Risk Factors," and "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" our Annual Report on Form 10-K and "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Part II, Item 1A. Risk Factors" of our Quarterly Report on Form 10-Q, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov).

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# Axonics Vision and Philosophy



To be the global leader in providing customer-centric solutions to improve the quality of life for adults with urinary and bowel dysfunction



**Clarity of Purpose**



**Thoughtful Innovation**



**Integrity and Quality**

# Company Overview



## Large and Significantly Underpenetrated Market

- In the U.S., 28M women have moderate to severe urinary incontinence<sup>1</sup> and 19M adults have fecal incontinence<sup>2</sup>
- High unmet clinical need exists due to limitations of drugs and legacy SNM technology (low efficacy, short duration, etc.)
- Market poised to meaningfully expand, driven by AXNX's innovative therapies and increased patient awareness

## Complete Portfolio of Innovative Incontinence Solutions

- AXNX initially introduced a rechargeable SNM device. R20™ is small, long-lived (20+ years), MRI compatible – all market firsts
- Completed SNM portfolio with introduction of F15™, a recharge-free system that offers 15+ years of longevity in the body
- Bulkamid®: next-gen SUI bulking hydrogel clinically proven to retain its bulking characteristics/efficacy for up to 7 years

## Strong Clinical Data in FDA Pivotal Studies

- SNM: 93% therapy responder rate at 24 months; leaks reduced from 5.6 at baseline to 1.0 at 24 months<sup>3</sup>
- Bulkamid: 77% of women reported that their incontinence was either “dry, much improved or improved” at 12 months<sup>4</sup>
- Strong safety profile, with no unanticipated adverse events reported in either of the studies

## Significant Commercial Footprint

- U.S. commercial team is comprised of ~415 professionals (sales reps/managers and clinical/therapy/field marketing specialists)
- Committed to providing best-in-class clinician and patient support; team has extensive urology/neuromodulation experience
- Secured agreements with majority of national and regional hospital systems in the U.S.

## Attractive Financial Profile

- Revenue of \$112M in 2020, year 1 of U.S. commercial launch; revenue guidance for 2023 is \$362M
- Long-term gross margin profile in mid-70s; significant operating leverage inherent in business model
- Well capitalized, with >\$340M of cash; debt-free balance sheet; adjusted EBITDA positive in 2022 and YTD 09/30/23

1. Patel, Ushma J et al. “Updated Prevalence of Urinary Incontinence in Women.” *Female Pelvic Medicine & Reconstructive Surgery*. 2022 Jan.

2. Ditah, Ivo et al. “Prevalence, trends, and risk factors for fecal incontinence in United States adults.” *Clin Gastroenterol Hepatol*. 2014 Apr.

3. ARTISAN-SNM pivotal study 2-year clinical results: <https://onlinelibrary.wiley.com/doi/epdf/10.1002/nau.24615>

4. Sokol ER, Karram MM, Dmochowski R. “Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study.” *J Urol*. 2014 Sep;192(3):843-9

# Management Team



Raymond W. Cohen

Chief Executive Officer

- 40+ years of experience



Kari Keese

Chief Financial Officer

- 15+ years of experience



VESSIX VASCULAR



Rinda Sama

Chief Operating Officer

- 20+ years of experience



VESSIX VASCULAR



Karen Noblett, M.D.

Chief Medical Officer

- 30+ years of experience



John Woock, Ph.D.

