

SECURITIES AND EXCHANGE COMMISSION

FORM UPLOAD

SEC-originated letters to filers

Filing Date: **2005-05-02**
SEC Accession No. **0000000000-05-021188**

([HTML Version](#) on [secdatabase.com](#))

FILED FOR

ev3 Inc.

CIK: **1318310** | IRS No.: **320138874** | State of Incorporation: **DE** | Fiscal Year End: **1231**

Type: **UPLOAD**

SIC: **3841** Surgical & medical instruments & apparatus

Mailing Address

9600 54TH AVENUE NORTH
SUITE 100
PLYMOUTH MN 55442-2111

Business Address

9600 54TH AVENUE NORTH
SUITE 100
PLYMOUTH MN 55442-2111
(763) 398-7000

April 29, 2005

L. Cecily Hines, Vice President
Ev3 Inc.
4600 Nathan Lane North
Plymouth, Minnesota 55442

Re: ev3 Inc.
Form S-1
File No. 333-123851
Filed April 5, 2005

Dear Ms. Hines:

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 supplemental information so we may better understand your disclosure. After reviewing this information, we may or may not 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 on any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

Prospectus Summary - Page 1

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 within that range. Also note that we will have additional comments after you include this and other missing information.

2. Revise the third paragraph of the prospectus summary and elsewhere throughout the filing to accurately reflect the history of the registrant. We note footnote 2 on page F-9. Quantify the roles of Warburg Pincus and The Vertical Group, Inc., and their current and previous equity and other interests in the registrant. Also explain in more detail the registrant's relationship with MTI and the extent to which the registrant's revenues are attributable to MTI operations.

3. Please define technical terms in the summary when they are first used, including:

- * Embolic protection
- * Thrombectomy
- * Balloon angioplasty
- * Liquid embolics
- * PLAATO
- * Atrial fibrillation
- * Aneurysm

4. Provide supplemental support for all industry and market statistics.

Corporate Reorganization - Page 3

5. Due to the blanks in this discussion and the reverse split discussion, we will defer or comments on this section until the disclosure is complete. Ensure that the discussion clearly states the value of what Warburg Pincus and The Vertical Group are giving up

and what they are getting in each of these transactions.

6. Explain the business reasons for this series of transactions.

Merger with ev3 LLC - Page 3

7. Disclose how many unit holders there are in ev3 LLC, identify the major holders, and quantify the extent of their ownership interest.

Our Structure - Page 5

8. In the second chart, identify the major shareholders of ev3 Inc., and quantify their ownership interest after the reorganization transactions are completed.

Risk Factors

9. Expand the first risk factor to quantify your members' deficit to date.

If third parties claim that we infringe ... - Page 11

10. Discuss under a separate caption the instances where you have been notified by other parties about potential infringement claims, beginning in the middle of page 12.

We may experience conflicts of interest... - Page 16

11. Expand the first paragraph to clarify that your current board of directors is comprised of seven members, four of which are also members of MTI's board of directors. Identify the four directors.

Capitalization Table - Page 38

12. Please remove the cash and cash equivalent caption from this table.

Management's Discussion - Page 44

Overview - Page 44

13. Quantify the percentage of the registrant`s revenues and net losses that are attributable to MTI.

Results of Operations - Page 47

Comparison of Year Ended December 31, 2004 to Year Ended December 31, 2003 - Page 48

14. Unless insignificant, please expand to quantify the effect of changes in prices on reported revenues. In general, your discussion should separately describe and quantify the effects of price changes and sales volumes on reported revenues.

Liquidity and Capital Resources - Page 53

15. Please expand the discussion of liquidity and capital resources to address any material acquisitions.

16. Please significantly expand your disclosures to discuss your financing arrangements with MII, MTI, Warburg Pincus and The Vertical Group. Your attention is invited to the disclosure requirements of SFAS 57.

MTI Financings and Liquidity - Page 56

17. The reference to "continuing cash from operations" as a source of liquidity for MTI is unclear in light of disclosure elsewhere that you expect operations to consume cash in 2005. Please revise or advise.

Critical Accounting Policies and Estimates - Page 57

18. What consideration have you given to disclosing your inter-company transaction policies under this heading?

19. We note that you used a "third party appraisal" to value the in-process research and development acquired in 2002. If you elect to make such a reference, please note that you will be required to identify the appraisal firm under "Experts" and include their consent in your registration statement. We will not object if you wish to indicate (instead) that management considered an appraisal when

estimating fair values.

Peripheral Vascular Market Opportunity Business - Page 69

20. Please revise to describe the typical applications of your peripheral stents. We note the only application mentioned is the carotid artery. Are your stents approved for other uses?

