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ORTHOFIX INTERNATIONAL N V  
Form 10-K/A  
April 29, 2004

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-K/A

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For the fiscal year ended December 31, 2003  
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: 0-19961

ORTHOFIX INTERNATIONAL N.V.  
(Exact name of registrant as specified in its charter)

Netherlands Antilles

N/A

-----  
(State or other jurisdiction of  
incorporation or organization)

-----  
(I.R.S. Employer Identification No.)

7 Abraham de Veerstraat  
Curacao  
Netherlands Antilles

N/A

-----  
(Address of principal executive offices)

-----  
(Zip Code)

599-9-4658525

-----  
(Registrant's telephone number, including area code)

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

None

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

Common Stock, \$0.10 par value

(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 at least the past 90 days. Yes  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 definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as

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defined in Rule 12b-2 of the Act). Yes [ X ] No [ ]

The aggregate market value of registrant's common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2003, as reported by the Nasdaq National Market, was approximately \$178.5 million. Shares of common stock held by executive officers and directors and persons who own 5% or more of the outstanding common stock have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not a determination for any other purpose.

As of April 28, 2004, 15,230,662 shares of common stock were issued and outstanding.

### EXPLANATION

The purpose of the amendment to our Form 10-K for the fiscal year ended December 31, 2003 is to include the Section 16(a) Beneficial Ownership Reporting Compliance information required by Item 10 of Part III of Form 10-K and all of the information required by Item 11, Item 12, Item 13 and Item 14 of Part III of Form 10-K, which we indicated in our Form 10-K would be provided in our definitive proxy statement or in an amendment to our Form 10-K not later than 120 days after the end of the fiscal year covered by that Form 10-K.

Item 10. Directors and Executive Officers of the Registrant  
-----

New Director Nominee

Mr. Walter von Wartburg, 64, is being nominated for Director of Orthofix International N.V. for the first time this year. He is an attorney and has practiced privately in his own law firm in Basel, Switzerland since 1999, specializing in life sciences law. Mr. von Wartburg has also been a Professor of administrative law and public health policy at the Saint Gall Graduate School of Economics in Switzerland for 25 years. Previously, he held top management positions with Ciba Pharmaceuticals and Novartis at their headquarters in Basel, Switzerland. In addition, Mr. von Wartburg currently serves as a director on the board of Nymox Pharmaceutical Corporation.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our insiders--our directors, executive officers, and greater-than-10% shareholders--file reports with the SEC on their initial beneficial ownership of Orthofix common stock and any subsequent changes. They must also provide us with copies of the reports.

To our knowledge, based solely on a review of the copies of such reports furnished to us and, with respect to our officers and directors, written representations that no other reports were required, during the fiscal year ended December 31, 2003, all Section 16(a) filing requirements applicable to our officers, directors and greater-than-ten-percent beneficial owners were complied with except as follows: Mr. Wallner reported on a Form 4 filed on May 21, 2003, shares of common stock he acquired indirectly on May 9, 2003, and Messrs. Benjamin, Brown, d'Abreu de Paulo, Federico, Gero, Hartsuiker, Hein and Henley reported on Form 4s filed on August 26, 2003, option grants to purchase shares of our common stock that they received on August 6, 2003, and Mr. Littlechild

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reported on a Form 4 filed on August 27, 2003, an option grant to purchase shares of our common stock that he received on August 6, 2003.

In making the above statements, we have relied on the written representations of our directors and officers and copies of the reports that have been filed with the SEC.

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Item 11. Executive Compensation

Executive Compensation Summary

The following table sets forth the compensation paid or accrued by us during the fiscal years ended December 31, 2003, 2002 and 2001 to, or on behalf of, our chief executive officer and our four most highly compensated executive officers as of December 31, 2003. We refer to these officers collectively as the "named executive officers."

