



DIVISION OF
CORPORATION FINANCE

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

Mail Stop 3030

May 5, 2010

Manny Villafana
Chairman and Chief Executive Officer
Kips Bay Medical, Inc.
3405 Annapolis Lane North, Suite 200
Minneapolis, Minnesota, 55447

Re: Kips Bay Medical, Inc.
Registration Statement on Form S-1
Filed April 8, 2010
File No. 333-165940

Dear Mr. Villafana:

We have reviewed your filing and have the following comments. Where indicated, we think you should revise your document in response to these comments. If you disagree, we will consider your explanation as to why our comment is inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure. After reviewing this information, we may raise additional comments.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filing. We look forward to working with you in these respects. We welcome any questions you may have about our comments or any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

Prospectus Cover Page

1. Please confirm that any preliminary prospectus you circulate will include all non-Rule 430A information. This includes the price range and related information based on a bona fide estimate of the public offering price within that range, and other information that was left blank throughout the document.

Prospectus Summary, page 1

2. Please revise your overview to disclose that you are a development stage company. Explain the terms “saphenous”, “nitinol”, “stenotic”, “on-pump or off-pump procedures” and other similar technical words and phrases.
3. In the opening paragraph, disclose your revenues and net loss for the most recently completed fiscal year and stub, as applicable.

Industry Background, page 1

4. We note the final clause of the final sentence of the first paragraph of this section. Please disclose whether CABG is best-suited for patients in a certain age range or with a certain stage of heart disease.
5. The risk of slow blood flow and subsequent blood clotting would appear inconsistent with your disclosure regarding the strain on saphenous veins due to the high pressure of arterial flows. Please revise to clarify and reconcile, if necessary, the second-to-last and third-to-last sentences in the first paragraph on page 2.
6. Please revise to briefly clarify why a thickened wall may lead to bypass graft failure.

Our Solution, page 2

7. We note that this section provides a list of the strengths, or benefits, of your product. Please balance your disclosure by disclosing relevant weaknesses.

Risk Factors, page 6

We will be highly dependent on third-party institutions..., page 15

8. With a view to disclosure, please tell us about your agreements with clinical investigators, clinical trial sites and contract research organizations, including:
 - the principal terms of the agreements;
 - the identities of the counter-parties to these agreements; and
 - the number of agreements.

Given this risk factor, please provide your analysis showing how you determined that these agreements need not be filed as exhibits to the registration statement.

Our operations involve hazardous materials..., page 16

9. We note your disclosure that you are subject to regulations regarding “hazardous and toxic materials.” Please describe all material governmental regulations to which you are subject in the business section of your prospectus, or explain why you have not done so.

Our charter documents and Delaware law..., page 19

10. Please revise the caption of this risk factor to refer to the risks relating to the issuance of preferred stock or provide a separate risk factor.

Special Note Regarding Forward-Looking Statements, page 21

11. Refer to the second-to-last sentence on page 21. Note that it is inappropriate to disclaim the accuracy of the information contained in the prospectus. Please tell us the basis for inclusion of information that you have characterized as inherently imprecise.

Use of Proceeds..., page 22

12. We note your disclosure in the fourth paragraph that the amounts you expend may vary significantly from expectations. You may reserve the right to change the allocation of proceeds provided you disclose the specific contingencies that would give rise to a change. See Instruction 7 to Item 504 of Regulation S-K. Please revise.

Management’s Discussion and Analysis..., page 27

13. Please revise Management’s Discussion and Analysis to provide a discussion of management’s assessment of trends or events that are likely to have a material impact on the company’s revenues. Your disclosure should comport with the MD&A guidance in SEC Release Nos. 33-8350 and 34-48960.

Overview, page 27

14. The second paragraph on page 27 appears to indicate that the aim of your trials is to demonstrate that the eSVS MESH vessels are as effective as the control vessels. In this regard, you disclose that your preliminary data supports this conclusion. However, in the first paragraph on page 27 and elsewhere in the registration statement, you express your belief that eSVS MESH vessels improve openness and blood flow and limit the need for reoperations and revascularization. Please reconcile this belief with your stated goal of establishing statistical non-inferiority. Further, please clarify why you believe that hospitals and patients would select eSVS MESH vessels if they are merely as effective as existing methods.