EVP, Chief Marketing and Strategy Officer

- 15+ years of experience

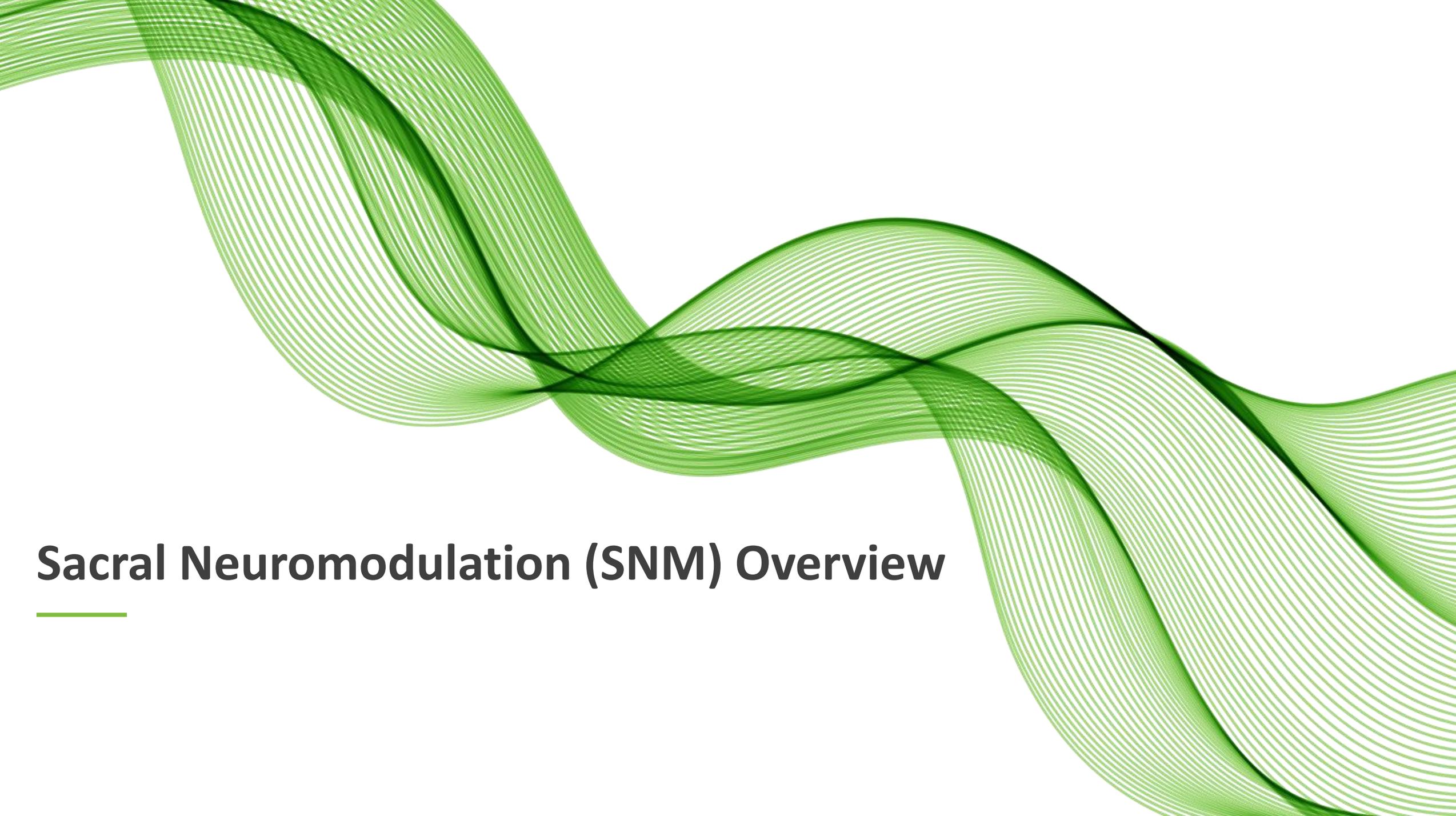


Al Ford

Chief Commercial Officer

- 30+ years of experience





# Sacral Neuromodulation (SNM) Overview



# Overactive Bladder and Bowel Dysfunction in Adults

*High prevalence with a debilitating impact on quality of life*

## Overactive Bladder (OAB)

Sudden urge to urinate without getting to the bathroom in time – results in urinary urge incontinence (UUI) and/or urinary frequency (UF)

## Fecal Incontinence (FI)

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

- 19 million women<sup>1</sup> in the U.S. have moderate to severe symptoms of urinary urge incontinence or mixed urinary incontinence (incontinence related to both urgency and stress)
- 19 million adults<sup>2</sup> in the U.S. have symptoms of fecal incontinence (some adults have dual incontinence, which is symptoms of both fecal incontinence and urinary urge incontinence)
- OAB and FI have a significant negative impact on quality of life, mental health, sleep, productivity, and social activities<sup>3</sup>
- 3 million adults in the U.S. are taking oral prescription medications for their OAB symptoms<sup>4</sup>
  - 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>5</sup> by government and private payors

1. Patel, Ushma J et al. "Updated Prevalence of Urinary Incontinence in Women." *Female Pelvic Medicine & Reconstructive Surgery*. 2022 Jan.
2. Ditah, Ivo et al. "Prevalence, trends, and risk factors for fecal incontinence in United States adults." *Clin Gastroenterol Hepatol*. 2014 Apr.
3. Reynolds, et al., "The Burden of Overactive Bladder on US Public Health." *Curr Bladder Dysfunct Rep*, Mar 2016.
4. IQVIA.
5. CMS National Coverage Determination (NCD) is established for sacral nerve stimulation.

# Sacral Neuromodulation Therapy

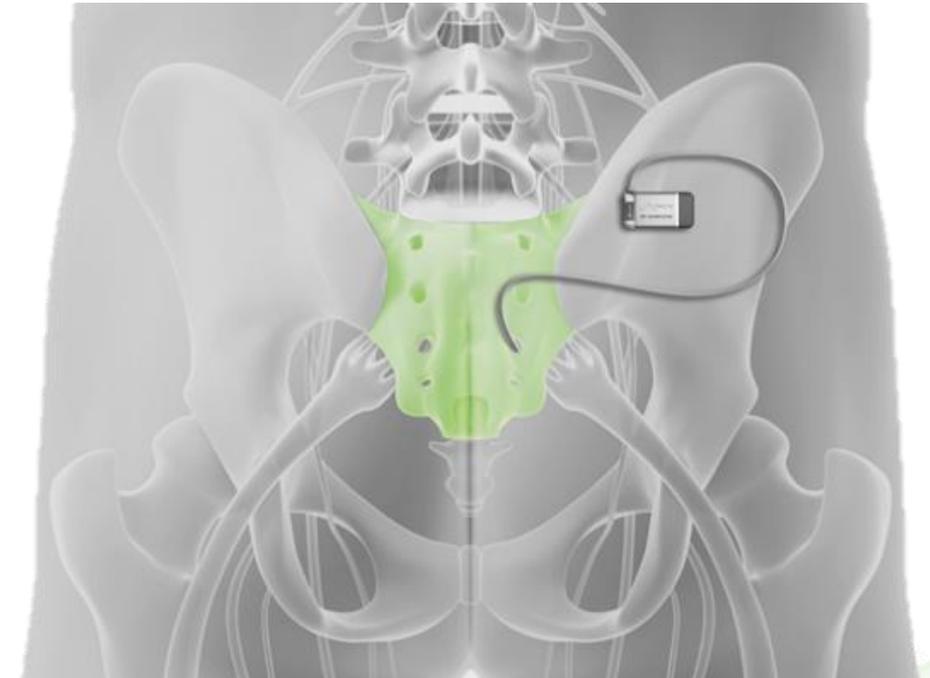
SNM therapy has been commercially available in the United States for **25 years** and has been **clinically proven** to provide a safe, effective, durable solution to OAB and FI