| Summary Compensation Table  |      |           |           |                               |                                     |
|---|------|-----------|-----------|-------------------------------|-------------------------------------|
| Annual Compensation   |      |           |           |                               |                                     |
| Name and Principal Position   | Year | Salary    | Bonus     | Other Annual Compensation (1) | Number of Shares Underlying Options |
| Charles Federico .....<br>Chief Executive Officer and President               | 2003 | \$450,944 | \$171,755 | -0-                           | 3                                   |
|   | 2002 | 450,640   | 40,000    | -0-                           |                                     |
|   | 2001 | 437,810   | 150,000   | -0-                           |                                     |
| Robert Gaines-Cooper .....<br>Chairman of the Board                           | 2003 | 200,625   | -0-       | -0-                           |                                     |
|   | 2002 | 260,813   | -0-       | -0-                           |                                     |
|   | 2001 | 321,000   | 80,250    | -0-                           |                                     |
| Edgar Wallner .....<br>Vice Chairman  | 2003 | 183,718   | -0-       | -0-                           |                                     |
|   | 2002 | 256,826   | -0-       | -0-                           |                                     |
|   | 2001 | 324,680   | 79,200    | -0-                           |                                     |
| Gary Henley.....<br>Senior Vice President and President,<br>Americas Division | 2003 | 269,673   | 133,000   | -0-                           | 1                                   |
|   | 2002 | 256,965   | 45,126    | -0-                           |                                     |
|   | 2001 | 219,710   | 88,000    | -0-                           |                                     |
| Thomas Hein .....<br>Chief Financial Officer                                  | 2003 | 239,099   | 100,000   | -0-                           | 1                                   |
|   | 2002 | 213,980   | 53,900    | -0-                           | 1                                   |
|   | 2001 | 188,826   | 76,072    | \$83,486 (5)                  |                                     |

(1) Excludes perquisites and other personal benefits unless the aggregate amount of such annual compensation exceeded \$50,000 or 10% of the total of annual salary and bonus reported for the named executive

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officer.

- (2) Amount shown consists of \$8,000 for contributions to vested and unvested accounts attributable under the Company's defined contribution plans and \$3,355 for insurance premiums paid by, or on behalf of, the Company with respect to term life insurance.
- (3) Amount shown consists of \$8,000 for contributions to vested and unvested accounts attributable under the Company's defined contribution plans and \$603 for insurance premiums paid by, or on behalf of, the Company with respect to term life insurance.
- (4) Amount shown consists of \$8,000 for contributions to vested and unvested accounts attributable under the Company's defined contribution plans and \$979 for insurance premiums paid by, or on behalf of, the Company with respect to term life insurance.
- (5) Amount shown consists of \$2,228 for long-term disability premiums, \$10,800 for car allowance, and \$70,458 for relocation expenses.

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Stock Options

The following table contains information regarding option grants by us to our named executive officers during the year ended December 31, 2003.

| Option/SAR Grants in Last Fiscal Year |   |  |                                       |                 |
|---------------------------------------|---|--|---------------------------------------|-----------------|
| Name                                  | Number of Securities Underlying Options/SARs Granted(1) | % of Total Options Granted to Employees in Fiscal Year | Individual Grants                     |                 |
|                                       |   |  | Exercise or Base Price (\$/Share) (2) | Expiration Date |
| Charles Federico .....                | 30,000  | 6.7  | 32.18                                 | 8/6/1           |
| Robert Gaines-Cooper .....            | -0-   | -0-  | -0-                                   | -0-             |
| Edgar Wallner .....                   | -0-   | -0-  | -0-                                   | -0-             |
| Gary Henley .....                     | 10,000  | 2.2  | 32.18                                 | 8/6/1           |
| Thomas Hein .....                     | 10,000  | 2.2  | 32.18                                 | 8/6/1           |

- (1) All option grants to the named executive officers were made pursuant to our Staff Share Option Plan and have a ten-year term. All options will vest and become exercisable on August 6, 2006.
- (2) All options were granted to the named executive officers at an exercise price equal to the fair market value of the underlying stock on the date of grant.

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- (3) This estimated hypothetical value is based on a Black-Scholes option pricing valuation model in accordance with SEC rules. We used the following assumptions in estimating this value: expected option term, 4.5 years; risk-free interest rate, 3.5%; expected volatility, 35%; and an expected dividend yield of 0%.

