UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 27, 2026

Beta Bionics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-42491**	**47-5386878**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

11 Hughes
Irvine, California 92618
(Address of Principal Executive Offices) (Zip Code)

(949) 427-7785
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	BBNX	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On October 27, 2026, Beta Bionics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2026. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained under this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release, dated October 27, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Beta Bionics, Inc.

Date: October 27, 2026

By: /s/ Sean Saint
Sean Saint
President and Chief Executive Officer

EXHIBIT 99.1

Beta Bionics Announces Third Quarter 2026 Financial Results and Updates Full Year 2026 Guidance

IRVINE, Calif., Oct. 27, 2026 (GLOBE NEWSWIRE) -- Beta Bionics, Inc. (Nasdaq: BBNX), a pioneering leader in the development of advanced diabetes management solutions, today reported its financial results for the quarter ended September 30, 2026 and updated its full year guidance for the year ending December 31, 2026.

Third Quarter 2026 Financial Highlights & Key Metrics

- Net sales of $35.5 million, up 30% compared to $27.3 million in the third quarter of 2025.
  - Durable Medical Equipment (DME) channel net sales of $21.9 million, up 4% compared to $21.0 million in the third quarter of 2025.
  - Pharmacy Benefit Plan (PBP) channel net sales of $13.6 million, up 118% compared to $6.2 million in the third quarter of 2025.
- Gross margin of 57.3%, up 179 basis points compared to 55.5% in the third quarter of 2025.
- New patient starts increased by a mid-single digit percentage versus the second quarter of 2026.
  - 69% of new patient starts came from multiple daily injections (MDI).
  - High 30s percentage of new patient starts reimbursed through the PBP channel.
- Loss from operations of $26.6 million, or negative 75% of sales, compared to $17.0 million or negative 63% of sales in the third quarter of 2025.
- Net loss of $24.4 million, or negative 69% of sales, compared to $14.2 million or negative 52% of sales in the third quarter of 2025.
- Adjusted EBITDA[(1)] of negative $18.9 million, or negative 53% of sales, compared to negative $12.2 million or negative 45% of sales in the third quarter of 2025.
- $373.6 million in cash, cash equivalents, short and long-term investments as of September 30, 2026.

[(1)] See “Non-GAAP Financial Measures” below for additional information. A reconciliation of the non-GAAP financial measure to its most directly comparable GAAP financial measure can be found in Table D.

Recent Strategic Highlights

- Announced FDA clearance of Mint™ and expectations for full U.S. commercial launch of Mint in the first quarter of 2027, with anticipated manufacturing capacity to produce at least 1.5 million total disposable units in the full year 2027.
- Completed public offering of common stock, raising approximately $161.3 million in net proceeds to the Company.
- Unveiled 3D Intelligence™ as the Company’s next-generation insulin dosing algorithm.
  - Following recent interactions with the U.S. Food and Drug Administration (FDA), the Company has withdrawn its 510(k) application for 3D Intelligence.
  - Beta Bionics will provide, in a revised 510(k), additional simulator validation data. The company intends to submit this revised 510(k) in mid-Q4 2026.
  - The Company expects to commercialize 3D Intelligence in the United States as iLet 3D™ and Mint 3D™ in the first half of 2027, with the potential for an earlier launch in the fourth quarter of 2026, subject to regulatory clearance by the FDA.
- Completed enrollment for the U.S. pivotal trial studying the iLet in adults with type 2 diabetes.
  - Company reiterates expectations to expand iLet’s indications for use to adults with type 2 diabetes in the United States around mid-year 2027, subject to regulatory clearance by the FDA.
- In the fourth quarter of 2026, the Company intends to initiate a pivotal trial studying a next-generation fully-closed loop (FCL) algorithm in adults with type 1 and type 2 diabetes.
  - The FCL algorithm in development is characterized by the complete removal of a meal announcement feature, with the only required input being the user’s body weight at pump initialization.
- Announced agreement to integrate the iLet and Mint with Senseonics’ Eversense® 365 continuous glucose monitoring system.
  - Commercial launch of the integrated iLet and Eversense 365 system expected in the fourth quarter of 2026.

2026 Full Year Guidance

- Estimated total revenue of approximately $124 million to $126 million (previously $121 million to $126 million).
  - Revenue guidance reflects a potential revenue deferral impact of up to $8.5 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.
- Estimated 37% to 39% of new patient starts reimbursed through the PBP channel (no change versus previous guidance).
- Estimated gross margin of 58.5% to 59.5% (no change versus previous guidance).