## 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®):

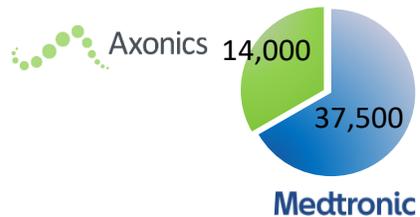
- Surgically explanted and replaced every 2-5 years due to battery depletion
- Size of implanted device can result in pain and discomfort
- Complicated patient programmer
- Explant required for a full-body MRI scan



# Axonics SNM – U.S. Market Opportunity

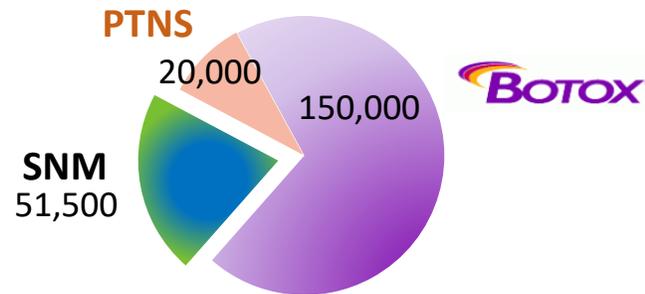


Adults implanted with SNM in 2022



Axonics SNM market share  
**27%**

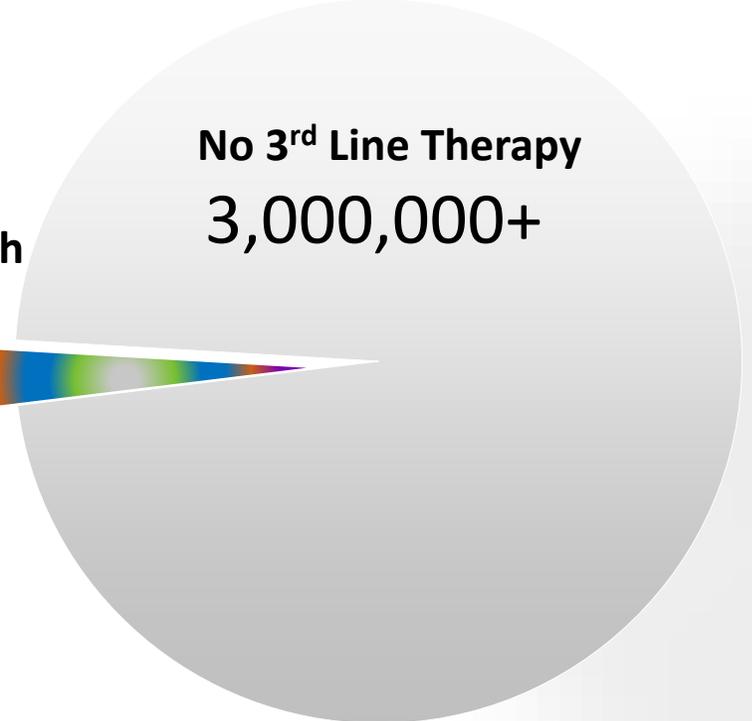
Adults treated with 3<sup>rd</sup> line therapy in 2022



SNM share of 3<sup>rd</sup> line therapy  
**23%**

Adults diagnosed with OAB by a physician in 2021

Adults treated with 3<sup>rd</sup> line therapy  
221,500



3<sup>rd</sup> line therapy market penetration  
**7%**

Source: Definitive Healthcare claims data and company estimates.