### Option Exercises and Year-End Option Values

The following table provides information about the number of our shares of common stock issued upon the exercise of options by our named executive officers during the year ended December 31, 2003, and the value realized by our named executive officers. The table also provides information about the number and value of our options held by our named executive officers at December 31, 2003.

| -----  |   |                       |   |              |  |
|--|---|-----------------------|---|--------------|--|
| Aggregated Option/SAR Exercises in Last Fiscal Year and<br>Fiscal Year-End Option/SAR Values |   |                       |   |              |  |
| Name   | Number of<br>Shares Acquired<br>on Exercise (#) | Value<br>Realized(\$) | Number of Securities Underlying<br>Unexercised Options at Fiscal<br>Year End(#) |              |  |
|  |   |                       | Exercisable   | Unexercisabl |  |
| Charles Federico .....   | -0-   | -0-                   | 265,000   | 130,000      |  |
| Robert Gaines-Cooper.....  | 275,000   | 2,596,000             | 100,000   | 87,500       |  |
| Edgar Wallner.....   | -0-   | -0-                   | 100,000   | 87,500       |  |
| Gary Henley .....  | 30,000  | 454,810               | 50,000  | 60,000       |  |
| Thomas Hein .....  | -0-   | -0-                   | 40,000  | 30,000       |  |
| -----  |   |                       |   |              |  |

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- (1) Based on the closing price of common stock, as reported on the Nasdaq National Market, at December 31, 2003, which was \$48.98 per share.

### Director Compensation

Directors who are our employees do not receive fees for service on the Board of Directors or any Board committee. During 2003, each of our non-employee directors received an annual retainer fee of approximately \$55,000 for their services. The Audit Committee chair received an additional annual fee of \$10,000 for his service. Each of the Nominating Committee and Compensation Committee chairs received an additional annual fee of \$5,000 for their services.

In addition, we grant options from time to time to our non-employee directors under our equity compensation plans. The decision to grant options to non-employee directors will be reviewed by the Board of Directors on an annual basis.

We reimburse our directors for travel and other related expenses incurred in connection with the business of Orthofix, including attending shareholder meetings, meetings of the Board of Directors or any Board committee.

Mr. Peter Hewett, a non-employee director, also serves as a consultant

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to the Company and as Chairman of Orthofix Inc.'s Board of Directors. In this capacity, he provides consulting and advisory services, at such times and on such special projects, as we request. Mr. Hewett reports directly to the Board of Directors in connection with these consulting and advisory services. In 2003, we paid \$128,675 in consulting fees to Mr. Hewett, which is in addition to his director fees. We also reimbursed Mr. Hewett for travel and other related expenses incurred in connection with the performance of such consulting and advisory services. In 2004, Mr. Hewett will receive a fee of \$1,500 per day for each day of requested consulting and advisory services, in addition to his director fees.

### Executive Employment Agreements

#### Executive Employment Agreement for Charles Federico

On July 1, 2001, we entered into an employment agreement with Mr. Charles W. Federico under which Mr. Federico serves as our President and Chief Executive Officer. The initial three-year term of the agreement ends on July 1, 2004, and automatically renews for successive one-year periods, unless either party notifies the other party of its intention not to renew the agreement within the requisite time period. Mr. Federico is entitled to the base salary and bonus as determined by our Board of Directors. For 2003, Mr. Federico received a base salary of \$450,944 and a bonus of \$171,755. Mr. Federico is also eligible to participate in all employee benefit plans, programs and arrangements in effect for senior executives.

If Mr. Federico is terminated without cause or resigns for good reason (as such terms are defined in his employment agreement) during the term of the agreement, he is entitled to convert his current position with us to a consultancy for the remainder of the then-existing term of employment, and receive a consulting fee of at least \$50,000 per year. Upon a change in control of the Company, Mr. Federico agrees to remain employed for at least six months from the effective date of such change in control, unless his employment is terminated earlier by the Company. During the three-month period immediately following such six-month period, Mr. Federico may terminate his employment for good reason and convert his agreement into a consulting agreement as described above. The employment agreement contains a non-solicitation of employees and customers provision that extends through the third anniversary of Mr. Federico's termination of employment, a non-competition provision that remains in effect for so long as Mr. Federico is employed by us and a confidentiality provision that lasts indefinitely.

#### Employment Agreements for Edgar Wallner and Robert Gaines-Cooper

On July 1, 1999, we entered into employment agreements with Messrs. Edgar Wallner and Robert Gaines-Cooper. Mr. Wallner originally served as our President and Chief Executive Officer until January 1, 2001 when he resigned as President and Chief Executive Officer and began serving as our Deputy Chairman of the Board of Directors under the same employment agreement. Mr. Wallner currently serves as Vice Chairman, and Mr. Gaines-Cooper serves as the Chairman of the Board of Directors.