Webcast & Conference Call Details

Beta Bionics will host a conference call and concurrent webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time), to review the company's third quarter 2026 performance. The link to the webcast will be available on the Company's website in the "Investors—Events & Presentations" section at https://investors.betabionics.com, and will be archived there for future replay. To access the live call by phone, please use the following link, which will provide you with dial-in details and a personal pin: https://register-conf.media-server.com/register/BIb765a5e68b554419b9df996402991220

Non-GAAP Financial Measures

Beta Bionics, Inc. (the "Company") prepares and presents the Company's financial statements in accordance with U.S. Generally Accepted Accounting Principles (GAAP). The Company believes adjusted EBITDA as a non-GAAP measure is useful in evaluating the Company's operating performance and uses adjusted EBITDA to evaluate ongoing operations and for internal planning and forecasting purposes. The Company believes that this non-GAAP financial measure, when taken together with the corresponding GAAP financial measures, provide meaningful supplemental information regarding the Company's performance by excluding certain items that may not be indicative of the Company's business, results of operations, or outlook. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in the Company's industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of the Company's non-GAAP financial measures as tools for comparison. A reconciliation is provided below for adjusted EBITDA to the most directly comparable financial measure stated in accordance with GAAP in Table D below.

The Company calculates adjusted EBITDA as net loss adjusted to exclude (i) depreciation expense, (ii) stock-based compensation expense, (iii) interest income, (iv) income tax expense, (v) change in fair value of warrant liabilities, (vi) litigation settlement and other related expense, and (vii) quality system remediation (previously labeled "Other non-recurring" in the Form 10-K for the year ended December 31, 2025), which relates to one-time remediation efforts in response to the FDA Form 483 and Warning Letter, including contractor support and various updates to the quality system.

Some of the limitations of adjusted EBITDA include: (i) adjusted EBITDA does not properly reflect capital commitments to be paid in the future and (ii) although depreciation and amortization expense are non-cash charges, the underlying assets may need to be replaced and adjusted EBITDA does not reflect these capital expenditures. The Company's adjusted EBITDA may not be comparable to similarly titled measures of other companies because they may not calculate adjusted EBITDA in the same manner as the Company calculates the measure, limiting its usefulness as a comparative measure. In evaluating adjusted EBITDA, you should be aware that in the future the Company will incur expenses similar to the adjustments in this presentation. The Company's presentation of adjusted EBITDA should not be construed as an inference that the Company's future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating the Company's performance, you should consider adjusted EBITDA alongside other financial performance measures, including the Company's net loss and other GAAP results.

Investors are encouraged to review the related GAAP financial measures and the reconciliation of this non-GAAP financial measure to its most directly comparable GAAP financial measure, and not to rely on any single financial measure to evaluate the Company's business. This non-GAAP measure has limitations as an analytical tool and should not be construed as an inference that the Company's future results will be unaffected by unusual or non-recurring items. Therefore, this non-GAAP financial measure should be considered in addition to, not as a substitute for, or in isolation from, measures prepared in accordance with GAAP.

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 its clinical and regulatory development plans for Mint, 3D Intelligence, iLet 3D, Mint 3D and the FCL algorithm in development; the potential regulatory clearance by the FDA of 3D Intelligence, iLet 3D, Mint 3D and the iLet in adults with type 2 diabetes, and the timing thereof; the timing or certainty of U.S. commercial launch of Mint, iLet 3D and Mint 3D; the

Company's anticipated manufacturing timeline and capacity of production of Mint at commercial launch and during 2027; the timing of submission of a new 510(k) application for 3D Intelligence; the design, results, and timing of its research and development efforts for the iLet in adults with type 2 diabetes and the FCL algorithm in development; expectations of the Company regarding the integration of iLet and Mint with the Eversense 365 system, and the timing or certainty of commercial launch of such integrated iLet; and the Company's anticipated growth and other measures of future operating results and financial performance, including 2026 full year guidance regarding estimates of revenue, including revenue deferral and revenue recapture, new patient starts reimbursed through the PBP channel 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, including, without limitation, risks inherent in developing product candidates, future results from the Company's ongoing and future studies and clinical trials, 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, risks that real-world data or future results may not be consistent with interim, initial or preliminary results or results from prior preclinical studies or clinical trials, 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 the section titled "Risk Factors" in the Company's 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 September 30, 2026, filed with the SEC on October 27, 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.