Clinical Studies - Page 85

21. Please explain the term "primary endpoint."

Government Regulation - Page 90

Other Regions - Page 96

22. If material to your current or future sales, please describe the regulatory system in Japan.

Intellectual Property Rights - Page 100

23. If material, describe patent expirations.

Management - Page 104

24. Please add the business experience information for Patrick D.Spangler.

25. With regard to Mr. Adams, please explain the terms "CAPLA" and "vascular brachy therapy."

26. With regard to Ms. Hines, please disclose her principal occupation during the period April 2000 - January 2002.

27. With regard to Mr. Dale Spencer, please disclose his principal occupation during the past five years.

Option Grants in 2004 - Page 112

28. Disclose how the reverse split will affect the number of options outstanding.

Employment Agreements - Page 113

29. Please describe the terms of your basic employment agreements, such as salary, bonus, options, term of office, etc., with the named executive officers.

Stock Plans - Page 115

Predecessor Plan - Page 115

30. Revise to clarify how exercise prices of assumed options will be determined.

2005 Incentive Stock Plan - Page 116

31. Revise to disclose whether options and rights may be granted at exercise prices less than 100% of market price at date of grant and how exercise prices will be determined.

32. State whether options will be qualified under tax rules.

Certain Relationships and Related Party Transactions - Page 118

Corporate Reorganization - Page 118

33. Please revise to clarify at what point the reverse split will occur, and the effect thereof on the number of shares of stock the affiliates will own after the offering.

34. When blanks are filled in, we will comment further on this section.

Principal and Selling Stockholders - Page 126

35. Identify the persons who have or share voting and/or investment control over the shares held by the entities listed in the table.

Underwriting - Page 137

36. Tell us about the nature and timing any discussions or arrangements you have had regarding the reserved (directed) shares with any parties for whom the underwriters will reserve shares.

Who will be eligible to purchase in the reserved share program?

How
will potential participants be notified of the offering?

How did you determine the number of shares to reserve?

Tell us the procedures that will be followed to implement the reserved share program.

Supplementally provide a copy of all written material used in connection with the reserved share program and analyze how that material is consistent with Rule 134.

Consolidated Financial Statements - Page F-1

General

37. Consideration should be given on an ongoing basis to the updating requirements of Rule 3-12 of Regulation S-X.

38. All amendments should contain a currently dated accountant's consent.

Reports of Independent Registered Accounting Firms - Page F-2

39. We note your "draft" report for the effect of the contribution of shares held by Warburg, Pincus Equity Partners described in Note 2.

Prior to going effective the audit report should be signed and unrestricted. This comment also applies to the auditors' consent.

Note 3. Summary of Significant Accounting Policies

Revenue Recognition - Page F-12

40. Please tell us the primary terms of your arrangements with your distributors, including payment, price protection, return, exchange, and other significant terms. We note that sales to distributors are generally recognized at the time of shipment, tell us when this would not be the case. Describe the primary terms of your arrangements

with stocking distribution partners and when sales through these individuals are recognized.

41. Supplementally clarify whether there are any post-shipment obligations (e.g. training, education) or any additional obligation after revenue is recognized and indicate how this impacts the accounting treatment.

42. We note that you have an agreement with Invatec to distribute their products in the United States. Supplementally tell how sales of these products are reported in your financial statements. Refer to EITF 99-19 in your response.

43. We note you introduced four new products from October 1, 2004 to December 31, 2004. In view of your limited history of commercial sales, please tell us how you have developed the requisite historical data on which to base estimates of returns for these new products. Refer to paragraphs 6f and 8 of SFAS 48.

Unit and Stock-Based Compensation - Page F-14

44. We note that you are using the minimum value method to estimate the value of your options. This method is appropriate for a nonpublic entity. However, as indicated under Appendix E of SFAS 123, a company that makes a filing with a regulatory agency in preparation for the sale of any class of equity securities in a public market is considered to be a public entity. Supplementally discuss the consideration that you have given to this guidance.

Note 5. Business Combinations - Page F-18

45. In a supplemental response tell us how you determined the allocation of the excess purchase price between goodwill and intangible assets in the acquisition of Intra Therapeutics and Dendron. Tell us how you determined the amount to allocate to intangibles. Tell us the main purpose of these acquisitions, whether you acquired customer lists and or/ relationships, customer backlogs, etc. For reference see EITF 02-17 and SFAS 141.

46. In view of the significant IPR&D write-off, your disclosures should be enhanced. Please state the significant appraisal

assumptions, such as the period in which material net cash inflows from significant projects are expected to commence, anticipated material changes from historical pricing, margins and expense levels and the risk adjusted discount rate applied to the projects` cash flows. Describe each individually significant project acquired, indicate the degree of completion at the acquisition date and disclose the anticipated cost and time of completion.

Note 7. Inventories - Page F-23

47. We note that you recorded a reserve for inventory obsolescence "related to acquisitions." Tell us more about this charge and confirm inventory was recorded at fair value at the date of acquisition.

Note 9. Goodwill and Other Intangible Assets - Page F-24

48. We note that you recorded impairment charges for goodwill in fiscal 2002 and 2003. Please revise the notes to your financial statements as follows:

- (a) Describe the facts and circumstances leading to the goodwill impairment.
- (b) Disclose the significant assumptions used to determine the fair value of the associated reporting unit under SFAS 142.
- (c) Disclose the number of reporting units used in your assessment of goodwill.

