SECURITIES AND EXCHANGE COMMISSION

# FORM 10-K/A

Annual report pursuant to section 13 and 15(d) [amend]

Filing Date: 2005-05-02 | Period of Report: 2004-12-31 SEC Accession No. 0000950116-05-001611

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# **FILER**

## **MED-DESIGN CORP**

CIK:943736| IRS No.: 232771475 | Fiscal Year End: 1231 Type: 10-K/A | Act: 34 | File No.: 000-25852 | Film No.: 05791846 SIC: 3841 Surgical & medical instruments & apparatus Mailing Address 2810 BUNSEN AVE VENTURA CA 93003

Business Address 2810 BUNSEN AVE VENTURA CA 93003 8053390375

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

FORM 10-K/A (Amendment No. 1)

|X| ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

OR

|\_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_\_ to

Commission file number: 0-25852

 $\label{eq:themapping} \begin{array}{c} \text{THE MED-DESIGN CORPORATION} \\ \text{(Exact name of registrant as specified in its charter)} \end{array}$ 

Delaware23-2771475(State or other jurisdiction of<br/>incorporation or organization)(I.R.S. Employer<br/>Identification No.)

2810 Bunsen Avenue, Ventura, CA93003(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code: (805) 339-0375

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$0.01 per share (Title of Class)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes |X| No |

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in the definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K |X|.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  $|\rm X|$  No | |

The aggregate market value of voting stock held by non-affiliates of the Registrant (computed by reference to the last reported sale price of such stock on June 30, 2004) was \$10,768,403. The number of shares of Registrant's common stock outstanding as of April 23, 2005 was 16,622,690.

## Explanatory Note

In Release No. 34-50754, The Securities and Exchange Commission issued an exemptive order providing a 45-day extension for the filing of management's annual report on internal control over financial reporting and the independent registered public accountants' attestation by eligible companies. We elected to utilize this extension period, and are filing this amendment to our Annual Report on Form 10-K, filed on March 31, 2005 to include Management's Annual Report on Internal Control over Financial Reporting and the Report of Independent Registered Public Accounting Firm in Item 9A. We are also providing information responsive to the disclosure requirements of Part III of Form 10-K.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Acting Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Disclosure controls and procedures are defined in SEC regulations as controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Due to the material weakness in internal control discussed in Management's Annual Report on Internal Control Over Financial Reporting on the following page of this report, the Acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2004.

As noted in Management's Annual Report on Internal Control Over Financial Reporting, the material weakness related to misapplication of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment of Long-Lived Assets," in connection with our evaluation of the recoverability of acquired license rights. Management is reviewing its processes for evaluation of acquired assets and application of the relevant accounting principles.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management's annual report on internal control over financial reporting is set forth on the following page of this report and is incorporated by reference herein.

(c) Change in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

2

MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of The Med-Design Corporation is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process 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. A company's internal control over financial reporting 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 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.

Management evaluated the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the framework established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded that the Company's internal control over financial reporting was not effective as of December 31, 2004 because of the material weakness outlined below.

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 financial statements would not be prevented or detected.

Management has identified the following material weakness in connection with its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2004:

The Company lacked effective controls over the processes and procedures involved in the application of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment of Long-Lived Assets" ("FAS 144") in connection with the Company's evaluation of the recoverability of acquired license rights. Specifically, in applying the impairment test for a long lived asset to be held and used, namely the acquired license rights, the Company analyzed future cash flows over a period that was less than the estimated useful life of the asset. Paragraph 18 of FAS 144 requires that the impairment test be based on all cashflows expected to result from the use and eventual disposition of the asset. The misapplication was identified by the Company's independent registered public accountants as part of the year-end audit. As a result, the Company recorded adjustments in the consolidated financial statements for the year ended December 31, 2004 to reverse a previously recorded impairment charge. The adjustment related to the fourth quarter of 2004 and did not affect prior periods.

The Company's independent auditors, BDO Seidman, LLP, have audited management's assessment of the Company's internal control over financial reporting. Their opinions on management's assessment and the effectiveness of the Company's internal control over financial reporting appear on the following page of this report.

Acting Chief Executive Officer

Chief Financial Officer

May 2, 2005

3

Report of Independent Registered Public Accounting Firm

Board of Directors The Med-Design Corporation Ventura, California

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that The Med-Design Corporation did not maintain effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Med-Design Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process 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. 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 dispositions 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 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 (3) 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.

