

**IMPACT OF SOX ON THE MEDICAL EQUIPMENT INDUSTRY**  
**Section 404 Material Weaknesses**  
**For Companies with Years Ended in 2006**  
**As of May 14, 2007**

The following is a copy of the nine adverse reports that were issued from companies in the Medical Equipment industry with years ended in 2006. These were all of the accelerated filers in the Medical Equipment industry with adverse Sarbanes-Oxley Section 404 management self assessments. This information was gathered using the online research tool called Audit Analytics an Ives Group, Inc company.

The following is a summary of the **material internal control weaknesses** reported in the nine adverse Section 404 Self Assessments:

IC - Accounting documentation, policy and/or procedures	9
IC - Material and/or numerous auditor /YE adjustments	6
IC - Restatement or nonreliance of company filings	3
IC - Senior management competency, tone, reliability issues	2
IC - Accounting personnel resources, competency/training	2
IC - Non-routine transaction control issues	1
IC - Restatement of previous 404 disclosures	1
IC - Ethical or compliance issues with personnel	1
IC - Untimely or inadequate account reconciliations	1

The following is a summary of the **material accounting weaknesses** reported in the nine adverse Section 404 Self Assessments. Section 404 is not just about internal control issues, but also about misapplication of financial accounting and reporting issues:

Acc - Foreign, related party, affiliated and/or subsid issues	2
Acc - Inventory, vendor and cost of sales issues	2
Acc - Tax expense/benefit/deferral/other (FAS 109) issues	2
Acc - Acquisition, merger, disposal or reorganization issues	1
Acc - Consolidation, (Fin46r/Off BS) & foreign curr transl issues	1
Acc - Deferred, stock-based or executive comp issues	1
Acc - Depreciation, depletion or amortization issues	1
Acc - Expense recording (payroll, SG&A) issues	1
Acc - Intercompany/Investment w/ sub/affil issues	1
Acc - Liabilities, payables, reserves and accrual est failures	1
Acc - Revenue recognition issues	1

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**STAAR SURGICAL CO**

Management Report on Internal Control Over Financial Reporting The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rule 13a-15(f) and for assessing the effectiveness of its internal control over financial reporting. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements in accordance with United States' generally accepted accounting principles. Our management, including the CEO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material errors. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations on all internal control systems, our internal control system can provide only reasonable assurance of achieving its objectives and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of internal control is also based in part upon certain assumptions about the likelihood of future events, and can provide only reasonable, not absolute, assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in circumstances, or the degree of compliance with the policies and procedures may deteriorate. The Company's management, with the participation of the CEO and CFO, conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of December 29, 2006, the end of our fiscal year. Management based its assessment on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. A material weakness is a control deficiency, or a combination of control deficiencies that results in more than a remote likelihood that a material misstatement of annual or interim financial statements will not be prevented or detected. In connection with the assessment described above, management has identified the following material weakness as of December 29, 2006: Failure to design and maintain controls over and in its German subsidiary sufficient to detect and prevent management override and fraud • Control Environment The Company did not maintain an effective control environment because of the following: (a) the Company did not adequately and consistently reinforce the importance of adherence to controls and the Company's code of conduct; (b) the Company failed to institute all elements of an effective program to help prevent and detect fraud by Company employees; and (c) the Company did not maintain effective corporate and regional management oversight and monitoring of operations to detect managements' override of established financial controls and accounting policies, execution of improper transactions and accounting entries to impact revenue and earnings, and reporting of these transactions to the appropriate finance personnel or the Company's independent registered public accounting firm.

As a result of the material weakness described above, management has concluded that our internal control over financial reporting was not effective as of the end of the fiscal year ended December 29, 2006. BDO Seidman LLP, the independent registered public accounting firm that audited and reported on the consolidated financial statements of



the Company contained in this report, has issued an attestation report on management's assessment of our internal control over financial reporting, which appears on Page F-3 of this Annual Report on Form 10-K.