Beta Bionics, Inc.
Statements of Operations and Comprehensive Loss (unaudited)
Table A

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except number of shares and per share data)	**2026**	**2025**	**2026**	**2025**
Net sales	$ 35,505	$ 27,253	$ 95,144	$ 68,130
Cost of sales	15,174	12,134	39,474	31,537
Gross profit	**20,331**	**15,119**	**55,670**	**36,593**
Gross margin	57.3%	55.5%	58.5%	53.7%
Operating expenses:				
Research and development	11,975	8,195	32,571	24,658
Sales and marketing	25,124	16,045	70,499	45,070
General and administrative	9,841	7,922	29,058	22,422
Total operating expenses	46,940	32,162	132,128	92,150
Loss from operations	**(26,609)**	**(17,043)**	**(76,458)**	**(55,557)**
Other income (expense):				
Interest income	2,258	2,833	6,811	8,274
Other (expense) income, net	(2)	1	(4)	(1)
Change in fair value of warrant liabilities	—	—	—	(12,450)
Total other income (expense), net	2,256	2,834	6,807	(4,177)
Net loss	**$ (24,353)**	**$ (14,209)**	**$ (69,651)**	**$ (59,734)**
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term and long-term investments	(487)	205	(1,280)	289
Comprehensive loss	**$ (24,840)**	**$ (14,004)**	**$ (70,931)**	**$ (59,445)**
Net loss per share attributable to common stockholders, basic and diluted	**$ (0.52)**	**$ (0.33)**	**$ (1.54)**	**$ (1.52)**
Weighted-average common shares outstanding, basic and diluted	46,541,997	43,634,006	45,224,038	39,293,798

Beta Bionics, Inc.
Balance Sheets (unaudited)
Table B

(In thousands, except number of shares)	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 81,551	$ 31,576
Restricted cash, current	100	100
Short-term investments	158,653	187,549
Accounts receivable, net	20,667	17,118
Inventories, net	22,971	21,722
Prepaid expenses and other current assets	9,004	9,840
Total current assets	292,946	267,905
Property and equipment, net	11,764	8,600
Operating lease right-of-use asset	5,401	6,627
Long-term investments	133,436	45,431
Other long-term assets	212	180
Total assets	**$ 443,759**	**$ 328,743**
Liabilities & Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,682	$ 4,998
Accrued expenses and other current liabilities	24,656	22,431
Operating lease liabilities	1,452	1,938
Deferred revenue	2,046	1,557
Total current liabilities	32,836	30,924
Operating lease liabilities, net of current portion	4,649	5,365
Deferred revenue, net of current portion	3,480	3,297
Other long-term liabilities	1,411	1,547
Total liabilities	**42,376**	**41,133**
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value, 700,000,000 shares authorized; 54,362,972 and 44,360,873 issued and outstanding at September 30, 2026 and December 31, 2025, respectively	5	4
Additional paid-in capital	841,843	657,140
Accumulated other comprehensive income (loss)	(877)	403
Accumulated deficit	(439,588)	(369,937)
Total stockholders' equity	**401,383**	**287,610**
Total liabilities and stockholders' equity	**$ 443,759**	**$ 328,743**

Beta Bionics, Inc.
Net Sales by Channel (unaudited)
Table C

(In thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
DME channel:				
iLet[(1)]	$ 11,563	$ 14,175	$ 34,303	$ 37,217
Single-use products	10,334	6,840	24,930	16,269
Total DME channel	21,897	21,015	59,233	53,486
PBP channel:				
iLet[(1)]	(37)	148	649	859
Single-use products	13,645	6,090	35,262	13,785
Total PBP channel	13,608	6,238	35,911	14,644
Total net sales	**$ 35,505**	**$ 27,253**	**$ 95,144**	**$ 68,130**

[(1)]iLet includes the over-time recognition software updates and mobile app access.

Beta Bionics, Inc.
Reconciliation of GAAP versus Non-GAAP Financial Results (unaudited)
Table D

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	**2026**	**2025**	**2026**	**2025**
Net loss	**$ (24,353)**	**$ (14,209)**	**$ (69,651)**	**$ (59,734)**
Add:				
Depreciation expense	892	386	2,186	1,036
Stock-based compensation expense	6,715	4,478	19,137	12,081
Interest income	(2,258)	(2,833)	(6,811)	(8,274)
Income tax expense (benefit)	2	(1)	4	1
Litigation settlement and other related expense	66	—	201	200
Quality system remediation[(1)]	30	—	654	—
Change in fair value of warrant liabilities	—	—	—	12,450
Adjusted EBITDA	**$ (18,906)**	**$ (12,179)**	**$ (54,280)**	**$ (42,240)**

[(1)]Amounts presented reflect the same category of expenses previously labeled "Other non-recurring" in our Form 10-K for the year ended December 31, 2025. These expenses relate to our one-time remediation efforts in response to the FDA Form 483 and Warning Letter, including contractor support and the various updates to our quality system to meet FDA expectations.

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.