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 of the Company will not be prevented or detected. The following material weakness was identified and included in management's assessment:

The Company's controls over the review of financial reporting did not operate effectively. This material weakness could have affected the Company's ability to prepare annual or interim financial statements in accordance with GAAP and resulted in the misapplication of Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment of Long-Lived Assets" ("SFAS 144"), in connection with the Company's evaluation of the recoverability of acquired license rights in the fourth quarter of 2004. In applying the impairment test for this asset, the Company analyzed future cash flows over a period that was less than the estimated useful life of the asset. SFAS 144 requires that the impairment test be based on all cash flows expected to result from the use and eventual disposition of the asset. Undiscounted cash flows for the estimated useful life of the asset were greater than its carrying amount. Thus no impairment had occurred. This caused the Company to reverse a previously recorded impairment charge. This adjustment related to the fourth quarter of 2004 and did not affect prior periods.

This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2004 consolidated financial statements, and this report does not affect our report dated March 29, 2005 on those consolidated financial statements.

4

In our opinion, management's assessment that The Med-Design Corporation did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, The Med-Design Corporation has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of The Med-Design Corporation as of December 31, 2004 and the related consolidated statements of operations, changes in stockholders' equity and comprehensive loss, and cash flows for the year then ended, and our report dated March 29, 2005 expressed an unqualified opinion.

/s/ BDO Seidman, LLP

Los Angeles, California April 27, 2005

5

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Name	Age	Position(s)
Vincent J. Papa (1)(2)	55	Chairman of the Board
Joseph N. Bongiovanni, III	60	Vice President, Secretary and Director
Ralph Balzano (3)	68	Director
Paul D. Castignani (1)(4)	59	Director
D. Walter Cohen (2)(3)	78	Director
James M. Donegan (4)	54	Director
Stephen E. Smith, Jr. (3)	47	Director
Pasquale L. Vallone (1)(2)	77	Director
Gilbert M. White (2)(3)	67	Director

David R. Dowsett	51	Acting Chief Executive Officer
Lawrence D. Ellis	54	Vice President, Chief Financial Officer

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(1) Member of the Audit Committee of the Board of Directors

(2) Member of the Compensation Committee of the Board of Directors

(3) Member of the Nominating Committee of the Board of Directors

(4) Member of the Investment Committee of the Board of Directors

Vincent J. Papa has served as Chairman of the Board since August 2004 and has served as a director since 1998. Mr. Papa has served as Senior Vice President and Secretary of Energy Merchants Corporation since 1999. From 1995 to 1999, Mr. Papa was a Managing Director and General Counsel for P.M.G. Capital Corp., a wholly-owned affiliate of the Pennsylvania Merchant Group.

Joseph N. Bongiovanni, III, has served as a director of Med-Design and our Vice President and Secretary since 1994. Since 1978, Mr. Bongiovanni has been the senior partner of the law firm of Bongiovanni & Berger.

Ralph Balzano has served as a director of Med-Design since January 2001. Mr. Balzano has been an independent systems consultant since January 2001 for Balzano LLC. He served as Chief Information Officer for the South Manhattan Network of New York Hospital Corporation from 1998 to 2000. Mr. Balzano served as Chief Information Officer for the City of New York and Commissioner of the Department of Information Technology & Telecommunications from 1994 to 1998.

Paul D. Castignani has served as a director of Med-Design since July 2002. Mr. Castignani has been an independent consultant since October 2003. From 1987 to 2003, Mr. Castignani held various positions at Eagle National Bank, most recently as Senior Vice President and Chief Financial Officer.

D. Walter Cohen, D.D.S. has served as a director of Med-Design since July 2002. Dr. Cohen is a practicing dentist with Louis Rose D.D.S. & Associates, where he has practiced since September 2003. From 1993 to 2003, Dr. Cohen was a Professor of Periodontics at the Medical College of Pennsylvania. He is also a former professor and dean of the School of Dental Medicine at the University of Pennsylvania. Dr. Cohen has authored or co-authored numerous books and articles on various medical topics. He is a member of the Institute of Medicine of the National Academy of Sciences. Dr. Cohen was also a member of the Board of Directors of Atrix Laboratories, Inc. until November 2004.

6

James M. Donegan has served as a director of Med-Design since 1995. Mr. Donegan was our Chairman of the Board from 1995 until August 2004 and our Chief Executive Officer and President from 1995 until October 2004. From 1991 to 1995, Mr. Donegan held various positions at Chase Manhattan Bank, including marketing executive for the Structured Investment Division and most recently as the Managing Director of Chase Futures Management, Inc.