The initial three-year term of these agreements ended on July 1, 2002, but these agreements have been subject to automatic renewal for successive one-year periods since that time. We have notified each of Messrs. Wallner and Gaines-Cooper of our intention not to extend their respective agreements beyond the term currently in effect. Therefore, the employment agreements with Messrs.

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Wallner and Gaines-Cooper will terminate as of July 1, 2004. Following the termination of these employment agreements, Mr. Wallner will continue to serve as Vice Chairman, and Mr. Gaines-Cooper will continue to serve as the Chairman of the Board of Directors.

The agreements provide that the executives are entitled to base salaries and bonuses as determined by our Board of Directors. For 2003, Mr. Wallner received a base salary of \$183,718 and a bonus of \$0 and Mr. Gaines-Cooper received a base salary of \$200,625 and a bonus of \$0. Messrs. Wallner and Gaines-Cooper are also eligible to participate in all employee benefit plans, programs and arrangements in effect for senior executives.

The effects of a termination without cause, a resignation for good reason or a change of control on Messrs. Wallner and Gaines-Cooper's service with the Company would be substantially similar to those described above for Mr. Federico. In addition, the agreements contain a non-solicitation of employees and customers provision that extends through the third anniversary of the executive's respective termination of employment, a non-competition provision that remains in effect for so long as the executive is employed by us and a confidentiality provision that lasts indefinitely.

### Executive Employment Agreements for Thomas Hein, Gary Henley and Bradley Mason

We entered into employment agreements with Mr. Hein and Mr. Henley, effective as of March 1, 2003. We also entered into an employment agreement with Mr. Mason, which became effective on December 30, 2003. Mr. Hein serves as the Chief Financial Officer, Mr. Henley serves as the President of Orthofix Americas Division and Mr. Mason serves as the President of Breg, Inc. The initial term of each agreement is two years, but each agreement will be automatically renewed for two successive one-year periods unless either party notifies the other party of its intention not to renew within the requisite time period. Under the agreements, the executives are entitled to base salaries and bonuses as determined by our Board of Directors. The agreements provide annual base salaries of at least \$231,000 for Mr. Hein, \$270,000 for Mr. Henley and \$250,000 for Mr. Mason, which may only be decreased if such decrease is a result of a general reduction (on the same percentage basis) affecting the base salaries of substantially all other executive officers. For 2003, the base salaries of each of Messrs. Hein and Henley were \$239,099 and \$269,673, respectively. In addition, for 2003, Messrs. Hein and Henley received annual bonuses of \$100,000 and \$133,000, respectively. Mr. Mason's employment agreement provides that he was granted an inducement stock option award to purchase 150,000 shares of common stock in accordance with the terms and conditions specified in the Performance Accelerated Stock Option Inducement Agreement, which is described below.

If an executive is terminated without cause, he is entitled to receive a lump sum payment equal to: (1) the average of his base salary at the highest rate in effect in the 90-day period immediately before the termination and his base salary for the year preceding the termination and (2) the average of his annual bonuses for the two years prior to the year in which the termination occurs. Upon a resignation for good reason (as such term is defined in the agreements), the executive is entitled to half the amount that he would receive had he been terminated without cause. In addition, the executives will be entitled to continuation of their welfare benefits for up to one year following their termination without cause or resignation for good reason. Similarly, any stock options held by the executives will remain outstanding for at least one year following a termination without cause and six months following a resignation for good reason (provided, however, that the inducement stock award granted to Mr. Mason will be governed by the terms and conditions of the applicable Performance Accelerated Stock Option Inducement Agreement). We are also obliged to provide the executives with reimbursement for outplacement

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services of up to \$20,000 upon a termination without cause or resignation for good reason.

