



DIVISION OF  
CORPORATION FINANCE

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

October 27, 2011

Jeff Mathiesen  
Chief Financial Officer  
Sunshine Heart, Inc.  
7651 Anagram Drive  
Eden Prairie, Minnesota

**Re: Sunshine Heart, Inc.  
Form 10  
Filed September 30, 2011  
File No. 001-35312**

Dear Mr. Mathiesen:

We have reviewed your filing 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 amending your filing, by providing the requested information, or by advising us when you will provide the requested response. 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 any amendment to your filing and the information you provide in response to these comments, we may have additional comments.

General

1. Please note that the Form 10 goes effective by lapse of time 60 days after the original filing date, pursuant to Section 12(g)(1) of the Securities Exchange Act of 1934. Upon the expiration of this 60-day time period, you will be subject to the reporting requirements under Section 13(a) of the Securities Exchange Act of 1934. In such event, we will continue to review your filing until all of our comments have been addressed. If this filing was made voluntarily, you should consider withdrawing it prior to the effective date if comments remain outstanding. You could then refile when you are prepared to resolve the comments. If so, please file your request for withdrawal before the automatic effectiveness date.

Market Data, page i

2. With regard to third party data referenced throughout, please provide copies of these industry publications, surveys, and other sources of statistics, clearly marking the relevant

sections of these reports. Also, please tell us whether these materials were prepared at your request or in connection with the registration statement.

Item 1 – Business, page 1

3. Please revise this section to describe the distribution methods for your products, whether you manufacture your products, sources and availability of raw materials and the names of principal suppliers. In this regard, we note your risk factor, “We depend on a limited number of manufacturers and suppliers...” on page 10. In addition, revise to describe the terms of any material agreements.

Our Product, page 2

4. Please revise to describe in greater detail how your product will be used. For example, we note your statement that your product may be turned on or off at any time allowing the patient intervals of freedom to perform certain activities. Please revise your disclosure to discuss whether the product is expected to be used all the time or for certain hours and whether the product can be used at home by a patient or whether use of your product requires a visit to a medical facility. Please also revise to disclose specifically the types of activities which are allowable and the restrictions on activities when the product is turned on or off.
5. We note that your product is implanted between the patient’s ribs and sternum. Please reconcile the implantation of the device with your statements that the device “does not directly contact the patient’s blood.”

Clinical Development, page 2

6. We note your statements on page 25 that you have completed enrollment in your feasibility clinical trial. Please revise to discuss any results from the current feasibility study and the status of the study. If you have conducted other clinical trials, please revise to discuss the dates and results of those clinical trials, as well. In addition, please discuss the status of your IDE application, including the remaining hurdles to approval.
7. We note also your statement on page 1 that you are seeking CE Mark approval for your product and that you anticipate that you will obtain approval in early 2012. Please revise to describe the status of your CE Mark approval, the steps you have taken to seek CE Mark approval and the steps which still need to be taken before approval.

Sales and Marketing, page 3

8. Please revise to clarify the “initial steps” you have taken to develop a network of physicians and clinics in Europe.

Competition, page 4

9. We note that your disclosure describes only the perceived advantages of your product relative to the competition. Please also describe the competitive disadvantages of your product relative to other products used at the same or earlier stages of heart failure. If you are unable to identify the disadvantages, add appropriate disclosure stating that the efficacy of your product, including potential competitive disadvantages, is not known.

Comparison of Year Ended December 31, 2010 to Year Ended December 31, 2009

Revenue, page 26

10. Please revise to clarify whether all of the revenues earned during the years ended December 31, 2010 and December 31, 2009 resulted from your feasibility clinical trial.

Sources of Liquidity, page 27

11. When note that your current funds are sufficient to continue your operations “into 2012.” Please specify when you expect to require additional funds and describe the course of action you propose to take in order to obtain additional financing.

Item 5 – Beneficial Owners of More than Five Percent of our Common Stock, page 29

12. Please revise to identify the natural persons with voting or investment power over the shares beneficially owned by entities listed in the table.

Directors and Executive Officers, page 29

13. Please revise the table to include Nicholas Callinan’s position as Chairman of the Board.

Directors, page 30

14. Please revise Paul Buckman’s biography to describe briefly the principal business of Pathway Medical Technologies, Inc. Please also revise to specify the dates when Dr. Mark Harvey and Donal O’Dwyer served as directors of the entities listed in their respective biographies.

Item 6 – Executive Compensation, page 33

15. Please revise to describe how the board set the salary of Dr. Peters and Debra Kridner, given that there are no employment agreements with these individuals.

Related Party Transactions, page 37

16. We note section 2 of Exhibit 10.15. Please revise to describe in greater detail the services that WSP provides. Additionally, please revise to clarify that this agreement requires that Williams Peter serve as your Medical Director and Chief Technical Officer.

Item 9 – Market Price of and Dividends...., page 37

17. We note your disclosure that 235,634,277 shares of your common stock may be sold by your existing stockholders without restrictions under Rule 144. Please revise to clarify whether this number includes those shares owned by your affiliates.

Common Stock, page 49

18. We note your statement that you are authorized to issue up to 196,000,000 shares of common stock. However, we note Article IV.A of your Articles of Incorporation which states that you are authorized to issue 1,960,000,000 shares of common stock. Please revise.

Financial Statements, page F-1

Note 4. Income Taxes, page F-12

19. We note your disclosures regarding the recognition of a \$670,000 tax benefit in 2010 as a result of your foreign subsidiary's R&D tax credit rebate. With a view toward enhanced disclosure, please explain to us in greater detail the nature of the rebate and the circumstances surrounding your recognition of it only during that period. Tell us what your expectations are for future rebates considering anticipated increases in research and development expenses and expected continued losses.

Exhibits

20. Please tell us why you have not filed your lease agreements for your corporate headquarters in Eden Prairie, Minnesota and your office space in St. Leonards, New South Wales, Australia.

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 the information the Securities Exchange Act of 1934 and all applicable Exchange Act rules require. 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.

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In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

You may contact David Burton at (202) 551-3626 or Lynn Dicker, accounting reviewer, at (202) 551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Allicia Lam at (202) 551-3316 or Daniel Morris, Special Counsel, at (202) 551-3314 with any other questions.

Sincerely,

/s/ Daniel Morris for

Amanda Ravitz  
Assistant Director

cc (by e-mail): Matthew R. Kuhn -- Faegre & Benson LLP