Stephen E. Smith has served as a director of Med-Design since September 2003. Mr. Smith has been involved in the Kennedy family financial investment and real estate development business for the past 20 years. He is also a Founding Partner of K.S.S. Realty Partners and is responsible for investor relations, capital raising and investment strategy. Mr. Smith founded and is Chairman of Social Media, a media company, and Kennedy Smith Sammaweera, a real estate investment and development business specializing in developing technology related to real estate.

Pasquale L. Vallone has served as a director of Med-Design since 1998. Mr. Vallone has been a consultant for U.S. Aviation Underwriters, Inc. since July 1997. Mr. Vallone served in the underwriting and technical areas at U.S. Aviation Underwriters for fifty years until his retirement as a Senior Vice President in June 1997.

Gilbert M. White has served as a director of Med-Design since 1994 and served as an Executive Vice President of Med-Design from 1995 until January 1998. Mr. White is currently an independent insurance consultant. From 1984 until joining Med-Design in 1995, Mr. White was Senior Vice President of Rollins Hudig Hall, a multinational insurance firm, where he designed, marketed and serviced complex insurance programs for large national and international clients.

David R. Dowsett has served as our acting Chief Executive Officer since October 2004. He served as our Vice President and Chief Operating Officer from

June 2002 until October 2004. From 1997 to May 2002, Mr. Dowsett served in a number of capacities at Becton, Dickinson and Company, most recently as Worldwide Director in the Infusion Therapy Systems business. Between 1980 and 1997, Mr. Dowsett held various sales, marketing and business development positions at C.R. Bard, a company engaged in the development, manufacturing and supply of healthcare products.

Lawrence D. Ellis has served as our Vice President and Chief Financial Officer since 1997. From 1991 to 1995, Mr. Ellis served as Controller for Phonotics, Inc., a company engaged in the research and development and manufacturing of fiber optic test equipment. In addition, Mr. Ellis has six years of public accounting experience with Ernst & Young, LLP.

## Code of Conduct

We have adopted a Code of Conduct that applies to our employees including our acting chief executive officer, chief financial officer, all other officers and our directors. Our Code of Conduct is posted on the Investor Relations section of our website at www.med-design.com and may be obtained free of charge by sending a written request to The Med-Design Corporation, Attention: Investor Relations, 2810 Bunsen Avenue, Ventura, California, 93003. We intend to satisfy the disclosure requirements regarding any amendment to, or waiver from, a provision of our Code of Conduct by disclosing such matters in the Investor Relations section of our website.

#### Audit Committee Financial Expert

Our Board of Directors has determined that Paul Castignani, a member of our Audit Committee, is an audit committee financial expert as defined in Securities and Exchange Commission regulations. Mr. Castignani is independent within the meaning of the rules of the Nasdaq Stock Market, Inc.

### Audit Committee

We have a standing Audit Committee that, among other things, was established by the Board of Directors for the purpose of overseeing our accounting and financial reporting processes and audits of our financial

7

statements. The members of our Audit Committee are Messrs. Paul D. Castignani, Vincent J. Papa and Pasquale L. Vallone. Mr. Castignani is the Chairman of our Audit Committee.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers, and persons who own more than ten percent of our common stock, to file reports of ownership of our securities and changes in ownership with the Securities and Exchange Commission. To our knowledge, based solely on a review of the copies of such reports furnished to us and representations of these persons that no other reports were required, during the year ended December 31, 2004, all of our directors, executive officers and greater than 10% stockholders complied with all Section 16(a) filing requirements.

### ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

Name and Principal Position

\_\_\_\_\_

The following table sets forth for the years ended December 31, 2004, 2003 and 2002, information regarding compensation we paid to our Chief Executive Officer and the other most highly paid executive officers whose total annual salary and bonus exceeded \$100,000 for the year ended December 31, 2004.

## Summary Compensation Table

Year

\_\_\_\_

<C>

<TABLE> <CAPTION>

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Long-Term Compensation -----Awards \_\_\_\_\_ Restricted Stock Other Annual Securities Bonus(\$) Compensation(\$) Underlying Options Awards(\$) \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ <C> <C>

Salary (\$)