## **I FLOW CORP /DE/**

Management Report on Internal Control Over Financial Reporting The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as amended, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. An internal control material weakness is a significant deficiency, or a combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2006. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on this assessment, management concluded that, as of December 31, 2006, the Company did not maintain effective internal control over financial reporting due to a material weakness identified in our internal control over financial reporting, resulting from the failure to maintain effective controls over the accounting for income taxes. Specifically, the Company did not maintain effective controls to determine the completeness and accuracy of the components of the income tax provision calculations and the related deferred income taxes as prepared by its outside tax specialist. This material weakness resulted in the restatement of the Company's financial statements for the quarter ended September 30, 2006. During the three and nine months ended September 30, 2006, the Company recorded a release of its valuation allowance for deferred tax assets due to the pending sale of InfuSystem. The remaining valuation allowance relates to temporary timing differences that are not currently determined to be more likely than not to be realized. As part of the release of the valuation allowance, the Company also reversed the valuation allowance related to the excess tax benefits from stock-based compensation expense from its deferred tax asset and recorded the corresponding credit to additional paid-in capital. In May 2006, the FASB issued additional guidance to SFAS 123R stating that if an entity reverses its valuation allowance under SFAS 109 subsequent to the adoption of SFAS 123R, the entity should reverse the valuation allowance related to the excess tax benefit only when the tax benefit is realized. The tax benefit is not expected to be realizable until the InfuSystem sale is completed. As such, the reversal of the valuation allowance related to the excess tax benefit was not allowed and both deferred tax asset and additional paid-in capital, as previously reported, were overstated as of September 30, 2006 by approximately \$8.7 million. In addition, the Company did not correctly classify current and non-current deferred tax assets in its consolidated balance sheet as of September 30, 2006 in accordance with the guidance in SFAS 109, which resulted in an overstatement of current and an understatement of non-current deferred tax assets of approximately \$7.2 million at September 30, 2006, as

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previously reported. The Company's independent registered public accounting firm has issued their report on management's assessment of the Company's internal control over financial reporting which appears on the following page. March 30, 2007

## **EXACTECH INC**

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Section 13a-15(f) of the Securities Exchange Act of 1934, as amended). Internal control over financial reporting is a process designed by, or under the supervision of, the Company's CEO and CFO to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in conformity with U.S. generally accepted accounting principles and include those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

### Management's Assessment

As of December 31, 2006, management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the framework established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on the criteria established by COSO and the identification of a material weakness (as further discussed below), management concluded that the Company's internal control over financial reporting was ineffective as of December 31, 2006 as it did not provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles.

A material weakness is a significant deficiency (within the meaning of Public Company Accounting Oversight Board (PCAOB) Auditing Standard No. 2), or combination of significant deficiencies, that result in there being a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. A significant deficiency is a control deficiency, or combination of control deficiencies, that adversely affects the Company's ability to initiate, authorize, record, process, or report external financial information reliably in accordance with generally accepted accounting principles, such that there is more than a remote likelihood that a misstatement of the Company's annual or interim financial statements, that is more than inconsequential, will not be prevented or detected.

We identified the following material weakness in our internal control over financial reporting—we did not have adequately designed procedures to allocate current and non current inventory balances as required by Accounting Research Bulletin No. 43 (ARB 43). Due to the circumstances described in Note 2 to the consolidated financial statements, management has concluded that a material weakness existed in the Company's design of the existing controls as of December 31, 2006 as defined under standards established by the Public Company Accounting Oversight Board. Management has not identified any other material weaknesses in its internal control over financial reporting. Solely as a result of this material weakness, we concluded that our internal controls over financial reporting

were not effective as of December 31, 2006.

#### Limitations on the Effectiveness of Controls

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

#### Auditor Report

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their attestation report which is included herein.

Remediation Plan – The Company's management has taken steps to remediate the material weakness identified in Managements Report on Internal Control over Financial Reporting, through the design of controls surrounding the balance sheet classification of inventory within current and non-current assets. Management will monitor, evaluate and test the operating effectiveness of these controls in future periods.