If there is a change in control of the Company, (1) the agreements automatically extend for one year from the date of the change in control (unless the then current term is greater than one year), (2) all stock options and stock appreciation rights will vest automatically (provided, however, that the inducement stock award granted to Mr. Mason will be governed by the terms and conditions of the applicable Performance Accelerated Stock Option Inducement Agreement) and (3) any forfeiture provisions included in the executives' restricted stock awards will immediately lapse. In addition, in the event that any of the executives is terminated without cause or resigns for

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good reason following a change in control, the individual is entitled to receive a lump sum payment equal to: (1) the greater of (a) the average of his base salary at the highest rate in effect in the 90-day period immediately before the termination and his base salary for the year preceding the termination and (b) the average of his base salary in effect immediately before the change in control and his base salary for the year preceding the change in control; (2) the greater of (x) the average of his annual bonuses for the two years before the year in which the termination occurs and (y) the average of his annual bonuses for the two years before the year in which the change in control occurs and (3) the executive's annual automobile allowance. The agreements also provide that, in the event that any payments made to the executive constitute "excess parachute payments" under Section 280G of the Internal Revenue Code of 1986, as amended, then the amounts to be paid to the executives will be reduced so that no excess parachute payments exist.

The agreements contain a non-competition provision that lasts for one year following a termination of employment for any reason, and confidentiality and assignment of inventions provisions that last indefinitely. In addition, Mr. Mason's agreement contains a nonsolicitation of clients, customers and employees provision that lasts for two years following a termination of employment for any reason.

### Performance Accelerated Stock Option Inducement Agreement with Bradley Mason

On December 30, 2003, in conjunction with the acquisition of Breg, Inc., Mr. Mason was granted an inducement stock option award pursuant to a Performance Accelerated Stock Option Inducement Agreement. The exercise price of \$38.00 per share represents the fair market value of our common stock on November 20, 2003, which was the date we announced the agreement to acquire Breg, Inc. The inducement grant includes both service-based and performance-based vesting provisions. Under the service-based provisions, subject to the continued employment of Mr. Mason, the inducement grant becomes 100% non-forfeitable and exercisable on the fourth anniversary of the grant date. Vesting of a portion of the options under the inducement agreement will be accelerated if certain stock price targets are achieved. The performance-based vesting provisions generally provide for the vesting of one-fifth of the inducement grant for each \$5.00 increase in the price of our common stock above \$40.00 per share. The total number of shares eligible for the accelerated vesting on an annual basis is limited to 25% of the number of shares subject to the inducement grant with a cumulative carryover for the unvested portion of shares eligible for accelerated vesting for each of the prior years. Prior to the expiration of the term of the options, only one-half of the vested options can be exercised in any one year.



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### Compensation Committee Interlocks and Insider Participation

During 2003, the Compensation Committee of our Board of Directors consisted of two members, John W. Littlechild and James F. Gero. Both Mr. Littlechild and Mr. Gero satisfy the independent director standards as defined by current Nasdaq rules and are "independent directors" for purpose of Rule 162(m) of the U.S. Internal Revenue Code of 1986, as amended, and are "non-employee directors" for purposes of Section 16 of the Securities Exchange Act of 1934, as amended. No interlocking relationship, as defined in the Securities Exchange Act of 1934, as amended, exists between our Board of Directors or Compensation Committee and the board of directors or compensation committee of any other entity.

Mr. Peter Hewett, a non-employee director, serves as a consultant to the Company and as Chairman of Orthofix Inc.'s Board of Directors. In this capacity, he provides consulting and advisory services, at such times and on such special projects, as we request. Mr. Hewett reports directly to the Board of Directors in connection with these consulting and advisory services. In 2003, we paid \$128,675 in consulting fees to Mr. Hewett, which is in addition to his director fees. We also reimbursed Mr. Hewett for travel and other related expenses incurred in connection with the performance of such consulting and advisory services. In 2004, Mr. Hewett will receive a fee of \$1,500 per day for each day of requested consulting and advisory services, in addition to his director fees.

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### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders

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#### Security Ownership of Certain Beneficial Owners

The following table shows each person, or group of affiliated persons, who beneficially owns, directly or indirectly, at least 5% of Orthofix common stock as of December 31, 2003. Our information is based on reports filed with the SEC by each of the firms or individuals listed in the table below. You may obtain these reports from the SEC.

The percent of class figure for the common stock is based on 14,980,010 shares of our common stock outstanding as of December 31, 2003, other than with respect to Mr. Robert Gaines-Cooper for which information is given and calculations are made as of April 15, 2004. Except as otherwise indicated, each shareholder has sole voting and dispositive power with respect to the shares indicated.