# SNM Market is Underpenetrated and Poised to Expand



## Key Drivers Accelerating SNM Market Growth

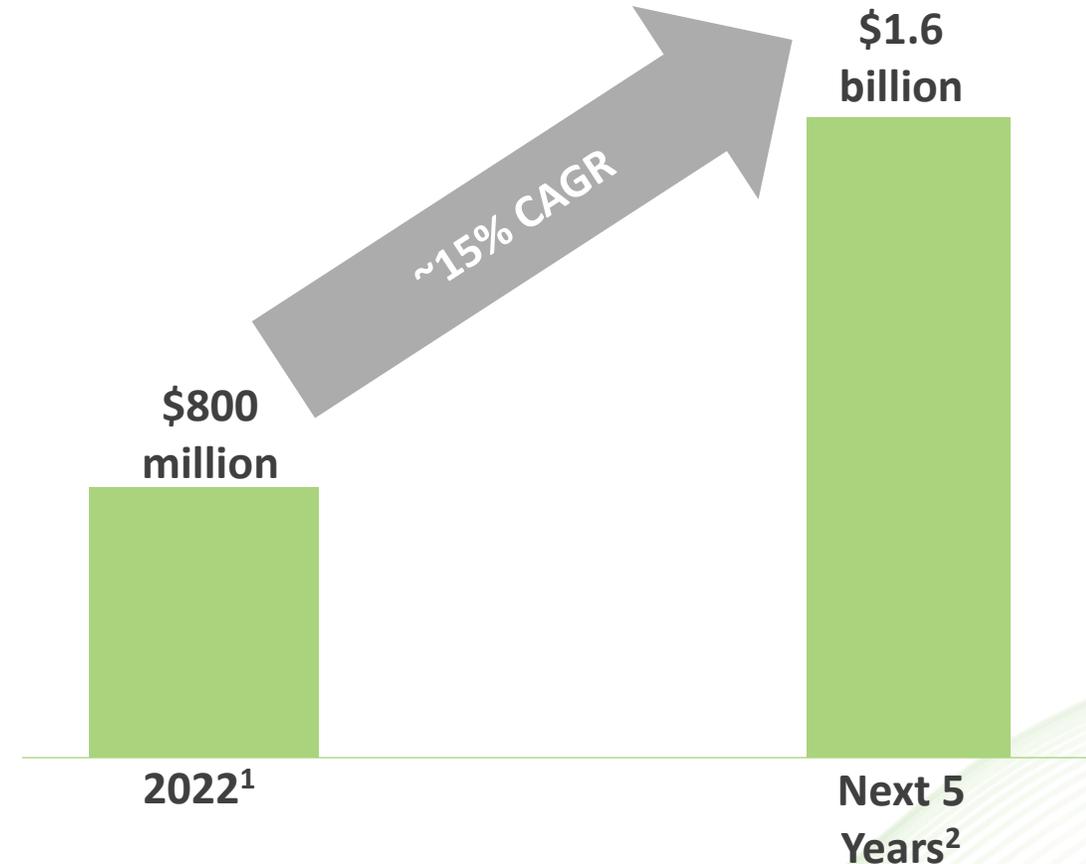
### Innovation by Axonics resulting in more patients saying “Yes” to SNM

- ✓ Long-lived miniaturized implants
- ✓ Full-body MRI compatibility
- ✓ Higher efficacy and patient satisfaction rates
- ✓ Simple, easy to use patient accessories
- ✓ Innovation driving increased physician confidence and enthusiasm

### 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



1. Based on claims data and Wall Street research.

2. This forward-looking statement is subject to a number of risks, uncertainties and assumptions. Please see disclaimer on slide 2 for more information.

# Axonics Introduced Several Market Firsts with the Launch of its Rechargeable SNM System

(first approved by FDA in Nov 2019; fourth-gen system, Axonics R20, was approved in Jan 2023)



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

- **Size of Implantable Neurostimulator (INS):** 60% smaller and half the weight vs. legacy technology (InterStim II®)
- **Implant Life:** 20+ years (4x the longevity of InterStim II®); requires recharging only once every 6-10 months for 1 hour
- **Constant Current Stimulation:** consistent and reliable therapy by adjusting output automatically
- **Full-Body MRI Compatible** with 1.5T and 3T scanners
- **Patient Remote Control:** intuitive, easy to use, and recharge-free

# Axonics F15 Recharge-Free System (FDA approval in March 2022)



*Completes Axonics portfolio of best-in-class SNM solutions*



## **Longest Lived Truly Recharge-Free SNM System**

- 15+ years of battery life
- Patients do not recharge *any* system components

## **The Smallest Recharge-Free System**

- 10cc in size
- Smaller and thinner than competitive device
- Smooth profile for patient comfort

## **Simple and Easy**

- Pocket-sized, intuitive patient remote control.
- Delivers constant current stimulation to reduce therapy adjustments

# Axonics Has Set a New Benchmark for Years of Longevity in the Body for Recharge-Free Neuromodulation Devices



Amplitude (mA)	0.10	0.50	1.00	1.3	1.50	2.00
<b>Axonics F15</b>	<b>25.0</b>	<b>22.4</b>	<b>17.6</b>	<b>14.9</b>	<b>12.1</b>	<b>8.9</b>
InterStim X™	<b>16.1</b>	<b>12.3</b>	<b>10.2</b>	-	<b>8.7</b>	<b>7.6</b>

Significantly longer life in the body than InterStim X™

\*Based on stimulation amplitude from ARTISAN-SNM patients.

Battery life from InterStim X™ System specifications Manual M988757A016 Rev B.

Default stimulation settings for both Axonics and Medtronic are shown at Frequency 14 Hz, Pulse Width 210 μs, single or double electrodes.

# Axonics is Committed to Continuous Innovation



Second-generation rechargeable INS extended the time between **recharging sessions to once a month** (from once every two weeks).

*Approved by the FDA in April 2020.*

Third-generation rechargeable INS provided patients the ability to make **broader stimulation parameter adjustments** at home.

*Approved by the FDA in February 2021.*

Fourth-generation rechargeable INS extended the time between **recharging sessions to just once every six months and increased device longevity to 20+ years.**

*Approved by the FDA in January 2023.*

Developed a **long-lived, recharge-free** INS that utilizes a primary cell battery.