Changes in Internal Controls – No change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fourth quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **DJO INC**

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- (1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- (2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- (3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting cannot provide absolute assurance of

achieving financial reporting objectives. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over our financial reporting. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become ineffective because of changes in conditions or that the degree of compliance with established policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2006 using the framework set forth in the report entitled Internal Control—Integrated Framework published by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. We completed the acquisitions of Axmed in January 2006 and Aircast in April 2006, as more fully described in Note 3 to the consolidated financial statements included in Part II, Item 8 herein. As part of our ongoing integration activities, we are in the process of incorporating the operations of Axmed and Aircast into our controls and procedures and we expect to complete the process by no later than January 2, 2007 for Axmed and April 7, 2007 for Aircast. Management has excluded from its evaluation of the effectiveness of its internal control over financial reporting as of December 31, 2006 certain elements of the internal control over financial reporting of Axmed and Aircast, which constituted approximately \$19.2 million and \$43.9 million of net revenues for Axmed and Aircast, respectively, for the year ended December 31, 2006 and \$10.0 million and \$16.4 million of total assets for Axmed and Aircast, respectively, as of December 31, 2006. We plan to include these businesses into our assessment of the effectiveness of our internal controls within one year of each respective acquisition. In conducting its assessment, management identified a material weakness in internal control over financial reporting as of December 31, 2006. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

As of December 31, 2006, we had a control deficiency regarding the transfer and integration of inventory from Aircast which took place in the fourth quarter of 2006. During the course of our independent registered public accounting firm's audit of our financial statements for the year ended December 31, 2006, it was determined that we did not perform adequate detailed procedures with regards to inventory in-transit and the reconciliation of the related intercompany transactions. Our performance of additional detailed procedures resulted in adjustments to the inventory and costs of goods sold which were material to net income. Such adjustments have been recorded by us in our financial statements included in Part II, Item 8 of this Form 10-K. This control deficiency results in a more than remote likelihood that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis by employees during the normal course of performing their assigned functions. Therefore, management has concluded that our internal control over financial reporting was not effective as of December 31, 2006.

Ernst & Young LLP, our independent registered public accounting firm, has issued an attestation report on management's assessment of our internal control over financial reporting which is included below.

## **BIOPHAN TECHNOLOGIES INC**

The management of Biophan Technologies, Inc. is responsible for establishing and maintaining adequate internal

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control over financial reporting for the company. With the participation of the Chief Executive Officer and the Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of November 30, 2005, February 28, 2006, May 31, 2006 and August 31, 2006, based on the framework and criteria established in Internal Control -- Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our Quarterly Report on Form 10-Q for the period ended November 30, 2005 (filed on January 17, 2006), in our Annual Report on Form 10-K for the year ended February 28, 2006 (originally filed on May 15, 2006 and amended on June 6, 2006) and in our Quarterly Reports on Form 10-Q for the periods ended May 31, 2006 (filed on July 10, 2006) and, August 31, 2006 (filed on October 13, 2006) management concluded that our internal control over financial reporting was effective as of the end of the periods covered by such reports. Subsequently, management identified a material weakness in internal control over financial reporting with respect to accounting for the investment in Myotech, LLC on November 30, 2005.

This material weakness resulted in this amendment to our Annual Report on Form 10-K for the year ended February 28, 2006 in order to restate the financial statements for the year ended February 28, 2006 and to restate financial information for the quarters ended November 30, 2005, May 31, 2006 and August 31, 2006.

Solely as a result of this material weakness, our management has revised its earlier assessment and has now concluded that our internal control over financial reporting was not effective as of February 28, 2006, or for the quarterly periods ended November 30, 2005, May 31, 2006 and August 31, 2006.