<C>

\_\_\_\_\_

Annual Compensation

\_\_\_\_\_

\_\_\_\_\_

<C>

<C>

James M. Donegan	2004	354,000		753,738(1)	 
Former Chairman, Chief Executive	2003	354,000		753,738(1)	 20,000
Officer and President	2002	354,000	50,000	753,738(1)	 200,000
	2004	218,400			 
David R. Dowsett(2)	2003	210,000		40,000(3)	 37,500
Acting Chief Executive Officer,	2002	115,272		40,000(3)	 300,000
Lawrence D. Ellis	2004	174,720			 
Vice President and	2003	168,000			 
Chief Financial Officer	2002	168,000	30,000		 89,000
Joseph N. Bongiovanni, III	2004	166,400			 
Vice President and Secretary	2003	160,000			 
	2002	160,000	30,000		 67,000

  |  |  |  |  |-----

- (1) Represents 59,702 shares of common stock for 2004, 2003 and 2002 awarded to Mr. Donegan as compensation for past service. In 2000, our Compensation Committee, after consultation with outside professional compensation consultants, determined that Mr. Donegan had been under-compensated since our inception and authorized an award of approximately 59,701 shares of common stock per year for the following four years as compensation for past service, or an aggregate of 238,806 shares.
- (2) Mr. Dowsett was initially employed by us as our Chief Operating Officer and Vice President on June 1, 2002.
- (3) Represents payments for relocation for Mr. Dowsett.

8

### Stock Options

No stock options were granted to executive officers in 2004.

## Fiscal Year-End Values

The following table summarizes the value of vested and unvested options for the persons named in the Summary Compensation Table at December 31, 2004. Year-end values are based upon a price of \$1.30 per share, which was the closing price of a share of our common stock on December 31, 2004 as reported on the Nasdaq National Market. No options were exercised by the named executive officers in 2004.

Aggregate Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

<TABLE> <CAPTION>

CAPITON			Number Of Securities Underlying Unexercised Options At Fiscal Year-End		Value Of Unexercised In-The-Money Options At Fiscal Year-End	
Name	Shares Acquired On Exercise	Value Realized	Exercisable	Unexercisable	Exercisable	Unexercisable
<s> James M. Donegan</s>	<c></c>	<c> \$</c>	<c> 525,800</c>	<c> 525,800</c>	<c> \$ 39,000</c>	<c> \$</c>
James Fr. Donegan		Ŷ	525,000	525,000	÷ 39,000	Ŷ
David R. Dowsett			150,000	187,500		
Lawrence D. Ellis			129,200	67,000		
Joseph N. Bongiovanni, III 						

  |  | 222,000 | 45,000 |  |  |

## Compensation of Directors

Non-employee directors receive \$1,000 per board of directors meeting attended and annually receive options to purchase 9,000 shares of our common stock, with an exercise price equal to the closing market price on the date of grant, as compensation for services on our board of directors. Non-employee directors also receive \$1,000 for each in-person committee meeting attended and \$1,000 for every three telephonic committee meetings attended. No other directors receive cash or other compensation for services on our board of directors or any board committee. All directors are entitled to reimbursement for reasonable expenses incurred in the performance of their duties as board members.

#### Employment Agreements

On June 1, 2002, we entered into a four-year employment agreement with David Dowsett, our current Acting Chief Executive Officer, which agreement was effective as of May 15, 2002. The agreement provides for an annual base salary of \$210,000, a stock option grant covering 300,000 shares and an automobile allowance of \$800 per month. The stock option was issued in two tranches, as to 187,500 shares on May 15, 2002 at an exercise price of \$11.70 per share and as to 112,500 shares on July 26, 2002 at an exercise price of \$6.51 per share. Of the shares underlying the May 15, 2002 grant representing 187,500 shares, 50,000 shares vested on October 15, 2002, 25,000 shares wested on May 15, 2003, 37,500 shares vested on May 15, 2004 and 37,500 shares will vest on each of May 15, 2005 and 2006. Of the shares underlying the July 26, 2002 grant representing 112,500 shares, all will vest on July 26, 2009. The options expire July 26, 2012. Vesting may be accelerated as to one-third, two-thirds and all unvested underlying shares if our earnings per share reaches specified levels.

On October 17, 2003, we extended our employment agreement with Mr. Dowsett to May 15, 2007. The extension does not affect his annual base salary but provided Mr. Dowsett with a stock option grant of 37,500 shares of common stock, which was made on October 17, 2003. The stock option has an exercise price of \$4.14 per share, vested in full on October 17, 2004 and expires on October 17, 2013.

9

On October 10, 2002, we entered into a three-year employment agreement with Lawrence D. Ellis, our Vice President and Chief Financial Officer. The agreement provides for an annual base salary of \$168,000, the grant of a stock option to purchase 89,000 shares of common stock and an automobile allowance of \$850 per month. The stock option has an exercise price of \$3.25 per share and expires October 10, 2012. Of the shares underlying the option, 22,000 shares vested immediately and the remaining shares will vest October 10, 2007. Vesting may be accelerated as to one-third, two-thirds and all unvested underlying shares if the market price of our common stock reaches specified levels.

