

**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): July 29, 2026

Beta Bionics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-42491

(Commission File Number)

47-5386878

(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 July 29, 2026, Beta Bionics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 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.

<u>Exhibit No.</u>	<u>Description</u>
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<u>99.1</u>	<u>Press Release, dated July 29, 2026.</u>
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: July 29, 2026

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

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

IRVINE, Calif., July 29, 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 June 30, 2026 and updated its full year guidance for the year ending December 31, 2026.

Second Quarter 2026 Financial Highlights & Key Metrics

- Net sales of \$32.0 million, up 38% compared to \$23.2 million in the second quarter of 2025.
 - Durable Medical Equipment (DME) channel net sales of \$20.4 million, up 9% compared to \$18.6 million in the second quarter of 2025.
 - Pharmacy Benefit Plan (PBP) channel net sales of \$11.6 million, up 153% compared to \$4.6 million in the second quarter of 2025.
- Gross margin of 59.0%, up 524 basis points compared to 53.8% in the second quarter of 2025.
- New patient starts increased by at least 10% but less than 20% sequentially versus the first 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 \$25.6 million, or negative 80% of sales, compared to \$19.9 million or negative 86% of sales in the second quarter of 2025.
- Net loss of \$23.4 million, or negative 73% of sales, compared to \$16.9 million or negative 73% of sales in the second quarter of 2025.
- Adjusted EBITDA⁽¹⁾ of negative \$17.7 million, or negative 55% of sales, compared to negative \$14.5 million or negative 63% of sales in the second quarter of 2025.
- \$225.2 million in cash, cash equivalents, short and long-term investments as of June 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

- In July, initiated enrollment for a pivotal trial studying the iLet in adults with type 2 diabetes in the U.S.
 - Beta Bionics expects to expand iLet’s indications for use to adults with type 2 diabetes in the U.S. around mid-year 2027, subject to regulatory clearance by the FDA.
- Announced updated expectations to fully commercialize Mint, Beta Bionics’ patch pump in development, by the end of the second quarter of 2027, subject to regulatory clearance by the U.S. Food and Drug Administration (FDA).
 - The company expects Mint manufacturing capacity to meet anticipated demand at full launch.
- Published a near real-time real-world data dashboard publicly available on the company’s website, setting a new standard for data transparency in the Automated Insulin Delivery category.
- In its most recent Phase 2a feasibility trial in New Zealand initiated in the first quarter of 2026 for the bihormonal system in development, the company identified opportunities to improve the glucagon asset’s excipient profile and the bihormonal dosing algorithm, with improvements expected to take less than one year prior to initiating additional feasibility trials.

2026 Full Year Guidance

- Estimated total revenue of approximately \$131 million to \$136 million (no change versus previous guidance).
- 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% (previously 57.5% to 59.5%).

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 second 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/BI3bd9f03fbd0f42bcb9f566c242240033>

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. The iLet Bionic Pancreas is the first FDA-cleared insulin delivery device 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 the iLet and other product candidates; the markets and market opportunities for the iLet, Mint, the bihormonal system and other product candidates, if approved; the timing, likelihood or success of its business strategy, including commercialization as well as plans and objectives of management for future operations; its anticipated growth and other measures of future operating results and financial performance, including 2026 full year guidance regarding estimates of revenue, new patient starts reimbursed through the PBP channel and gross margin; the design, results, and timing of its research and development efforts and planned trials for the iLet in adults with type 2 diabetes; the design, results and timing of its research and development efforts and feasibility trials for the bihormonal system in development, including the expected timelines with respect to improvements to the glucagon asset's excipient profile and the bihormonal dosing algorithm; and the timing or certainty of the FDA's approval of Mint, the timing or certainty of the commercialization of Mint and related updates and the Company's manufacturing capacity at launch. 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, 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 Securities and Exchange Commission, including the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026. 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

