



Beta Bionics Announces FDA Clearance of Mint™, the Company's Transformative Patch Pump, and Unveils 3D Intelligence™ as its Next-Generation Insulin Dosing Algorithm

September 14, 2026

- *Mint features a new and innovative patch pump architecture*
- *Full Mint U.S. commercialization expected to begin in Q1 2027*
- *Manufacturing capacity expected to produce at least 1.5 million disposable Mint units during 2027*
- *3D Intelligence, the Company's next-generation insulin dosing algorithm, has been submitted to the FDA through a 510(k) application*
- *Expectations to commercialize 3D Intelligence in the U.S. by the end of 2026 as iLet 3D™, and at the time of full Mint launch as Mint 3D™, subject to regulatory clearance by the FDA*
- *Updated full year 2026 guidance*

IRVINE, Calif., Sept. 14, 2026 (GLOBE NEWSWIRE) -- Beta Bionics, Inc. (Nasdaq: BBNX), a pioneering leader in the development of advanced diabetes management solutions, today announced U.S. Food and Drug Administration (FDA) clearance of Mint, the Company's patch pump featuring a transformative reusable and disposable architecture that does not require recharging, integrates with industry-leading continuous glucose monitors (CGM) and enables smartphone control for iOS and Android users. Mint is expected to meaningfully expand the Company's addressable insulin delivery market, particularly among people with diabetes seeking a patch pump form factor.

Additionally, the Company is unveiling 3D Intelligence, its anticipated next-generation insulin dosing algorithm, which has been submitted to the FDA through a 510(k) application. 3D Intelligence is designed with three algorithm experiences intended to enable a more customizable treatment approach tailored to each user's unique insulin requirements.

Subject to regulatory clearance by the FDA, Mint 3D and iLet 3D will represent Beta Bionics' next-generation automated insulin delivery (AID) platforms, designed to maximize user choice through optionality in hardware and algorithm experience.

"We believe that our next-generation AID platform, consisting of Mint 3D and iLet 3D, will represent a transformational advancement for people living with diabetes, subject to regulatory clearance by the FDA," said Sean Saint, President & CEO of Beta Bionics. "Beta Bionics puts people with diabetes at the center of everything we do, and each element of Mint 3D and iLet 3D reflects that philosophy. Delivering choice is critical to the community we serve, and that is what Mint 3D and iLet 3D are intended to offer: the choice of wearing a patch pump or tubed pump along with an algorithm experience that is uniquely suited to each individual, all with a particular focus on improving affordability through our efforts to expand access for both iLet and Mint in the pharmacy channel."

Expectations for Full Launch of Mint in the United States

The Company expects to initiate the full commercial launch of Mint in the United States in the first quarter of 2027, ahead of its previous target, and anticipates manufacturing capacity to produce at least 1.5 million total disposable units in the full year 2027. The Company believes it may be able to exceed the 1.5 million unit target by accelerating staffing, improving efficiency through additional automation, and enhancing manufacturing yield.

Mint is expected to launch exclusively through the pharmacy channel, with approximately 40% of insured U.S. lives expected to be able to purchase it using their pharmacy benefit. The Company anticipates coverage for Mint to increase to at least 50% of insured U.S. lives within the first year of full commercialization as it leverages its market access footprint.

Mint 3D Features Expected at the Time of Full Launch in the United States*

- Transformative, two-piece reusable and disposable architecture
 - Smaller compared to the industry-leading patch pump
 - Seamless disposable patch change process with no phone re-pairing required
 - Firmware-over-the-air updates
 - Limits environmental waste
 - Three days of wear time, with an additional 12-hour grace period
 - 200-unit insulin reservoir

- Never requires recharging
- Waterproof with an IPX8 rating for up to 5 feet deep for 60 minutes
- Comprehensive software and digital integration
 - Powered by Beta Bionics' 3D Intelligence algorithm*
 - Compatible with industry-leading continuous glucose monitors: Dexcom G7, Dexcom G7 15 Day, and Abbott's FreeStyle Libre 3 Plus
 - iOS and Android smartphone controlled

*Commercialization of Mint 3D is subject to regulatory clearance. The device is currently investigational and not available for sale. Actual product specifications and features may vary.

3D Intelligence Features & Expectations for Launch in the United States*

3D Intelligence represents the next generation of Beta Bionics' fully adaptive automated insulin delivery technology. Building on the Company's experience with iLet and its real-world use across more than 40,000 users, 3D Intelligence is designed to give people with diabetes greater choice in how their insulin delivery algorithm responds to their individual needs.

3D Intelligence is designed to offer clinicians three selectable algorithm experiences that they can choose based on each patient's unique insulin needs.