15. Please confirm, if true, that the control vessels are simply non-MESH saphenous veins.

Critical Accounting Policies and Estimates, page 29

Significant Factors, Assumptions and Methodologies Used in Determining Fair Market Value of Common Stock, page 30

16. We see that you have provided a discussion regarding the determination of the fair value of your common stock. Please update your analysis through the date of your response and revise to also include any stock options issued by the company or principal stockholder since April 2009 (one year ago) through the date of your response. Include the following information for each issuance or grant date:

- a. Number of shares issued or issuable in the grant
- b. Purchase price or exercise price per share
- c. Any restriction or vesting terms
- d. Management's fair value per share estimate
- e. How management determined the fair value estimate
- f. Identity of the recipient and relationship to the company and tell us how you considered your relationship with Kips Bay Investments, LLC (KBI) in determining the fair value
- g. Nature and terms of any concurrent transactions with the recipient
- h. Amount of any recorded compensation element and accounting literature relied upon

In the analysis requested above, highlight any transactions with unrelated parties believed by management to be particularly evident of an objective fair value per share determination. Provide a progressively bridged schedule of management's fair value per share determinations to the current estimated IPO price per share. Also, indicate when discussions were initiated with your underwriter(s). We will delay our assessment of your response pending inclusion of the estimated IPO price in the filing.

17. Please revise your discussion to include the nature of the milestones reached as part of your Investment Agreement with KBI to substantiate why the exercise of the option supports the increase in fair value from \$2.00 per share at March 2008 to \$5.83 at June 2008. Please also revise to clarify your relationship with KBI as part of your disclosure, we note your current disclosure references KBI as only a 'third party.'

Liquidity and Capital Resources, page 33

18. With a view towards disclosure, please tell us whether you intend to enter into a credit facility or loan agreement. If not, please tell us whether you anticipate any adverse effects to you stemming from the lack of available credit. Please also expand the disclosure in the final risk factor on page 20.

Royalty Payments, page 36

19. Revise the registration statement to fully describe the transfer of intellectual property from Medtronic to you. For instance, please distinguish more clearly between the intellectual property that has been sold to you, if any, and that which has been licensed to you. In addition, in light of your disclosure in the final paragraph of this section, please explain any ambiguity related to the operation of the reversion terms, including the specific intellectual property which would be affected (i.e., intellectual property that was sold, licensed or both) and the circumstances which would trigger reversion.

Business, page 38

20. You cite statements from articles or reports of the American Heart Association, the Millennium Research Group, the World Health Organization, the New England Journal of Medicine and the European Journal of Cardio-Thoracic Surgery in several places in the business section and elsewhere in your disclosure. Please provide us with copies of the articles or reports you cite. Clearly mark the supporting statements in the supplemental materials.
21. We note your disclosure in the second paragraph on page 38 that an independent study shows CABG to be a more effective treatment than drug eluting stents. Please identify who prepared this study and provide us with a copy of the study marking the supporting statements. Also, with a view to balanced disclosure, please tell us whether there are any existing studies that reach a different conclusion and provide us with copies of those studies.
22. Please tell us whether the industry reports that you cite here and throughout your document are publicly available for a nominal fee, whether they were commissioned by you and whether they were prepared for use in your registration statement.
23. We note that on page 38 you cite data on the number of CABG procedures performed during 2006 and on page 47 you cite data regarding the number of procedures performed per hospital in 2003. Please tell us why you are providing data that is several years old and why you cannot provide more recent data.

Conduct trials to expand indications..., page 40

24. You disclose that several trials are expected to begin in 2010. Are you referring to the IDE trial that you expect to begin in the second half of 2010? Please clarify. If you expect to commence and complete other trials in 2010, revise to discuss identify these trials. In addition, please disclose the expected costs to you or provide an appropriate cross-reference.

International Human Clinical Trial, page 43

25. Please revise the first paragraph on page 44 for clarity.

Europe and Other International Markets, page 46

26. Refer to the fourth full paragraph on page 51. Revise here to disclose the limitations on your ability to market and promote your product.
27. We note that you have identified distributors. Please clarify whether you have entered into any distribution agreements. If so, please file these agreements, as appropriate.
28. Please clarify the reference to a “gateway approval.”

