

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

September 6, 2013

Via E-mail

Kim D. Blickenstaff President and Chief Executive Officer Tandem Diabetes Care, Inc. 11045 Roselle Street San Diego, CA 92121

**Re:** Tandem Diabetes Care, Inc.

**Draft Registration Statement on Form S-1** 

Submitted August 12, 2013

CIK No. 1438133

Dear Mr. Blickenstaff:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### Artwork

- 1. Please note that you may include text in your artwork only to the extent necessary to explain briefly the visuals in the presentation. Text such as "touch simplicity," "advanced technology," and "manufacturing excellence" does not appear necessary to explain the visuals. Additionally, it is unclear why the visuals and accompanying text in the right column on the third page of your graphics is necessary. Please revise accordingly.
- 2. We note that the third page of the front graphics and on the back prospectus cover page include products that you do not design, develop or sell or that are currently in development. Given the prominence of the artwork, it is inappropriate to include products that you do not sell or that are in development, have not been approved by

regulatory agencies, and may never generate revenue in such a prominent manner. Please revise.

## Market and Industry Data and Forecasts, page ii

3. We note your statement that forecasts are "particularly likely to be inaccurate." It is unclear why you believe it is appropriate to include such information in a registration statement. Please remove this language disclaiming responsibility for your disclosure and remove any forecast that is likely to be inaccurate.

## Prospectus Summary, page 1

4. Please revise the italicized introductory paragraph to clarify that the Summary discusses all material aspects of the offering. Refer to Item 503(a) of Regulation S-K.

## Overview, page 1

- 5. We note your disclosure highlighting sales in the year ended December 31, 2012 and sixmonth period ended June 30, 2013. Please balance your disclosure by highlighting your net losses in these periods. Also disclose the accumulated deficit as of June 30, 2013.
- 6. In the first paragraph, please revise to clarify what you mean by "Micro-Delivery Technology." In the fourth paragraph, please briefly explain the significance of your pump being one of the first cleared under the FDA's Infusion Pump Improvement Initiative. Finally, in the fifth paragraph, please revise to disclose the basis for your belief that you have an opportunity to "rapidly" increase sales.
- 7. We note your statement in the third paragraph here and in the third paragraph on page 2 regarding the size of the target market. Please revise to identify the source of this data.
- 8. Please provide us support for your statement in the fifth paragraph that a significant number of customers have converted from multiple daily injection to t:slim for their insulin therapy, and tell us, with a view toward disclosure, what percentage of your customers converted.

#### The Market, page 2

9. We note the inclusion of third-party data in the prospectus, such as the market data from The International Diabetes Federation, the National Diabetes Information Clearinghouse, JDRF and others. Please provide us with copies of the sources of this data, clearly marking the relevant sections of the reports that support the data you have included in the prospectus and the page number of your prospectus where such data has been used. Also tell us whether the data was commissioned for use in connection with the registration statement.

10. Please tell us how you calculated the 7% "annual increase in pump use" as disclosed on page 2, including any assumptions used. Also tell us whether the rate calculated takes into account patients who return to insulin injections or otherwise stop using the pump.

#### Our Solution, page 3

- 11. We note your disclosure here and elsewhere concerning use of the "science of human factors" to guide your product development process. Please revise to explain how your approach is "fundamentally different from the traditional medical device development process."
- 12. Please provide us objective, independent support for your statements here and in your Business section regarding the superior or unique design and performance of your insulin pump. By means of nonexclusive example, we note your statements that t:slim is the "slimmest and smallest durable insulin pump on the market" and that it is "capable of delivering the smallest increment of insulin to users of any pump currently available."

## <u>Implications of being an Emerging Growth Company, page 5</u>

13. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

#### Risk Factors, page 10

14. We note your risk factor beginning on page 10 combining the risks relating to reliance on a sole product and the risks relating to market acceptance of your product. Please revise to provide separate risk factor disclosure for each of these distinct risks. Please also add risk factor disclosure that discusses the risks relating to market adoption of your insulin pump as compared to traditional injection therapy, separate from a discussion of risks relating to adoption of your pump technology compared with established pump technology. Also add appropriate risk factor disclosure of the risks associated with the relatively short life span of the t:slim product, or tell us why you do not believe such disclosure is required.

## Our financial performance..., page 32

15. With a view toward disclosure, please explain the basis for your belief that the t:slim product is not subject to the 2.3% annual excise tax on medical devices.