On October 10, 2002 we entered into a three-year employment agreement with Joseph N. Bongiovanni, our Vice President and Corporate Secretary. The agreement provides for a base salary of \$160,000, the grant of a stock option for 67,000 shares of common stock and an automobile allowance of \$850 per month. The stock option has an exercise price of \$3.25 per share and expires October 10, 2012. Of the shares underlying the option, 22,000 shares vested immediately and the remaining shares will vest October 10, 2007. Vesting may be accelerated as to one-third, two-thirds and all unvested underlying shares if the market price of our common stock reaches specified levels.

## Separation of Employment Agreement with James A. Donegan

James M. Donegan resigned as our President and Chief Executive Officer on October 14, 2004. In connection with his resignation, we entered into a Separation of Employment Agreement and General Release with Mr. Donegan, effective as of October 14, 2004 (the "Agreement"). In connection with the execution of the Agreement, most of the provisions of Mr. Donegan's employment agreement, including the compensatory provisions therein (which provided, among other things, for one-year's severance to Mr. Donegan if he was terminated without cause), terminated. The employment agreement was to expire in October 2005.

Pursuant to the Agreement, Mr. Donegan will continue to serve as one of our directors and will make himself available, on a part-time basis, for consultation with us, reporting directly to our Board of Directors or its committees.

Under the Agreement, we are paying Mr. Donegan aggregate severance of \$497,275.16. Of that amount, \$346,303.98 is being paid in bi-weekly installments from October 14, 2004 through November 15, 2005 (the "Initial Severance Period"), and the remaining \$150,971.18 will be paid in bi-weekly installments from November 15, 2005 through November 14, 2006 (the "Second Severance Period"). During the Initial Severance Period, Mr. Donegan will make himself available for consultation at reasonable times via telephone up to five hours per month. During the Second Severance Period, Mr. Donegan will make himself available for consultation at reasonable times via telephone up to three hours per month. Mr. Donegan may, but is not required to, provide additional consultation at no additional cost to us, other than the reimbursement of his

expenses in connection therewith.

In addition, we are providing medical, life and disability coverage to Mr. Donegan during the Initial Severance Period on the same terms as are available to other senior executives under our medical, life and disability plans. In the event such coverage is no longer available, we will pay any premiums that may be required to continue Mr. Donegan's coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act ("COBRA") through the end of the Initial Severance Period. The estimated cost of this benefit is \$13,200.

In addition, options held by Mr. Donegan to purchase 120,000 shares of our common stock at an exercise price of \$3.25 per share became fully vested on the effective date of the Agreement. Prior to the Agreement, such options would have vested in 2007 or 2008, subject to earlier vesting if the price of our common stock reached specified levels. We also granted to Mr. Donegan fully vested options to purchase an additional 30,000 shares of our common stock at an exercise price of \$0.92 per share, which was the last reported sale price per share on the Nasdaq National Market on October 14, 2004. The options expire in October 2014. In the event of a merger in connection with which options of our executive officers and/or other directors are repriced, we will reprice all options held by Mr. Donegan.

We also agreed that, as required by law, Mr. Donegan will receive a pro rata contribution to his account in our 401(k) plan for the period in which he was employed during 2004. In addition, Mr. Donegan received all benefits accrued or earned as of the date of the Agreement, including accrued and unused vacation time.

10

We also paid \$2,500 per month to cover Mr. Donegan's rent at his corporate residence in California until April 30, 2005, the date of termination of the lease for such residence.

As consideration for the benefits described above, Mr. Donegan provided a general release from any claims against us and any individual or organization related to us. Mr. Donegan also agreed to certain nondisclosure, nonsolicitation and noncompetition covenants.

## Compensation Committee Interlocks and Insider Participation

Gilbert M. White served on our Compensation Committee during 2004. Mr. White served as our Executive Vice President from June 1995 to January 1998.

11

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS  $% \left( {{\left( {{{\left( {{{\left( {{{\left( {{{}} \right)}} \right.} \right.} \right.} \right)}} \right)} \right)}$ 

The following table sets forth as of April 10, 2005 (unless otherwise indicated) information with respect to the beneficial ownership of our common stock (i) by each person known to us to own beneficially five percent or more of our outstanding common stock (the only voting class outstanding), (ii) by each director, (iii) by each of the officers named in the Summary Compensation Table included in this report and (iv) by all executive officers and directors as a group.