- **Original** – the algorithm currently available with iLet, with proven real-world experience across more than 40,000 users.**
- **Optimized** – an enhanced experience that builds on the currently available algorithm and incorporates learnings from the Company's real-world experience with iLet.
- **Conservative** – an alternative experience designed to provide a more measured response when correcting high glucose levels.

Clinicians will be able to select the experience that best meets each user's individual needs. Together, these three experiences are intended to provide greater personalization while preserving the core simplicity and automation of the currently available iLet experience.

Subject to regulatory clearance by the FDA, the 3D Intelligence insulin dosing algorithm is expected to power both iLet 3D and Mint 3D. Commercialization of iLet 3D in the United States is expected by the end of 2026, and commercialization of Mint 3D in the United States is expected simultaneous with the full Mint launch in the first quarter of 2027, in each case, subject to regulatory clearance by the FDA.

*Commercialization of iLet 3D and Mint 3D is subject to regulatory clearance by the FDA. The devices are currently investigational and not available for sale. Actual product features may vary.

**Minor differences in adaptation compared to previous algorithm are not anticipated to have a significant impact on outcomes.

2026 Full Year Guidance & Key Considerations for 2027

For the full year 2026, the Company estimates total revenue of approximately \$121 million to \$126 million (previously \$131 million to \$136 million), reflecting a potential revenue deferral impact of up to \$10 million in the fourth quarter of 2026 as new prospective iLet users could choose to await the launch of Mint.

- During the full year 2027, the Company expects Mint to recapture any revenue lost in the fourth quarter of 2026.

For the full year 2026, the Company reiterates its expectations for 37% to 39% of new patient starts to be reimbursed through the pharmacy channel.

- For the full year 2027, the Company expects pharmacy coverage for iLet to increase year over year, while the percentage of iLet new patient starts reimbursed through the pharmacy channel is expected to decline year over year as more pharmacy-covered individuals adopt Mint.
- With the contribution from Mint, pharmacy channel revenue as a percentage of total revenue is expected to increase in 2027 relative to the prior year.

For the full year 2026, the Company reiterates its expectations for gross margin of 58.5% to 59.5%.

- The Company expects Mint to be modestly dilutive to full year 2027 gross margin, and highly accretive to the Company's long-term gross margin profile at scale.

About Beta Bionics

Beta Bionics, Inc. is a commercial-stage medical device company engaged in the design, development, and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring people with diabetes (PWD) by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease. Beta Bionics' proprietary insulin dosing algorithm is the first FDA-cleared algorithm that autonomously determines every insulin dose and offers the potential to substantially improve overall outcomes across broad populations of PWD. To learn more, visit www.betabionics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding: expectations of Beta Bionics, Inc. (the "Company") regarding the potential clearance by the FDA, including of 3D Intelligence, and the timing thereof; the implications and potential benefits of the FDA's clearance of Mint; the timing or certainty of full commercial launch of Mint, iLet 3D and Mint 3D in the United States and related updates; the Company's anticipated manufacturing timeline and capacity of production of Mint at commercial launch and during 2027; the implications and potential benefits of 3D Intelligence, iLet 3D, and Mint 3D for people with diabetes; the anticipated specifications and features of 3D Intelligence and Mint 3D; the anticipated coverage for Mint at commercial launch and within the first year of commercialization; and the Company's 2026 full year guidance and expectations for 2027 regarding estimates of revenue, including revenue deferral and revenue recapture, new patient starts reimbursed through the pharmacy channel, pharmacy channel coverage and gross margin. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "may," "goal," "potential" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the Company. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks and uncertainties, including business, regulatory, economic and competitive risks and uncertainties about the Company, risks inherent in developing product candidates, the Company's ability to obtain adequate financing to fund its product development and other expenses, the Company's ability to manufacture and scale production of its products and manage its supply chain, the Company's ability to obtain adequate reimbursement and payer coverage for its products, trends in the industry, the Company's relationships with its existing and future collaboration partners, the legal and regulatory framework for the industry, future expenditures and the potential impacts of global macroeconomic conditions. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The actual results may vary from the anticipated results and the variations may be material. Other factors that may cause the Company's actual results to differ from current expectations are discussed in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on February 24, 2026, as updated by its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the SEC on July 29, 2026, and other filings that Beta Bionics may make from time to time with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this press release is given. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Relations:

Blake Beber
Head of Investor Relations
ir@betabionics.com

Media and Public Relations:

Felicia Sanborn
Vice President of Marketing
media@betabionics.com

Source: Beta Bionics, Inc.