# Use of Proceeds, page 41

16. Please refer to Regulation S-K, Item 504 and revise to disclose the approximate dollar amount of proceeds intended for each stated purpose.

## Capitalization, page 43

17. Please revise to remove cash and cash equivalents from the table on page 43 since this is not a component of capitalization for purposes of this disclosure.

## Management's Discussion and Analysis, starting on page 48

## Comparison of Six Months..., page 50

18. Please revise to disclose what portion of your revenues was derived from pump-related supplies and accessories. Please also disclose whether your margins for pump-related supplies and accessories materially differ from your t:slim margins.

# Liquidity and Capital Resources, page 52

19. Please revise to disclose your estimated working capital needs and capital expenditures over the next year and discuss plans to fund your liquidity requirements.

#### Contractual Obligations and Commitments, page 55

20. We note your disclosure prior to the table that subsequent to fiscal year end, you entered into the term loan agreement with Capital Royalty Partners. Please revise to quantify, either with the statement prior to the table, by footnote to the table or otherwise, the payments due to Capital Royalty Partners for the periods presented in the table.

# Critical Accounting Policies and Management Estimates and Assumptions

## Stock Based Compensation, pages 57-61

- 21. We reference the discussion on pages 57-60 of the use of third-party valuation specialists for the valuation of capitalized intellectual property, common stock and option grants. Please tell us the extent of the reliance that that you placed on the work of the third party specialists. In that regard, please tell us how you considered Question 141.02 of the Compliance and Disclosure Interpretations on Securities Act Sections, which can be found at http://www.sec.gov/divisions/corpfin/guidance/sasinterp.htm.
- 22. Please tell us whether you have had any preliminary pricing discussions with your underwriters. If so, please tell us about the substance of those discussions and whether they were considered in determining the estimated fair value of your common stock.

- 23. After pricing information is available, please revise to provide a specific discussion of each significant factor contributing to significant differences between the estimated fair value of your stock and the estimated IPO price (or pricing range) for the 12 months prior to the IPO. Please note that we are deferring final evaluation of share-based compensation until the estimated offering price is specified, and we may have further comments in that regard when you file an amendment containing that information.
- 24. Please explain how you determined the estimated fair value of \$15 per share in January 2012 through July 2012. We note that the convertible preferred stock issuances were at a significantly lower price. In addition, further clarify the reason that the estimated fair value per common share was lowered to \$2.96 in March 2013. Please explain the specific developments and circumstances that resulted in a significantly lower valuation.
- 25. Please disclose how you considered the convertible preferred stock issuances in fiscal 2012 and 2013 in the valuation of your common shares. We note that the preferred issuances were at \$4.40 per share in fiscal 2012 and 2013 and that the estimated value of common shares during this period from page 61 was significantly different. We also note that preferred shares convert to an equal number of common shares.

## Our Solution, page 67

26. In an appropriate section of your document, please balance your disclosure regarding the advantages of your technology with any material challenges of the technology. In this regard, we note the disadvantages section of the table on page 64 is provided as comparison between injections and pumps generally, and is not specific to your technology compared with traditional injection therapy or other insulin pumps.

#### Sales and Marketing, page 75

27. We note your disclosure on page F-10 indicating that you have customers that accounted for greater than 10% of your revenues. Please revise your disclosure to identify these customers. Refer to Regulation S-K, Item 101(c)(1)(vii).

#### Third-Party Reimbursement, page 77

- 28. We note your disclosure on page 77 indicating that your products are described by existing codes for Medicare reimbursement and your disclosure on page 11 that many third-party payors look to CMS coverage determinations when setting their own coverage policies. Accordingly, please expand your disclosure to address existing CMS reimbursement coverage for insulin pumps and disposable cartridges and discuss any trends related to CMS reimbursement policies.
- 29. We refer to your disclosure on page 4 concerning your intent to add third-party payors and your disclosure on page 12 indicating that traditional insulin pump suppliers enjoy

competitive advantages because they have established relationships with healthcare providers and third-party payors. Accordingly, please expand your discussion of third-party reimbursement to compare the size of your third-party payor coverage relative to that of your competitors'. Also, we note that your disclosure on page 70 indicates that there are "areas where you have concentrated (y)our initial sales." Accordingly, please expand your disclosure, as applicable, to identify geographic regions, market segments or other areas where you have concentrated your initial sales efforts.