<TABLE> <CAPTION>

Name and Address	Number of Shares Beneficially Owned (1)	Percent of Class Beneficially Owned
 <s> Vincent J. Papa</s>	<c> 118,000(2)</c>	<c> *</c>
Joseph N. Bongiovanni, III	232,000(3)	1.4%
Ralph Balzano	75,333(4)	*
Paul D. Castignani	56,624(5)	*
D. Walter Cohen	46,544(6)	*
James M. Donegan	1,224,273(7)	9.4%
Stephen E. Smith, Jr	17,794(8)	*

Pasquale L. Vallone	210,026(9)	1.2%
Gilbert M. White	205,634(10)	1.2%
David R. Dowsett	165,100(11)	*
Lawrence D. Ellis	138,200(12)	*
State of Wisconsin Investment Board	2,347,500(13)	14.0%
Evan Sturza	1,002,500(14)	6.0%
Adage Capital Partners LP	1,726,893(15)	10.3%
Pioneer Global Asset Management S.p.A	1,563,000(16)	9.3%
All current Directors and Officers as a Group (12 persons)	2,579,588(17)	14.2%

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=\*Less than one percent (1%)

- (1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible notes currently exercisable or convertible, or exercisable or convertible within 60 days of April 10, 2005, are deemed outstanding for computing the percentage ownership of the person holding such securities but are not deemed outstanding for computing the percentage ownership of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the person named in the table has sole voting and investment power with respect to all shares of common stock shown as beneficially owned by such person.
- (2) Includes options to purchase 86,000 shares of common stock.

- (3) Includes options to purchase 219,000 shares of common stock.
- (4) Includes options to purchase 75,333 shares of common stock.
- (5) Includes options to purchase 52,544 shares of common stock.
- (6) Includes options to purchase 27,544 shares of common stock and warrants to purchase 18,000 shares of common stock.
- (7) Includes 1,600 shares of common stock held by Mr. Donegan as custodian for his son, and 525,800 shares underlying options. The address of Mr. Donegan is The Med-Design Corporation, 2810 Bunsen Avenue, Ventura, California 93003.
- (8) Includes options to purchase 17,794 shares of common stock.
- (9) Includes options to purchase 61,000 shares of common stock.
- (10) Includes 1,400 shares of common stock held by Mr. White's spouse and options to purchase 50,000 shares of common stock.
- (11) Includes options to purchase 150,000 shares of common stock.
- (12) Includes options to purchase 112,200 shares of common stock and warrants to purchase 16,000 shares of common stock.
- (13) The information in this table is as of December 31, 2004. The principal business address of the State of Wisconsin Investment Board is P.O. Box 7842, Madison, Wisconsin, 53707. The information in the table and this note is based on the Schedule 13G/A filed with Securities and Exchange Commission on February 8, 2005 by the State of Wisconsin Investment Board.
- (14) The information in this table is as of December 31, 2004. The principal business address of Evan Sturza is 1370 Avenue of the Americas, 27th Floor, New York, New York, 10019. The information in this table and note is based on the Schedule 13G filed with the Securities and Exchange Commission on October 1, 2004 by Evan Sturza.

- (15) The shares listed include shares underlying warrants to purchase 335,998 shares of common stock. Adage Capital Partners, L.P., a Delaware limited partnership ("Adage"), shares voting and investment power as to the shares listed with Adage Capital Partners GP, L.L.C., a Delaware limited liability company ("Adage GP"), Adage Capital Advisors, L.L.C., a Delaware limited limited liability company ("Adage Advisors"), Robert Atchinson and Phillip Gross. Adage GP is the general partner of Adage, Adage Advisors is the managing members of Adage GP and Messrs. Atchinson and Gross are the managing members of Adage Advisors, Mr. Atchinson and Mr. Gross is 200 Clarendon Street, Boston, Massachusetts, 02116. The information in the table and this note is based on the Schedule 13G/A filed with the Securities and Exchange Commission on February 14, 2005 by Adage GP and Messrs. Atchinson and Gross.
- (16) The information in this table is as of December 31, 2004. The principal business address of Pioneer Global Asset Management S.p.A. is 60 State Street, 19th Floor, Boston, Massachusetts, 02109. The information in this table and note is based on the Schedule 13G filed with the Securities and Exchange Commission on August 20, 2004 by Pioneer Global Asset Management.
- (17) Includes options and warrants to purchase 3,670,076 shares of common stock.