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| Name and Address<br>of Beneficial Owner                    | Amount and Nature of<br>Beneficial Ownership |
|--|--|
| FMR Corp. ....<br>82 Devonshire Street<br>Boston, MA 02109 | 2,133,147 (1)                                |
| Robert Gaines-Cooper .....                                 | 620,200 (2)                                  |
| Orthofix International N.V.                                | 873,000 (3)                                  |

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7 Abraham de Veerstraat  
Curacao, Netherlands Antilles

|  |           |     |
|--|-----------|-----|
| Federated Investors, Inc. ....                               | 1,177,860 | (4) |
| Federated Investors Tower<br>Pittsburgh, PA 15222-3779       |           |     |
| Kayne Anderson Rudnick Investment<br>Management, LLC .....   | 973,913   | (5) |
| 1800 Avenue of the Stars, 2nd Floor<br>Los Angeles, CA 90067 |           |     |
| Wellington Management Company, LLP .....                     | 873,590   | (6) |
| 75 State Street<br>Boston, MA 02109                          |           |     |

(1) Based on an amendment to a Schedule 13G filed on February 17, 2004 by FMR Corp., a parent holding company, Edward C. Johnson 3d, Abigail P. Johnson, Fidelity Management and Research Company, Fidelity Low Priced Stock Fund and Fid Diversified International. FMR Corp. reported sole voting power with respect to 94,347 of the reported shares and sole dispositive power with respect to all of the reported shares. Fidelity Management & Research Company ("Fidelity"), an investment adviser and wholly owned subsidiary of FMR Corp., is the beneficial owner of 2,039,647 of the reported shares. Fidelity Management Trust Company, a bank and a wholly-owned subsidiary of FMR Corp., is the beneficial owner of 80,300 of the reported shares. Edward C. Johnson, Chairman of FMR. Corp., and FMR Corp., through their control of Fidelity and Fidelity Management Trust Company, each have sole power to dispose of the shares beneficially owned by the Fidelity funds and Fidelity Management Trust Company, and sole voting power with respect to the shares beneficially owned by Fidelity Management Trust Company. The power to vote the shares beneficially owned by the Fidelity funds resides with the Board of Trustees of the Fidelity funds. Fidelity International Limited ("FIL"), an investment adviser and former subsidiary of Fidelity and FMR Corp., is the beneficial owner of, and has sole voting and dispositive power with respect to, 13,200 of the reported shares.

(2) Amount consists of 432,700 shares owned directly and 187,500 currently exercisable stock options.

(3) Amount shown consists of 693,000 shares owned by a trust in which Mr. Gaines-Cooper has an indirect interest and 180,000 shares owned by LMA International S.A. A trust, of which Mr. Gaines-Cooper is a settlor, owns a 40% interest in LMA International S.A.

(4) Based on an amendment to a Schedule 13G filed on February 13, 2004 by Federated Investors, Inc., a parent holding company, Voting Shares Irrevocable Trust and John F. Donahue, Rhodora J. Donohue and J. Christopher Donahue, collectively, as the Trustees of the Voting Shares Irrevocable Trust. Federated Investors, Inc., Voting Shares Irrevocable Trust and the Trustees reported sole voting and

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dispositive power with respect to, and disclaimed beneficial ownership of, the reported shares. We have not attempted to independently verify any of the foregoing information, which is based solely upon the information contained in the Schedule 13G/A.

- (5) Based on an amendment to a Schedule 13G filed on February 10, 2004 by Kayne Anderson Rudnick Investment Management, LLC, an investment advisor. Kayne Anderson Rudnick Investment Management, LLC reported sole voting and dispositive power with respect to the reported shares. We have not attempted to independently verify any of the foregoing information, which is based solely upon the information contained in the Schedule 13G/A.
- (6) Based on an amendment to a Schedule 13G filed on February 12, 2004 by Wellington Management Company, LLP, an investment advisor. Wellington Management Company, LLP reported shared voting power with respect to 646,140 of the reported shares and shared dispositive power with respect to all of the reported shares. We have not attempted to independently verify any of the foregoing information, which is based solely upon the information contained in the Schedule 13G/A.