Intellectual Property, page 47

29. Refer to the first paragraph of this section. We note that certain of your patent applications currently stand rejected. With a view towards disclosure, please tell us the significance of these rejections to your business and whether you expect to ultimately receive approval of the rejected applications.
30. Please provide us with copies of documentation that demonstrates you are the applicant for each of the patent applications referenced in the first paragraph.
31. Please tell us why you have not filed as an exhibit the assignment of the “Transferred Patent Rights” as referenced in the assignment and license agreement with Medtronic.

Competition, page 48

32. Please clarify if any of your competitors are developing or have developed a similar product.
33. Please expand your disclosure to address the proportion of the market for treatment of cardiovascular disease held by CABG surgery relative to the other treatment options on page 40 and the competitiveness of CABG surgery within that market.

34. We note your disclosure in the first full paragraph on page 42 that procedures to repair failed CABG grafts carry increased mortality rates. Revise to address this competitive disadvantage and other known disadvantages. Also, revise your risk factors as appropriate.

Manufacturing and Suppliers, page 48

35. Please disclose the anticipated costs of the additional knitting machines, if material.

Third Party Reimbursement, page 54

36. Your disclosure indicates that your product will be ready for market in the European Union before it is available in the United States. However, your discussion of third-party reimbursement focuses almost exclusively on the United States system. Please expand your discussion of third-party reimbursement in Europe. Refer to the second-to-last paragraph of this section.

Scientific Advisory Board, page 56

37. Please expand your description of the role and powers of the scientific advisory board. Furthermore, with a view to disclosure, please tell us how members of the scientific advisory board are appointed, the terms of their appointments, whether you have any agreements with them and how they are compensated.

Management, page 58

38. We note your disclosure that you have one director and that you will have four additional directors upon closing of the offering. Please reconcile this disclosure with section 3 of the investment agreement with Kips Bay Investments, LLC, filed as exhibit 10.2.
39. We note that the registration statement contains several unsubstantiated statements. We note, for example and without limitation, the following statements in the description of Manny Villafana's experience:
- "a novel heart valve that still dominates the mechanical valve replacement market"; and
 - "a long life lithium iodine pacemaker that became and continues to be the standard of care in the pacemaker market."

Provide the staff with supporting supplemental materials for unsubstantiated claims or make appropriate revisions throughout the registration statement, as necessary.

Certain Relationships and Related Transactions..., page 70

40. Please revise to clarify your description of the terms of the Investment Agreement with Kips Bay Investments, including the operation of performance milestones.
41. Please reconcile the dates you state the notes with Kips Bay Investments LLC were entered into, the dates of the notes listed as exhibits 10.4 and 10.5 in the exhibit index and the notes referenced in the first recital in the Loan and Security Agreement.
42. Refer to the third paragraph on page 71. Please provide your analysis demonstrating how you determined that the Loan and Security Agreement filed as exhibit 10.3 has terminated. Refer to section 8(b) of that agreement in your analysis. File any agreement terminating the Loan and Security Agreement as an exhibit.
43. With a view to disclosure, please tell us whether Kips Bay Investments has approved the issuance of stock in the proposed offering in accordance with Section 6.3 of the Investment Agreement filed as exhibit 10.2 or otherwise explain how you determined section 6.3 does not apply in these circumstances. File any approval as an exhibit.

Principal Stockholders, page 72

44. With respect to the shares held by Kips Bay Investments LLC, please disclose the identity of each entity and each natural person other than Nasser Kazeminy who exercises the sole or shared voting and/or dispositive powers with respect to the shares.

Outstanding Shares, page 73

45. The second sentence of this section appears to contain a legal conclusion that you are not qualified to make. Please attribute the statement to counsel or remove it.

Certain United States Federal Tax Considerations..., page 84

46. Your disclosure should address all material tax consequences not just the certain consequences referenced in the first sentence.
47. Disclaimers of responsibility for tax disclosure, such as the language contained in the last paragraph on page 86, are generally inappropriate. Please delete this language and similar language. In this regard, please remove any statements that investors “should consult” their own tax advisors.

Financial Statements, page F-1

General

48. Please update your financial statements to comply with the requirements of Rule 3-12 of Regulation S-X. Also, all amendments should contain a currently dated accountant's consent.