13

### Equity Compensation Plan Information

The following table provides information as of December 31, 2004 with respect to compensation plans under which equity compensation is authorized, as well as individual compensatory arrangements

## <TABLE>

<CAPTION>

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
<s> Equity compensation plans approved by security holders</s>	<c> 3,670,076(1)</c>	<c> \$7.59</c>	<c>24,822</c>
Equity compensation plans not approved by security holders			
Total	3,670,076	\$ 7.59	24,822

</TABLE>

 Includes warrants to issue 1,565,532 shares of common stock issued to employees, consultants and shareholders of Med-Design.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Joseph N. Bongiovanni, III, the senior partner of the law firm of Bongiovanni & Berger, is a director, Vice President and Corporate Counsel of Med-Design. During the fiscal years ended December 31, 2004 and 2003, Bongiovanni & Berger received \$18,335 and \$22,717, respectively, for legal services billed to Med-Design and for use of office space and other office related expenses.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table shows the fees that we incurred in 2004 for audit services provided by BDO Seidman LLP, the independent public accounting firm that audited our 2004 consolidated financial statements, and the fees that we incurred in 2003 for audit and other services provided by PricewaterhouseCoopers LLP Pwc, the independent public accounting firm that audited our 2003 consolidated financial statements.

## AUDITOR FEES

	2004	2003
Audit Fees (1): Audit Related Fees (2): Tax Fees (3): All Other Fees:	\$ 253,081	\$ 181,569 4,832 25,000
Total:	\$ 253,081	\$ 211,606

 Audit fees represent fees for services rendered for the audit of our financial statements and review of our quarterly financial statements.

- (2) Audit-related fees represent fees for other assurance and related services that are reasonably related to the performance of the audit or review of our financial statements.
- (3) For fiscal 2003, tax fees related to the preparation of federal, state and local returns and tax compliance provided by Pwc.

14

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) Documents filed as part of this Report:

1. Financial Statements. The following financial statements and notes thereto of Med-Design were incorporated by reference into Item 8 of the initial Form 10-K filed by Med-Design with the Securities and Exchange Commission on March 31, 2005:

<TABLE> <CAPTION>

	Page
<s></s>	<c></c>
Reports of Independent Registered Public Accounting Firms	F-2
Consolidated Balance Sheets as of December 31, 2004 and 2003	F-4
Consolidated Statements of Operations for the years ended December 31, 2004, 2003	and 2002 F-5
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the yea	rs ended
December 31, 2004, 2003 and 2002	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003	and 2002 F-7
Notes to Consolidated Financial Statements	F-8

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2. All schedules are omitted because they are inapplicable, or not required, or the information is shown in the financial statements or notes thereto.

3. List of Exhibits. The following is a list of exhibits filed as part of this Amendment No. 1. Where so indicated by footnote, exhibits which were previously filed are incorporated by reference.

NUMBER	DESCRIPTION
EXHIBIT	

- 3.1(1) Certificate of Incorporation of Med-Design.
- 3.2(8) Certificate of Amendment to Certificate of Incorporation of Med-Design
- 3.3(1) Bylaws of Med-Design.
- 4.1(1) Specimen of Common Stock Certificate of Med-Design.
- 10.1(4) Amended and Restated Non-Qualified Stock Option Plan.
- 10.2(2) Lease Agreement dated June 15, 1995 between Moen Development and MDC Research Ltd. and guaranteed by Med-Design.
- 10.3(16) Renewal Lease Agreement dated November 1, 2003, Moen Development and MDC Research Ltd.
- 10.4(9) Asset Purchase Agreement dated April 1, 2004 between Med-Design and Luther Needlesafe Product, Inc.

- 10.5(4) Licensing and Option Agreement dated December 11, 1998 with Becton, Dickinson and Company.
- 10.6(4) Equity agreement dated December 11, 1998 with Becton, Dickinson and Company.
- 10.7(5) Addendum to License Agreement dated December 11, 1999 with Becton, Dickinson and Company.
- 10.8(5) Second Addendum to License Agreement dated January 25, 2000 with Becton, Dickinson and Company.
- 10.9(6) Warrant Agreement dated April 25, 2000 between Med-Design and Lawrence Ellis.\*
- 10.10(6) Licensing Agreement dated May 11, 2000 with Becton, Dickinson and Company.
- 10.11(7) 2001 Equity Compensation Plan.
- 10.12(16) Separation of Employment Agreement dated October 10, 2004 between Med-Design and James Donegan.