Security Ownership of Management

The following table sets forth the beneficial ownership of our common stock, including stock options currently exercisable and exercisable within 60 days, as of April 15, 2004 by each director, each nominee for director, each executive officer listed in Summary Compensation Table and all directors and executive officers as a group. The percent of class figure is based on 15,227,362 shares of our common stock outstanding as of April 15, 2004. All directors and executive officers as a group beneficially owned 2,957,281 shares of Orthofix common stock as of such date. Unless otherwise indicated, the beneficial owners exercise sole voting and/or investment power over their shares.

| Name of Director or Executive Officer | Amount and Nature of Beneficial Ownership |
|---------------------------------------|---|
| Robert Gaines-Cooper .....            | 620,200 (1)                               |
|                                       | 873,000 (2)                               |
| Edgar Wallner .....                   | 436,100 (3)                               |
| Charles Federico .....                | 254,591 (4)                               |
| Thomas Hein .....                     | 48,121 (5)                                |
| Peter Clarke .....                    | 200,000 (6)                               |
| Gary Henley .....                     | 51,000 (7)                                |

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|  |             |
|--|-------------|
| Galvin Mould .....   | 10,000 (8)  |
| Bradley R. Mason .....   | 170,754 (9) |
| Jerry Benjamin .....   | 69,282 (10) |
| Alberto d'Abreu de Paulo.....                                    | 12,000 (11) |
| Frederik Hartsuiker .....  | 18,500 (12) |
| Peter Hewett .....   | 97,300 (13) |
| John Littlechild .....   | 45,861 (14) |
| James Gero .....   | 50,572 (15) |
| Walter von Wartburg (16).....                                    | -0-         |
| Directors and executive officers<br>as a group (15 persons)..... | 2,957,281   |

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\* Represents less than one percent.

- (1) Amount shown consists of 432,700 shares owned directly and 187,500 currently exercisable stock options.
- (2) Amount shown consists of 693,000 shares owned by a trust in which Mr. Gaines-Cooper has an indirect interest, and 180,000 shares owned by LMA International S.A. A trust, of which Mr. Gaines-Cooper is a settlor, owns a 40% interest in LMA International S.A.
- (3) Amount shown consists of 45,000 shares owned directly, 142,500 currently exercisable stock options, and 248,600 shares owned indirectly.
- (4) Amount shown consists of 3,691 shares owned directly, 250,000 currently exercisable stock options, and 900 shares owned indirectly.
- (5) Amount consists of 621 shares owned directly and 47,500 currently exercisable stock options.
- (6) Amount consists of 200,000 currently exercisable stock options.
- (7) Amount consists of 50,000 currently exercisable stock options and 1,000 shares owned indirectly.
- (8) Amount consists of 10,000 currently exercisable stock options.
- (9) Amount consists of 170,754 shares owned indirectly.
- (10) Amount consists of 59,282 shares owned directly and 10,000 currently exercisable stock options.

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- (11) Amount consists of 2,000 shares owned directly and 10,000 currently exercisable stock options.
- (12) Amount consists of 8,500 shares owned directly and 10,000 currently exercisable stock options.
- (13) Amount consists of 24,000 shares owned directly and 73,300 currently exercisable stock options.
- (14) Amount consists of 35,861 shares owned directly and 10,000 currently exercisable stock options.
- (15) Amount consists of 25,572 shares owned directly and 25,000 currently exercisable stock options.
- (16) Mr. von Wartburg is a new nominee for director.

Equity Compensation Plan Information

We maintain three equity compensation plans, the Staff Share Option Plan (including the Performance Accelerated Stock Option program), the Executive Share Option Plan and the Employee Stock Purchase Plan, which have been approved by our shareholders. There are currently no more shares available for issuance under the Executive Share Option Plan or the Performance Accelerated Stock Option program. We have also granted inducement stock option awards (described below) that have not been approved by our shareholders.

The following table provides aggregate information regarding the shares of our common stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2003. The table does not include information about the proposed 2004 Long-Term Incentive Plan, which has not yet been approved by our shareholders and under which no grants have been made. In addition, the table does not include shares subject to outstanding options and warrants that we have assumed in mergers and other acquisitions. Footnote 1 to the table sets forth the total number of shares of common stock issuable upon the exercise of options and warrants granted under plans assumed in mergers and outstanding at December 31, 2003, and the weighted average exercise price of those options. We cannot grant additional awards under those plans.

| Plan Category(1)                                       | (a)<br>Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights | (b)<br>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights | Num<br>Rema<br>Fut<br>Eq<br>P<br>Secu |
|--|--|--|---------------------------------------|
| Equity Compensation Plans Approved by Security Holders | 1,819,629 (2)  | \$19.67  |                                       |