(In thousands, except number of shares and per share data)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2026	2025	2026	2025
Net sales	\$ 32,013	\$ 23,238	\$ 59,639	\$ 40,877
Cost of sales	13,111	10,735	24,300	19,403
Gross profit	18,902	12,503	35,339	21,474
Gross margin	59.0%	53.8%	59.3%	52.5%
Operating expenses:				
Research and development	10,240	8,873	20,596	16,463
Sales and marketing	24,640	15,623	45,375	29,025
General and administrative	9,600	7,879	19,217	14,500
Total operating expenses	44,480	32,375	85,188	59,988
Loss from operations	(25,578)	(19,872)	(49,849)	(38,514)
Other income (expense):				
Interest income	2,177	3,005	4,553	5,441
Other expense	(2)	(2)	(2)	(2)
Change in fair value of warrant liabilities	—	—	—	(12,450)
Total other income (expense), net	2,175	3,003	4,551	(7,011)
Net loss	\$ (23,403)	\$ (16,869)	\$ (45,298)	\$ (45,525)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term and long-term investments	(294)	(91)	(793)	84
Comprehensive loss	\$ (23,697)	\$ (16,960)	\$ (46,091)	\$ (45,441)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.53)	\$ (0.39)	\$ (1.02)	\$ (1.23)
Weighted-average common shares outstanding, basic and diluted	44,545,293	43,390,652	44,554,141	37,087,726

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

(In thousands, except number of shares)	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,318	\$ 31,576
Restricted cash, current	100	100
Short-term investments	136,171	187,549
Accounts receivable, net	18,053	17,118
Inventories	23,918	21,722
Prepaid expenses and other current assets	8,474	9,840
Total current assets	231,034	267,905
Property and equipment, net	10,748	8,600
Operating lease right-of-use asset	5,816	6,627
Long-term investments	44,648	45,431
Other long-term assets	141	180

Total assets	\$ 292,387	\$ 328,743
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,351	\$ 4,998
Accrued expenses and other current liabilities	17,194	22,431
Operating lease liabilities	1,591	1,938
Deferred revenue	1,881	1,557
Total current liabilities	26,017	30,924
Operating lease liabilities, net of current portion	4,921	5,365
Deferred revenue, net of current portion	3,454	3,297
Other long-term liabilities	1,629	1,547
Total liabilities	36,021	41,133
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Common stock, \$0.0001 par value, 700,000,000 shares authorized; 44,981,606 and 44,360,873 issued and outstanding at June 30, 2026 and December 31, 2025, respectively	5	4
Additional paid-in capital	671,986	657,140
Accumulated other comprehensive income (loss)	(390)	403
Accumulated deficit	(415,235)	(369,937)
Total stockholders' equity	256,366	287,610
Total liabilities and stockholders' equity	\$ 292,387	\$ 328,743

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
DME channel:				
iLet ⁽¹⁾	\$ 12,651	\$ 13,414	\$ 22,740	\$ 23,042
Single-use products	7,762	5,230	14,596	9,429
Total DME channel	20,413	18,644	37,336	32,471
PBP channel:				
iLet ⁽¹⁾	221	205	686	711
Single-use products	11,379	4,389	21,617	7,695
Total PBP channel	11,600	4,594	22,303	8,406
Total net sales	\$ 32,013	\$ 23,238	\$ 59,639	\$ 40,877

⁽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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net loss	\$ (23,403)	\$ (16,869)	\$ (45,298)	\$ (45,525)
Add:				
Depreciation expense	709	347	1,294	650
Stock-based compensation expense	7,016	4,799	12,422	7,603
Interest income	(2,177)	(3,005)	(4,553)	(5,441)
Income tax expense	2	2	2	2

Litigation settlement and other related expense	135	200	135	200
Quality system remediation ⁽¹⁾	62	—	624	—
Change in fair value of warrant liabilities	—	—	—	12,450
Adjusted EBITDA	\$ (17,656)	\$ (14,526)	\$ (35,374)	\$ (30,061)

⁽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.

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Source: Beta Bionics, Inc.