



Axonics® Expands into Stress Urinary Incontinence with the Acquisition of Bulkamid®

February 25, 2021

Combination creates a global leader for incontinence solutions

Acquisition of Bulkamid is expected to be immediately accretive to Axonics

IRVINE, Calif.--(BUSINESS WIRE)--Feb. 25, 2021-- Axonics Modulation Technologies, Inc. (Nasdaq: AXNX), a medical technology company that has developed and is commercializing novel implantable sacral neuromodulation (SNM) devices for the treatment of urinary and bowel dysfunction, today announced that it has acquired privately-held Contura Ltd. and its flagship product, Bulkamid, a best-in-class urethral bulking agent for women with stress urinary incontinence (SUI).

Axonics acquired London-based Contura Ltd. for total consideration of \$200 million in cash and stock, and a potential future milestone of \$35 million.

SUI is a large and highly underpenetrated market with a prevalence of an estimated 20 million women in the U.S. alone. It is a condition that afflicts women of all ages, with childbirth as one of the main contributing factors. SUI is caused by weakness in the pelvic floor, preventing the urethra from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities such as coughing, laughing, exercising or lifting an object.

Bulkamid is a next generation hydrogel that is injected into the urethral wall in a minimally invasive, office or outpatient facility procedure, to restore the natural closing pressure of the urethra. Bulkamid is clinically proven to retain its bulking characteristics and maintain efficacy for many years, providing women with long lasting relief of their SUI symptoms.

Bulkamid received CE Mark approval in 2003 and is a covered service from a reimbursement standpoint in most European countries. Sales in 2019 from international markets were approximately \$12 million.

The U.S. Food & Drug Administration approved Bulkamid in early 2020. The product was introduced mid-2020 in a limited rollout that resulted in gaining several dozen accounts and \$2 million in U.S. sales. Bulkamid is reimbursed by Medicare and commercial payors in the U.S.

Bulkamid is currently sold through a direct salesforce in the U.S., U.K., Germany, France, Nordic countries and in addition, through distributors in over 30 international markets around the world. In the United States, there are currently five sales professionals.

Raymond W. Cohen, CEO of Axonics, said, "This acquisition is highly synergistic, leverages our expansive commercial footprint and gives us the opportunity to expand our SNM business around the world. Axonics will provide urogynecologists and urologists with a complete suite of clinically differentiated incontinence solutions for their patients, thereby enhancing Axonics' value proposition to new and existing customers. Interestingly, in many cases, the patient seeking treatment presents with mixed incontinence, meaning with both SUI and urge urinary incontinence symptoms. Similar to SNM, we see the highly underpenetrated SUI market as poised for significant and durable growth in the years ahead, driven by outstanding clinical results and increased patient awareness."

Strategic Rationale

- **Leverages commercial footprint.** The acquisition of Bulkamid leverages Axonics' existing commercial footprint of over 220 sales and clinical specialists in the U.S. and Europe that call on urogynecologists and urologists. Axonics can now offer customers best-in-class solutions for patients with various types of overactive bladder and SUI.
- **Clinically differentiated SUI solution.** Bulkamid is a unique, next-generation bulking agent that we believe addresses the shortcomings of existing particulate-based bulking agents while also offering an alternative to patients who desire to avoid sling surgery and instead opt for a minimally invasive solution. Bulkamid has generated extensive clinical validation and a strong safety profile, with over 70,000 women treated to date.
- **Large, highly underpenetrated SUI market.** An estimated 20 million women suffer from SUI in the U.S. alone, though the majority of women are unaware of treatment options and have not sought treatment. While Bulkamid is still in the initial phase of commercial development in the U.S., we believe there is significant demand for the product.
- **Compelling financial profile.** The acquisition of Bulkamid is expected to be revenue growth, gross margin, and operating margin accretive to Axonics in 2021 and beyond.

Transaction Details

- Total upfront consideration is comprised of \$141,250,000 paid in cash and the issuance of 1,096,583 shares of Axonics stock.
- The upfront cash consideration is funded with a new \$75 million term loan from Silicon Valley Bank and existing cash on the balance sheet.
- The \$35 million milestone payment is subject to the achievement of \$50 million of Bulkamid sales in any consecutive

12-month period prior to December 31, 2024.

- Axonics entered into a manufacturing agreement for the supply of the Bulkamid hydrogel. Axonics has rights to a technology transfer after June 30, 2022 that would enable Axonics to insource the manufacturing of Bulkamid.

Webcast and Conference Call

Axonics will host a conference call today, February 25, 2021, at 4:30 p.m. Eastern Time, to discuss the acquisition and fourth quarter 2020 financial results. Prior to the start of the conference call, a slide presentation on the Bulkamid transaction will be posted on the conference call [webpage](#).

The live teleconference may be accessed by dialing 888-771-4371 (U.S.) or 847-585-4405 (International) and using passcode 50112306.

The live webcast of the conference call may be accessed by visiting the [Events & Presentations](#) section of the Axonics investor relations website. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Axonics website for 90 days.

About Axonics Modulation Technologies, Inc.

Based in Irvine, Calif, Axonics has developed and is commercializing novel implantable SNM devices for patients with urinary and bowel dysfunction, and through its acquisition of Bulkamid, offers solutions for patients with stress urinary incontinence. These conditions significantly impact quality of life. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, and another estimated 40 million adults are reported to suffer from fecal incontinence/accidental bowel leakage. Stress urinary incontinence affects an estimated 20 million women in the U.S. Axonics' clinically proven products are offered at hundreds of medical centers across the U.S. and abroad. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. For more information, visit www.axonics.com.

Forward-Looking Statements

Statements made in this press release that relate to future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. Words such as "planned," "expects," "believes," "anticipates," "designed," and similar words are intended to identify forward-looking statements. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including the risks and uncertainties disclosed in Axonics filings with the Securities and Exchange Commission, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Axonics undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

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