## **CYBERONICS INC**

**Management's Report on Internal Control Over Financial Reporting** Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, the design of any system of control is based upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all future events, no matter how remote, or that the degree of compliance with the policies or procedures may not deteriorate. Accordingly, even effective internal control over financial reporting can only provide reasonable assurance of achieving financial reporting objectives. In connection with the preparation of our annual consolidated financial statements, our management, under the supervision and with the participation of our CEO and CFO, assessed the effectiveness of our internal control over financial reporting based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operating effectiveness of our internal control over financial

reporting. During this evaluation, management identified a material weakness in our internal control over financial reporting, as described below. Management has concluded that, as a result of this material weakness, our internal control over financial reporting was not effective as of April 28, 2006 based upon the criteria issued by COSO. A material weakness is a control deficiency, or a combination of control deficiencies, that result in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As of April 28, 2006, we had inadequate controls over the accounting for and disclosure of stock-based compensation. Specifically, we identified a material weakness comprised of the following internal control deficiencies:

- Failure to recognize stock option granting practices as a significant risk and to ensure that all individuals involved in the granting process understood their appropriate roles and responsibilities and the consequences of their actions; • Lack of communication between individuals involved in the compensation approval process and personnel responsible for the accounting treatment of equity-based awards;
- Lack of accounting expertise and knowledge related to accounting for certain equity-based awards; • Inadequate policies and procedures regarding maintenance of records supporting the granting activities, grant date, and authorization of equity-based transactions;
- Inadequate policies and procedures regarding preparation and retention of documentation of stock option granting procedures and practices; and
- Inadequate supervision and training for personnel involved in the stock option granting process. This material weakness resulted in the material misstatement of stock-based compensation expense in the company's consolidated financial statements for the 2004 and 2005 fiscal years and each of the quarters of fiscal 2005 and 2006 and the Company is restating previously issued financial statements for the 2004 and 2005 fiscal years and each of the quarters of fiscal years 2005 and 2006. KPMG LLP, an independent registered public accounting firm, has issued an audit report on management's assessment of internal control over financial reporting. (c) Changes in Internal Control Over Financial Reporting There were no changes in our internal control over financial reporting during the fourth quarter of the fiscal year ended April 28, 2006 in connection with the aforementioned evaluation that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. In response to the material weakness identified by our management, we have dedicated significant resources to improve our control environment and to remedy the material weakness identified. These efforts include the following:
  - Establishing that all equity grants, other than grants to our Board, must be approved by the Compensation Committee at a meeting of the Compensation Committee held on or before the effective date of the grant;
  - Establishing that equity grants to non-executive members of our Board must be approved by a vote of the full Board at a meeting of our Board held on or before the effective date of the grant;
  - Establishing that all internal approvals of grant awards must be obtained in writing prior to any Board Compensation Committee action granting an equity award;
  - Establishing predefined dates for the granting of all equity-based awards; and
  - Establishing responsibility in one office for maintenance of records documenting all grant approvals. In addition, the

following measures will be implemented in the fiscal year ending April 27, 2007:

- Establishing additional education and training for personnel in areas associated with the stock option granting processes and other compensation practices to increase competency levels of the personnel involved; and
- Establishing documented communication channels between Compensation Committee and personnel responsible for accounting treatment of the stock option grants upon approval. Audit Committee Oversight The adequacy of our internal control over financial reporting, the accounting principles employed in our financial reporting and the scope of independent audits are reviewed by the Audit Committee, consisting solely of outside directors. The independent auditors meet with, and have confidential access to, the Audit Committee to discuss the results of their audit work.

## **WRIGHT MEDICAL GROUP INC**

Management's Annual Report on Internal Control over Financial Reporting Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Under the supervision of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2006, based on the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, we have identified a material weakness in internal control over financial reporting described below, and as such, and based upon the criteria issued by COSO, our management has concluded that our internal control over financial reporting was not effective as of December 31, 2006. A material weakness is a control deficiency, or combination of deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006, has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report included within this Annual Report. Inadequate Controls over the Calculation of Depreciation Expense As of December 31, 2006, the Company had ineffective policies and procedures relating to the calculation of depreciation expense for its surgical instruments. Specifically, we did not have policies and procedures in place to ensure that depreciation expense was calculated based on the appropriate cost basis of these assets, resulting in an error in depreciation expense and accumulated depreciation, which was corrected in our 2006 financial statements. Management has determined that this deficiency resulted in a more than remote likelihood that a material misstatement of our annual or interim financial statements would not be prevented or detected. (c) Changes in Internal Control over Financial Reporting There were no changes in our internal control over financial reporting during the quarter ended December 31, 2006, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. (d) Remediation of Controls over the Calculation of Depreciation Expense In response to the material weakness noted above, we performed an in-depth review of the Company's policies and procedures for determining depreciation expense and adjusted the calculation to include the correct cost basis for the surgical instruments. Additionally, the method for capturing the proper cost basis of these assets has been revised to appropriately calculate depreciation expense in the future. The calculation of depreciation expense will continue to be reviewed on a monthly basis as part of our internal control over financial reporting. Based upon the corrective actions identified above, we believe that the controls we have implemented have been designed to remediate the material weakness as of the filing date of this Annual Report.