Report of Independent Registered Public Accounting Firm, page F-2

49. We see that the filing includes balance sheets of Kips Bay Medical, Inc. (a development stage company) as of December 31, 2008 and 2009 and the related statements of operations, stockholders' equity (deficit), and cash flows for the *period from May 1, 2007 (date of inception) to December 31, 2007*, the years ended December 31, 2008 and 2009, and for the period from May 1, 2007 (date of inception) to December 31, 2009. However, we note that your auditors' report refers to and opines on "the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009." Please have your auditors revise the introductory and scope paragraphs of their report to reference the correct 2007 fiscal period that was audited.

Statements of Cash Flows, page F-6

50. We see from disclosures on page F-7 that your short term investments have maturities of greater than three months. Accordingly, please tell us why this statement does not show gross purchases and sales of short term investments. Refer to FASB ASC 230-10-45.

Note 6. Convertible Promissory Notes and Equity Financing, page F-14

Investment Agreement with Kips Bay Investments, page F-14

51. With a view towards full disclosure, please revise to disclose the milestone achieved in April 2008 that resulted in KBI's exercise of the first option. Please note our comment above and reconcile your disclosures herein with your discussion regarding the fair value of your shares on page 30.
52. We note your disclosure that the second purchase option is considered a derivative liability and must be measured at fair value. Please revise to provide the disclosures required by FASB ACS 820-10-50.

53. In this regard, we see that you estimated the fair value of your investor stock purchase option liability and determined the value to be \$1.6 million at January 1, 2009 and \$960,000 at December 31, 2009. Please revise to explain how you determined the fair value at each respective period as well as the underlying reason for the change in fair value between periods.
54. Please revise to more fully describe the nature of your related party relationship with KBI, including any common ownership. Refer to FASB ASC 850-10-50.

Note 10. Subsequent Event, page F-19

55. Please revise to disclose the second milestone that was achieved by the company that led to KBI's exercise of the second stock purchase option in February 2010.
56. We see that you agreed to convert the \$250,000 of interest on the Notes that was paid approximately one year earlier in cash, into common shares at an a conversion price of \$.625 per share. Please tell us how this transaction was addressed by the Investment Agreement with KBI and also tell us how you accounted for the conversion (and valued the shares issued in connection therewith).

Undertakings, page II-4

57. Please provide the undertakings required by Item 512(a)(5)(ii) and Item 512(a)(6) of Regulation S-K.

Exhibits

58. We note your request for confidential treatment. We will review and provide comments on your request separately. Comments on your request must be resolved before we may accelerate the effectiveness of this registration statement.
59. Please file all material agreements and any other material agreements or otherwise outstanding exhibits as soon as practicable. Because we may have comments on these exhibits, please file the exhibits allowing adequate time for their review.
60. Please tell us the authority on which you rely to file only "forms of" contracts as exhibits like you propose to do in exhibit 10.14 rather than the final, signed agreements.
61. We note your disclosure on page II-1 that your amended and restated bylaws will become effective upon the closing of this offering. Please tell us the legal basis on which you rely to not file your existing bylaws as an exhibit and revise your disclosure to clarify whether you are referring to your existing or proposed bylaws.

62. We note that Exhibit 10.2, the investment agreement, appears to be missing exhibit F. Please ensure that you have filed complete copies of all agreements.

As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes all information required under the Securities Act of 1933 and that they have provided all information investors require for an informed investment decision. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event the company requests acceleration of the effective date of the pending registration statement, it should furnish a letter, at the time of such request, acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in connection with our review of your filing or in response to our comments on your filing.

We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. We will act on the request and, pursuant to delegated authority, grant acceleration of the effective date.

Manny Villafana
Kips Bay Medical, Inc.
May 5, 2010
Page 12

We direct your attention to Rules 460 and 461 regarding requesting acceleration of a registration statement. Please allow adequate time after the filing of any amendment for further review before submitting a request for acceleration. Please provide this request at least two business days in advance of the requested effective date.

You may contact Julie Sherman at (202) 551-3640 or Jay Webb, Staff Accountants at (202) 551-3603 if you have questions regarding comments on the financial statements and related matters. Please contact Ruairi Regan at (202) 551-3269 or me at (202) 551-3314 with any other questions.

Sincerely,

Daniel Morris
Special Counsel

cc (by facsimile): Robert K. Ranum, Esq.