

**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): January 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**  
(IRS Employer  
Identification No.)

**11 Hughes**  
**Irvine, California 92618**  
(Address of principal executive offices)

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

**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<br>symbol(s) | Name of each exchange<br>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 8.01 Other Events.**

On January 29, 2026, Beta Bionics, Inc. (the “Company”) received a warning letter (the “Warning Letter”) from the U.S. Food and Drug Administration (the “FDA”) following inspection of the Company’s facility in Irvine, California that occurred from June 9, 2025 through June 26, 2025. In the Warning Letter, the FDA cited deficiencies in the response letters sent by the Company to the FDA following the FDA’s issuance of a Form 483, List of Investigational Observations (the “Form 483”), which was issued to the Company by the FDA in connection with the aforementioned inspection that took place in June 2025.

The Warning Letter highlights non-conformities observed by the FDA in relation to the Company’s Quality Management System, Medical Device Reporting, and Correction and Removals, which were previously communicated by the FDA in the Form 483. The Warning Letter does not restrict the Company’s ability to produce, market, manufacture or distribute products, nor restrict the Company’s ability to seek FDA 510(k) clearance of new products.

The Company takes the observations described in the Warning Letter seriously, and is currently preparing a written response to the Warning Letter. Several corrective actions have already occurred including improvements to the processes identified in the warning letter. Additional corrective actions may be identified and executed based upon feedback from the FDA provided in the Warning Letter. The Company intends to provide regular updates to the FDA in response to the Form 483 and Warning Letter. However, the Company cannot provide any assurances that the FDA will be satisfied with its response or as to the expected date of the resolution of the matters included in the Warning Letter. Until the deficiencies cited in the Warning Letter are resolved to the FDA’s satisfaction, additional legal or regulatory action may be taken without further notice.

The Company does not expect the Warning Letter to materially impact the Company’s previously disclosed guidance that it expects to launch the commercialization of Mint by the end of 2027.

## **Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this Current Report on Form 8-K that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding: the Company’s guidance for Mint commercialization, the Company’s responses to and interactions with the FDA, the corrective actions resulting from the Warning Letter and the impact of any further action by the FDA. 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. 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 most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this Current Report on Form 8-K 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.

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**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.**

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

Dated: January 30, 2026

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