Note 10. Investments - Page F-25

49. We note that you recorded an additional gain of \$14,647 related to the achievement of a defined milestone as it relates to the sale of Enteric 2002. Please tell us where this is recorded in your statement of operations. If classified as operating income, tell us why this classification is appropriate.

Note 12. Notes Payable - Page F-27

50. Supplementally and in detail show us how the beneficial conversion features were measured. Refer to EITF 98-5 and 00-27. Support your presentation as a component of minority interest on the balance sheet.

Redeemable Convertible Preferred Membership Units - Page F-27

51. We note that the preference shares are convertible to common units only if the initial public offering aggregate proceeds raise at least \$100 million with proceeds to the company of at least \$40 million. If your offering range does not raise at least \$100 million, the pro forma adjustment will not be accurate. Please advise.

52. Revise to disclose the liquidation preference of preference membership units on the face of the balance sheet as required by SFAS 129, paragraph 6 and Rule 4-08 (d) of Regulation S-X.

Note 14. Equity Based Compensation Plans - Page F-29

53. Supplementally tell us how you accounted for the options granted with an exercise price below market value during fiscal year 2004.

54. Provide us with an itemized chronological schedule detailing each issuance of your ordinary shares, stock options and warrants by the company or principal stockholder since January 2004 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
- 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. Progressively bridge 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.

Note 18. Commitments and Contingencies - Page F-40

55. Revise to disclose the monetary damages of E3.6 million in U.S. dollars as well.

56. Supplementally describe, in greater detail, the significant contractual provisions of the supply agreement with Invatec (page 13). How are prices established? Describe any predetermined pricing formula, if applicable. We note that Invatecs has the right to recover damages, please explain. Revise to disclose your obligations under this agreement in the notes and MD&A if material.

57. Even if there is no accrual for a loss contingency because one or both of the conditions in paragraph 8 of SFAS 5 are not met, you should disclose an estimate of the possible loss or range of loss or state that such an estimate cannot be made. Refer to SAB Topic 5:Y. Revise or advise.

Note 19. Related Party Transactions - Page F-43

58. Supplementally provide us with a schedule of activities with MTI. Confirm that your historical financial statements reflect all cost of doing business, including cost incurred on your behalf by your parent company, MTI and any other related companies. Refer to SAB Topic 1-B for guidance. We may have further comments after reviewing your response.

Note 20. Segment and Geographic Information - Page F-44

59. Revise the filing to report revenues for each product or each group of similar products. See paragraph 37 of SFAS 131.

60. If revenues derived from any particular foreign country are material, revise to disclose the name of the country and the amount of revenue from the country. Refer to paragraph 38(a) SFAS 131.

61. SFAS 131 requires disclosure of long-lived assets by geographic area. This disclosure should present tangible assets only and should not include intangibles or investments. See question 22 in the FASB Staff Implementation Guide to Statement 131. Revise as necessary.

Electronic Distribution

62. Identify any members of the underwriting syndicate that will engage in any electronic offer, sale or distribution of the shares and describe their procedures to us supplementally. If you become aware of any additional members of the underwriting syndicate that may engage in electronic offers, sales or distributions after you respond to this comment, promptly supplement your response to identify those members and provide us with a description of their procedures.

Briefly describe any electronic distribution in the filing.

Also, in your discussion of the procedures, tell us how your procedures ensure that the distribution complies with Section 5 of the Securities Act. In particular:

- * the communications used;
- * the availability of the preliminary prospectus;
- * the manner of conducting the distribution and sale, such as
- * The use of indications of interest or conditional offers; and
- * the funding of an account and payment of the purchase price.

Finally tell us whether you or the underwriters have any arrangements with a third party to host or access your preliminary prospectus on the internet. If so, identify the party and the website, describe the material terms of your agreement and provide us with a copy of any written agreement. Provide us also with copies of all information concerning your company or prospectus that has appeared on their website. Again, if you subsequently enter into any such arrangements, promptly supplement your response.

We may have further comment.

Request for Confidential Treatment

63. We note you expect to or have filed a request for confidential treatment of certain portions of exhibits to the registration statement. Comments, if any, will be furnished after we complete our

review and will need to be resolved prior to effectiveness of the registration statement.

* * * * *

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 supplemental 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 filings reviewed by the staff to be certain that they have provided all information investors require for an informed 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 a 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.

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) 824-5506 or Angela Crane at (202) 942-1931 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Morris at (202) 942-1980 or me at (202) 942-1880 with any other questions.

Sincerely,

Peggy Fisher

Assistant Director

cc. Tracy Kimmel (King & Spalding)
VIA TELEFAX 212-556-2222

??

??

??

??

L. Cecily Hines, Vice President

Ev3 Inc.

April 29, 2005

Page 13