## **VNUS MEDICAL TECHNOLOGIES INC**

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING Our management is responsible for

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establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and timely reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has assessed the effectiveness of our internal control over financial reporting as of December 31, 2006. In making this assessment, our management used the criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management's assessment identified the following material weakness in our internal control over financial reporting as of December 31, 2006. The Company did not maintain effective controls over the completeness and accuracy of accrued liabilities and operating expenses. Specifically, the Company failed to maintain effective controls over the cutoff of vendor invoices to ensure that all liabilities were recorded in the appropriate accounting period. This control deficiency resulted in an audit adjustment to the Company's 2006 annual consolidated financial statements. Additionally, this control deficiency could result in a misstatement of accrued liabilities and related operating expenses that would result in a material misstatement of the Company's annual or interim consolidated financial statements that would not be prevented or detected. Because of the material weakness above, we have concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2006. Management's assessment of the effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report appearing in Item 8 of this Annual Report on Form 10-K.

## **BAUSCH & LOMB INC**

Management's Report on Internal Control Over Financial Reporting Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process, under the supervision of the Company's Chief Executive Officer and Chief Financial Officer, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the Company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the

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Company's assets that could have a material adverse effect on the financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. It should be noted that any system of internal control, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of December 30, 2006 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of annual or interim financial statements will not be prevented or detected. In connection with the assessment described above, management has identified the following material weaknesses as of December 30, 2006: (1) Control Environment The Company did not maintain an effective control environment because of the following: (i) the Company did not adequately and consistently reinforce the importance of adherence to controls and the Company's code of conduct and (ii) the Company did not maintain a sufficient complement of personnel with an appropriate level of knowledge, experience and training in the application of GAAP, including accounting for income taxes, and in internal controls over financial reporting commensurate with its financial reporting requirements. This material weakness contributed to the additional material weakness discussed in Item 2 below and to control deficiencies as well as adjustments, including audit adjustments, to the 2006 annual consolidated financial statements in the financial reporting and close process. (2) Controls Over Tax Accounting The Company did not maintain effective controls over the determination and reporting of its income tax payable, deferred income tax assets and liabilities, the related valuation allowances and income tax expense. Specifically, effective controls were not designed and in place to: (i) ensure management maintained the appropriate level of personnel resources with adequate experience and expertise in the area of U.S. GAAP accounting for income taxes; (ii) ensure roles and responsibilities with respect to accounting for income taxes were clearly defined; (iii) identify and evaluate in a timely manner the tax implications of certain non-routine transactions, including transactions related to acquisitions; (iv) provide reasonable assurance as to the completeness and accuracy of the provision for income taxes and income taxes payable including tax reserves and return to provision adjustments; and (v) reconcile differences between the tax and financial reporting basis of its assets and liabilities with its deferred income tax assets and liabilities. In addition, the Company did not maintain effective controls over indirect taxes, including VAT and certain import related taxes related to its Brazilian subsidiary. This material weakness resulted in adjustments, including audit adjustments, to the 2006 annual consolidated financial statements.

Additionally, each of these material weaknesses above could result in a material misstatement to the Company's interim or annual consolidated financial statements and disclosures which would not be prevented or detected. As a result of these material weaknesses described above, management has concluded that, as of December 30, 2006, the Company's internal control over financial reporting was not effective based on the criteria in Internal Control-Integrated Framework issued by the COSO. Management's assessment of the effectiveness of the Company's internal control over financial reporting as of December 30, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included under the Report of Independent Registered Public Accounting Firm in this Annual Report on Form 10-K.