*Approved by the FDA in March 2022.*



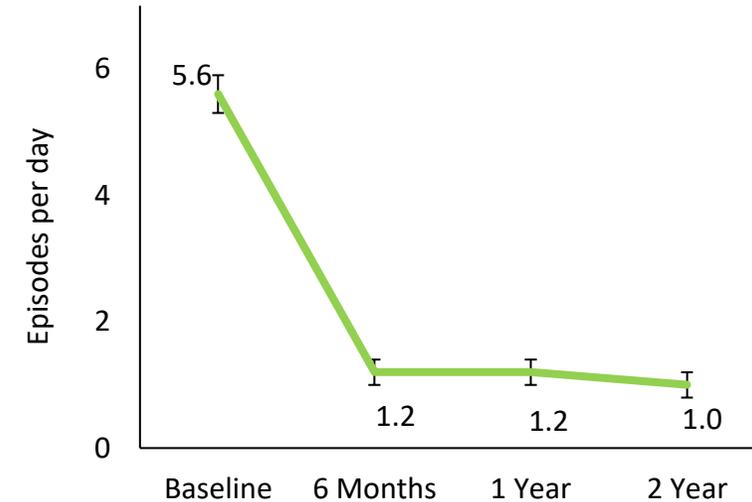
# Axonics PMA Study Had the Highest Therapy Responder Rate Ever Reported in Clinical Literature

**93%**  
therapy responders  
at 2-years post-implant

**82%**  
better than 75% improved



**LEAKS**



## Safety at 2-Years

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

# Published Clinical Data Has Validated Axonics Therapy's Efficacy and Patient Satisfaction



**Medtronic**  
InterStim Micro

**Medtronic**  
InterStim X

Clinical data on patient experience	2-year ARTISAN experience	No studies completed	No studies completed
Therapy success rate	93%	No data	No data
Patient satisfaction with therapy	94%	No data	No data
Patients would undergo therapy again	93%	No data	No data
Acceptability of charging experience	94%	No data	No data
Charging is "EASY"	91%	No data	No data



# Bulkamid Overview



# Stress Urinary Incontinence in Adult Women



## What is Stress Urinary Incontinence?

- SUI is the unintentional passing of urine during activity or exertion, such as during coughing, laughing, or exercise
- SUI is caused by a weakness of the pelvic floor muscles, preventing the urethra from closing fully when sudden pressure is put on the bladder
- SUI afflicts women of all ages, with childbirth as one of the main contributing factors
- 22 million women<sup>1</sup> in the U.S. have moderate to severe symptoms of SUI or mixed urinary incontinence (incontinence related to both stress and urgency)

BULKAMID®



Bulkamid is a best-in-class urethral bulking hydrogel

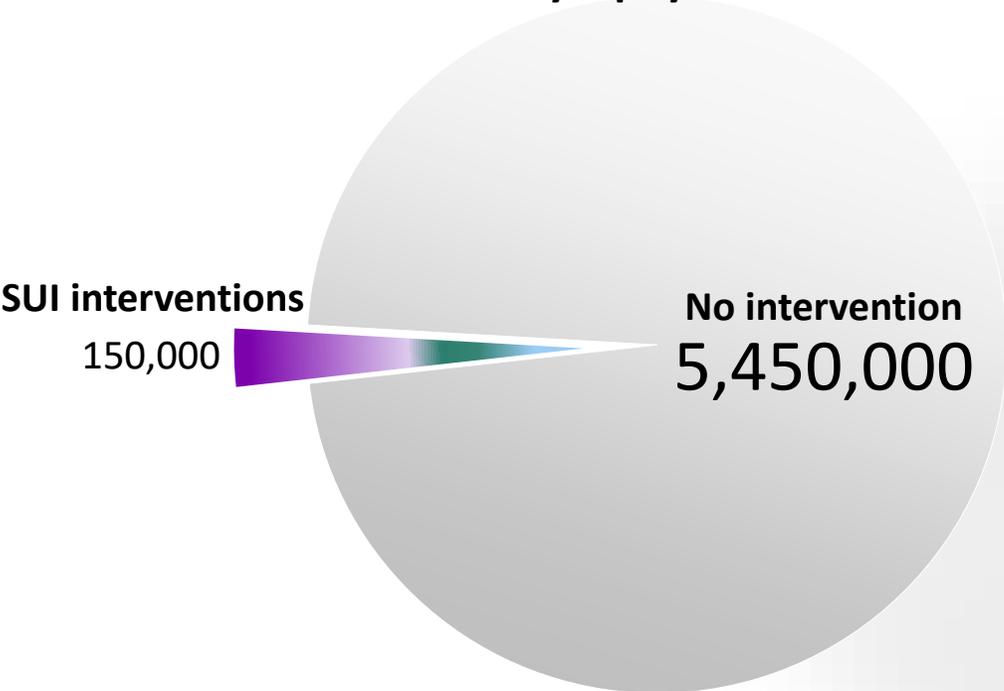
- ✓ Durable cushion volume and shape
- ✓ Biocompatibility – no immunogenicity
- ✓ Easy to inject – no migration or leakage<sup>2</sup>
- ✓ Provides durable SUI relief out to 7 years<sup>3</sup>
- ✓ Simple, fast, easy-to-learn and perform procedure
- ✓ Minimally invasive – performed in physician's office or outpatient facility

1. Patel, Ushma J et al. "Updated Prevalence of Urinary Incontinence in Women." Female Pelvic Medicine & Reconstructive Surgery. 2022 Jan.  
2. Christensen LH. Dermatol Surg. 2009.  
3. R. Appel, R. Dmochowski and S. Herschorn. BJU International. 2006.