## Research and Development, page 78

30. Please expand your discussion of the agreements with DexCom and JDRF to describe more fully the payment provisions of the agreements. For instance, describe and quantify the milestone payments and clarify whether the licenses provide for royalty payments. If so, please quantify. Finally, please clarify the intellectual property status of any products jointly developed with JDRF.

## Clinical Advisory Board, page 79

31. Please expand your disclosure to clarify how members of the board are compensated.

## <u>Intellectual Property, page 79</u>

- 32. We note your risk factor disclosure on page 25 indicating that two U.S. patents and various other pending patents are particularly important to the pumping mechanism and therefore the functionality of your products. Please revise your disclosure on page 79 to specifically identify the particular patents and patents pending referenced in the risk factor.
- 33. Please expand the third paragraph of this section to identify the entity or person with whom you entered into the agreements mentioned here and specify the technology and products to which these agreements relate. Also disclose the royalty rate for any sublicenses that you may enter into that will be payable under the agreement, and clarify whether you have entered into any sublicenses.

## FDA's Pre-Market Clearance and Approval Requirements, page 80

34. Please revise your disclosure in the second paragraph under this subheading to clarify the classification of the t:slim and t:connect products for which you received FDA clearance. Further identify the classification of the t:flex device for which you plan to submit a 510(k) application and the joint t:slim/DexCom product for which you plan to submit a PMA application, as noted on page 81.

## Board of Directors, page 92

35. We note your risk factor disclosure on page 32 indicating that following the offering your executive officers, directors and 5% holders may be able to determine the outcome of all maters submitted to shareholders. To the extent that you will satisfy the criteria necessary to elect treatment as a "controlled company" pursuant to NASDAQ listing rules, please revise your disclosure to discuss how this exemption could impact your corporate governance.

## Market Comparisons, page 98

36. Please expand your disclosure to identify the companies within the peer group you reference.

# Equity-Based Awards, page 99

37. Please expand your narrative disclosure to discuss any grants of awards to named executive officers after December 31, 2012.

## Description of Capital Stock, page 111

38. Your disclosure may not be qualified by reference to state law. Please revise accordingly.

## Shares Eligible for Future Sale, page 118

39. Please quantify the number of shares outstanding after the completion of the offering that will be subject to the lockup agreements and/or Rule 144 restrictions.

#### **Financial Statements**

40. Please update the financial statements when required by Rule 8-08 of Regulation S-X.

# Note 6. Loan and Warrant Agreements, page F-26

41. In the first full paragraph on page F-26 it states that the fair value of the common stock of \$0.96 was used to value the warrants. Please explain how this fair value was determined and tell us why it is different than the estimated fair value amounts disclosed on page 61.

## Note 7. Related Party Transactions, page F-26

42. Please explain to us how you valued the shares returned by the former official in partial repayment of his note receivable and explain significant differences between that value and the estimated fair value per share disclosed on page 61.

# Note 8. Stockholders' Equity -- Common Stock Options, page F-30

43. Please explain how the price of \$44 for the Series C Preferred Stock issued in May 2009 was determined and the reason for the significant difference with the price of the Series D Preferred Stock issuances of \$4.40 in fiscal 2012 and 2013.

## Item 15. Recent Sales of Unregistered Securities, page II-1

44. We note that your disclosure under caption (d) "Grants of Stock Options" is provided on an aggregate basis. Please revise to disaggregate this disclosure; for instance, disclose the dates of sale and the amounts of securities sold. Refer to Regulation S-K Item 701(a). Also revise to ensure that you have disclosed the issuances of shares upon the exercise of options for the full three year period required. Currently the disclosure in the second bullet point under caption (d) is provided through June 30, 2012, yet from your statement of shareholders' equity it appears you issued shares upon the exercise of stock options between December 31, 2012 and June 30, 2013.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Jeanne Bennett at (202) 551-3606 or Brian Cascio, Accounting Branch Chief, at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Joseph McCann at (202) 551-6262 or Mary Beth Breslin, Senior Attorney, at (202) 551-3625 with any other questions.

Sincerely,

/s/ Mary Beth Breslin for

Amanda Ravitz Assistant Director

cc (via email): Ryan C. Wilkins, Esq. - Stradling Yocca Carlson & Rauth, P.C.