- 10.13(10) Employment Agreement dated October 10, 2002 between Med-Design and Joseph Bongiovanni.
- 10.14(10) Employment Agreement dated October 10, 2002 between Med-Design and Lawrence D. Ellis.
- 10.15(11) Employment Agreement dated May 15, 2002 between Med-Design and David Dowsett
- 10.16(11) Employment Agreement extension dated October 17, 2003 between Med-Design and David Dowsett
- 10.17(12) Developing and Licensing Agreement for Safety "Seldinger" Needle Device between Med-Design and Enpath Medical, Inc. dated as of August 25, 2000) the "Enpath Agreement").
- 10.18(13) Addendum Number One to the Enpath Agreement.
- 10.19(14) Addendum Number Two to the Enpath Agreement.
- 10.20(16) Plastics Engineering & Development Incorporated Manufacturing Agreement dated as of May 22, 2003.
- 10.21(16) New Alliance of Independent Medical Distributors, Inc. Exclusive Master Sales & Distribution Agreement dated as of November 1, 2003 Agreement.
- 21.1(16) List of Subsidiaries of Med-Design
- 23.1 Consent of BDO Seidman, LLP\*\*
- 23.2(16) Consent of PricewaterhouseCoopers LLP
- 31.1 Certificate of the Chief Executive Officer required by Rule 15d 14(a).\*\*
- 31.2 Certificate of the Chief Financial Officer required by Rule 15d 14(a).\*\*
- 32.1(16) Certificate of the Chief Executive Officer required by Rule 15d 14(b).
- 32.2(16) Certificate of the Chief Financial Officer required by Rule 15d 14(b).
- 99.1(16) Experts
- \* Constitutes management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K
- \*\* Filed herewith

(1) Incorporated by reference to Form SB-2 filed April 7, 1995 and Amendment Nos. 1, 2 and 3 thereto (File No. 33-901014).

(2) Incorporated by reference to Form 10-KSB filed on March 29, 1996.

(3) Incorporated by reference to Form 10-KSB filed on March 31, 1998.

(4) Incorporated by reference to Form 10-KSB filed on March 31, 1999.

(5) Incorporated by reference to Form 10-KSB filed on March 7, 2000.

(6) Incorporated by reference to Form 10-K filed March 23, 2001.

(7) Incorporated by reference to Schedule 14A filed on June 28, 2001.

(8) Incorporated by reference to Form 10-K filed on April 1, 2002.

(9) Incorporated by reference to Form 8-K filed on April 15, 2004.

(10) Incorporated by reference to Form 10-K filed on March 28, 2003.

(11) Incorporated by reference to Form 10-K filed on March 12, 2004.

(12) Incorporated by reference to Form 10-K filed on March 31, 2005.

(13) Incorporated by reference to Exhibit 10.1 to Form 8-K filed by Enpath Medical, Inc. on September 19, 2000.

(14) Incorporated by reference to Exhibit 10.1 to Form S-3 filed by Enpath Medical, Inc. on October 16, 2001.

(15) Incorporated by reference to Form 8-K filed on January 3, 2005.

(16) Incorporated by reference to Form 10-K filed on March 31, 2005.

16

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THE MED-DESIGN CORPORATION

Dated: May 2, 2005

By: JOSEPH N. BONGIOVANNI, III Joseph N. Bongiovanni, III Vice President and Secretary

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Med-Design Corporation

Ventura, California

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (Registration Nos. 333-05927, 333-22201, 333-31858, 333-65472, 333-86432, 333-99161, 333-108759 and 333-115511) and S-8 (Registration Nos. 333-75957, 333-90933, 333-49194 and 333-99163) of The Med-Design Corporation of our report dated April 27, 2005 on the effectiveness of the Med-Design Corporation's internal control over financial reporting, included in its 2004 Annual Report on Form 10-K/A.

/s/ BDO Seidman, LLP

Los Angeles, California

May 2, 2005

## CERTIFICATION

I, David R. Dowsett, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 10-K of The Med-Design Corporation;

2. Based on my knowledge, Amendment No. 1, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Amendment No. 1 to the annual report;

3. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed with such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

4. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions): a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 2, 2005

DAVID R. DOWSETT

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David R. Dowsett Acting Chief Executive Officer

## CERTIFICATION

I, Lawrence D. Ellis, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 10-K of The Med-Design Corporation;

2. Based on my knowledge, Amendment No. 1, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Amendment No. 1 to the annual report;

3. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed with such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

4. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions): a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 2, 2005

LAWRENCE D. ELLIS

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Lawrence D. Ellis Chief Financial Officer