# Bulkamid – U.S. Market Opportunity

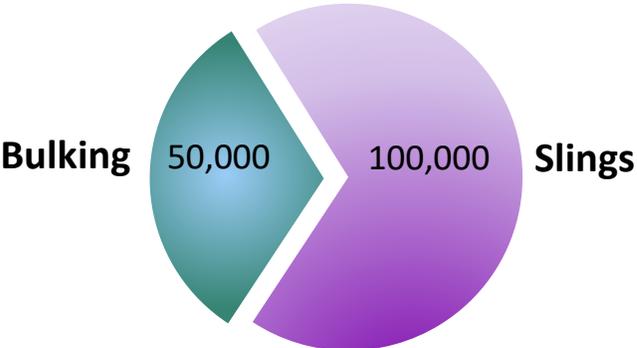


Women diagnosed with SUI by a physician in 2021



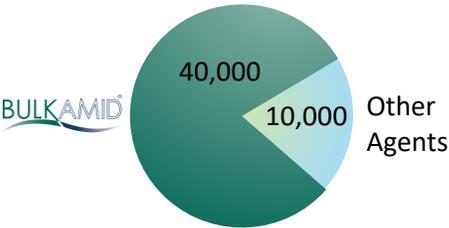
SUI intervention market penetration  
**3%**

Women treated with SUI intervention in 2022



SUI treatment market share  
**33%**

Women treated with bulking in 2022

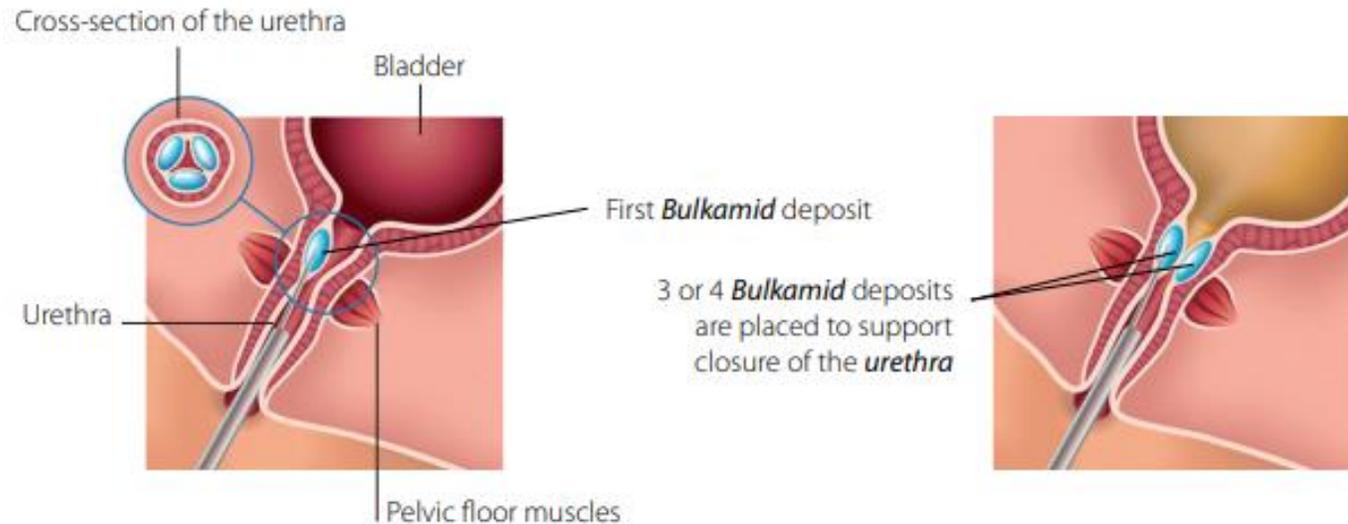


Bulkamid market share  
**80%**

Source: Definitive Healthcare claims data and company estimates.

