

**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): May 9, 2025

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)
12400 High Bluff Drive
San Diego California
(Address of principal executive offices)

001-36189
(Commission
File Number)

20-4327508
(I.R.S. Employer
Identification No.)
92130
(Zip Code)

Registrant's telephone number, including area code: (858) 366-6900

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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	TNDM	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 Items

On May 9, 2025, SteadiSet Infusion Set (SteadySet) received 510(k) clearance from the United States Food and Drug Administration (FDA) for up to three days of use. SteadySet is a wearable infusion set that delivers insulin from an insulin pump to the body and features an integrated inserter with a hidden needle designed for one-handed insertion. SteadySet is designed to provide adult patients with Type 1 diabetes continuous insulin delivery during the indicated use period. The submission was made by Capillary Biomedical, LLC (CapBio), a wholly owned subsidiary of Tandem Diabetes Care, Inc. (the Company). The Company intends to submit, through CapBio, a separate 510(k) submission to the FDA to extend the indicated use time of SteadySet to up to seven days. Commercial activities for SteadySet are not anticipated to start until after FDA clearance of the extended use time.

Forward-Looking Statements

This report contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements relate to the intended submission of a separate 510(k) notification in support of SteadySet Infusion Set for up to seven days of use, and the anticipated timing for commercial activities. These forward-looking statements are subject to numerous risks and uncertainties, including risks associated with a 510(k) notification submission and FDA clearance, the risk that we may encounter other challenges that may delay commercial launch, risks related to the competitive landscape, and other risks identified under the “Risk Factors” heading of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Actual results could differ materially from those anticipated or projected in the forward-looking statements. Tandem undertakes no obligation to update or review any forward-looking statement in this report because of new information, future events or other factors.

<u>Number</u>	<u>Description</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

Tandem Diabetes Care, Inc.

By: /s/ SHANNON M. HANSEN
Shannon M. Hansen
Executive Vice President, Chief Legal, Privacy & Compliance Officer
and Secretary

Date: May 12, 2025