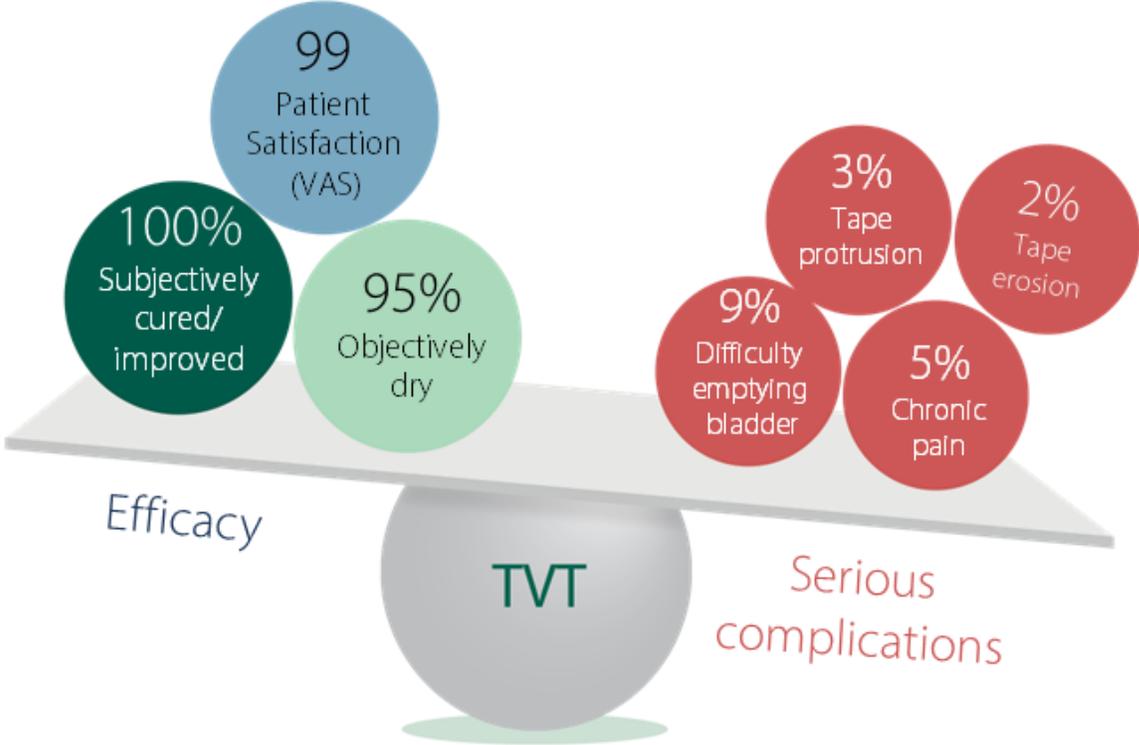
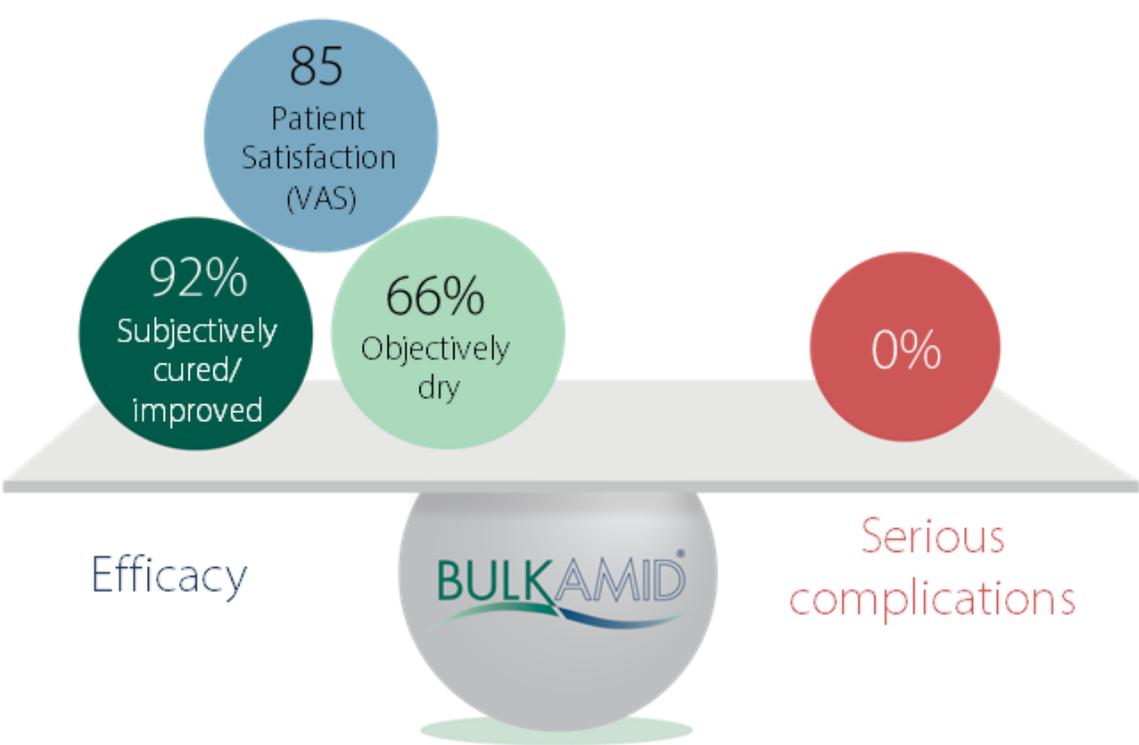
# Bulkamid Procedure Overview

- ❖ Bulkamid is injected into the soft tissue of the urethra and adds volume to support the closing mechanism of the urethra, preventing urine from leaking out unintentionally during normal daily activities.
  - ❖ The injections are made into 3-4 locations in the urethral wall; the total volume injected is 1.5-2.0 mL.
- ❖ Urethral bulking does not close the urethra totally; the urethra still opens normally to allow for urination.
- ❖ The procedure takes around 10-15 minutes and can be performed in a physician's office or outpatient facility under local anesthesia.



# RCT Results: Bulkamid vs. TVT (sling surgery)

In a randomized controlled trial of 224 women, Bulkamid demonstrated strong efficacy and patient satisfaction with no serious complications





# **Sales and Marketing Overview**



# Comprehensive Practice Support with Broad Geographic Coverage



Commercial team comprised  
of ~440 sales and  
clinical support professionals  
(~415 in U.S. and 25 in Europe/Australia)

# Axonics DTC Campaign



LEAD GENERATION

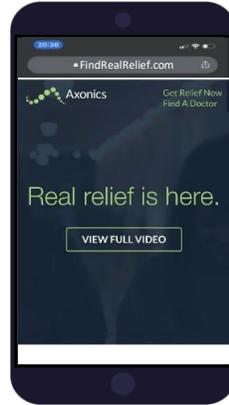
LEAD QUALIFYING

CONNECT & ACTIVATE

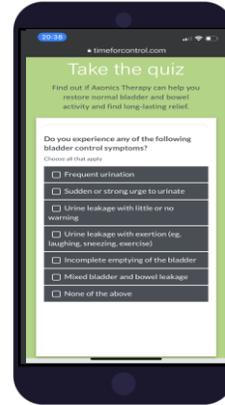
TV, YouTube, Radio



FindRealRelief.com  
Landing Page



Quiz  
Completion



Nurse Call



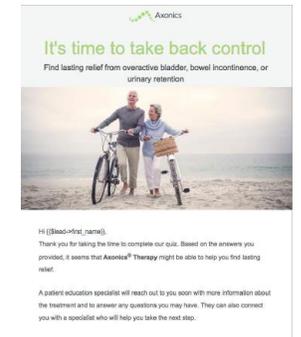
Referral to Provider



Facebook, SEO,  
Paid Search



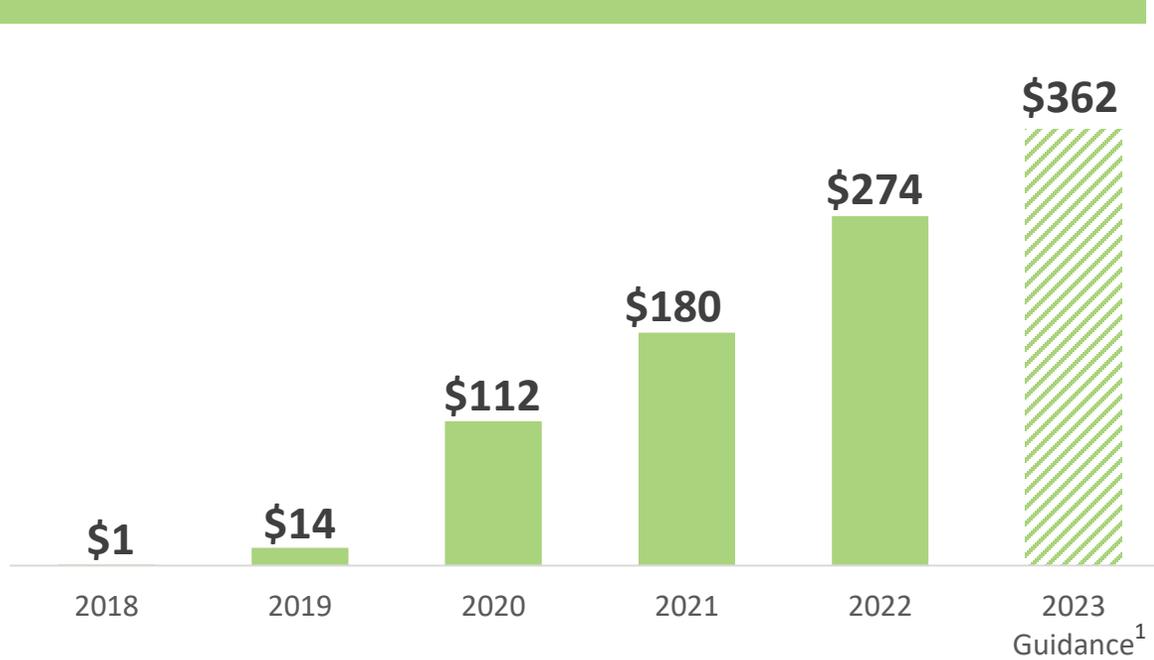
Nurturing



# Financial Overview



## Total Revenue (\$ in millions)



Y/Y growth	2021	2022	2023
	62%	52%	32%

## Revenue

- FY22 revenue of \$274 million (+52% y/y)
- FY23 revenue guidance<sup>1</sup> of \$362 million (+32% y/y)
  - SNM: \$288.5 million
  - Bulkamid: \$73.5 million

## Gross Margin

- FY22 gross margin of 72% vs. 64% in FY21
- YTD 09/30/23 gross margin of 74.7%

## Adjusted EBITDA

- YTD 09/30/23 adjusted EBITDA of \$33 million

## Balance Sheet

- Cash: \$345 million; debt-free

1. This forward-looking statement is subject to a number of risks, uncertainties and assumptions. Please see disclaimer on slide 2 for more information.

# Axonics Investment Thesis



Bladder/bowel incontinence market is large, underpenetrated and poised to expand

Axonics incontinence solutions generate high rates of patient and physician satisfaction

Best-in-class clinical data with demonstrated efficacy, durability, and safety

Commercial team with significant experience in urology and neuromodulation

Strong organic growth outlook with attractive margin profile