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|  |             |         |
|--|-------------|---------|
| Equity Compensation Plans Not Approved by Security Holders | 200,000 (4) | \$38.00 |
| Total  | 2,019,629   | \$21.48 |

- (1) The table does not include information for equity compensation plans we assumed in mergers and other acquisitions. As of December 31, 2003, a total of 31,873 shares of common stock was issuable upon the exercise of options and warrants assumed in mergers and other acquisitions, including 6,054 shares issuable upon the exercise of options and warrants granted under plans assumed in connection with our acquisition of American Medical Electronics Inc., and 25,819 shares issuable upon the exercise of warrants granted under plans assumed in connection with our acquisition of Kinesis Medical Inc. The weighted average exercise price of all options and warrants granted under plans assumed in mergers and other acquisitions and outstanding at December 31, 2003, was \$30.39. We cannot grant additional awards under these assumed plans.
- (2) Options were granted pursuant to the following plans: the Staff Share Option Plan (including the Performance Accelerated Stock Option program) and the Executive Share Option Plan. As mentioned above, there are currently no more shares available for issuance under the Executive Share Option Plan or the Performance Accelerated Stock Option program.
- (3) Includes 255,845 shares available for issuance pursuant to the Employee Stock Purchase Plan and 157,313 shares available for grant under the Staff Share Option Plan.
- (4) On December 30, 2003, in conjunction with the acquisition of Breg, Inc., we granted inducement stock option awards to two key executives of Breg, Inc. These option grants were not approved by shareholders, and were granted in reliance on the NASD exception to shareholder approval for equity grants to new hires. The exercise price of \$38.00 per share represents the fair market value of our common stock on November 20, 2003, which was the date we announced the agreement to acquire Breg, Inc. The inducement grants include both service-based and performance-based vesting provisions. Under the service-based provisions, subject to the continued employment of the executive, the inducement grants become 100% non-forfeitable and exercisable on the fourth anniversary of the grant date. Vesting of a portion of the options under the inducement agreement will be accelerated if certain stock price targets are achieved. The performance-based vesting provisions generally provide for the vesting of one-fifth of the inducement grants for each \$5.00 increase in the price of our common stock above \$40.00 per share. The total number of shares eligible for the accelerated vesting on an annual basis is limited to 25% of the number of shares subject to the inducement grants with a cumulative carryover for the unvested portion of shares eligible for accelerated vesting for each of the prior years. Prior to the expiration of the term of the options, only one-half of the vested options can be exercised in any one year.

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### Item 13. Certain Relationships and Related Transactions

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#### Certain Relationships and Related Transactions

Certain of our directors own beneficial interests in LMA International S.A., or LMA. Mr. Gaines-Cooper is the Chairman of LMA and is the settlor of a trust which owns 40% of LMA. Mr. Peter Clarke and Mr. Peter Hewett serve as directors of Laryngeal Mask North America, a subsidiary of LMA. LMA, which owns the distribution rights in Italy to the Laryngeal Mask (used to administer anesthesia) produced by The Laryngeal Mask Company Ltd., has awarded the distribution rights for the Laryngeal Mask in Italy to D.M.O. S.r.l, a subsidiary of Orthofix International.

Effective January 14, 2003, we completed a Share Purchase Agreement to acquire the remaining 48% minority interest in our United Kingdom distribution company, Intavent Orthofix Limited (IOL). We purchased the 48% interest from Intavent Limited (Intavent) for a cash purchase price of \$20,450,000. IOL distributes Orthofix products, Laryngeal Mask products and other orthopedic products. Concurrent with the completion of the Share Purchase Agreement, we completed a Distribution Agreement with Intavent and a Guarantee Agreement with LMA International S.A. (LMA) for the supply of Laryngeal Mask products in the United Kingdom, Ireland and Channel Islands for an initial period of seven years. Mr. Robert Gaines-Cooper, Chairman of Orthofix, is a settlor of trusts, which own a 30% interest in Intavent and a 40% interest in LMA. IOL has been and will continue to be a consolidated subsidiary of Orthofix.

Arrow Medical Limited (Arrow) supplies impads for use with the A-V Impulse System to Novamedix Distribution Limited, a wholly owned subsidiary of Orthofix. LMA owns a 27% interest in Arrow. Mr. Gaines-Cooper is the Chairman of LMA and is the settlor of a trust which owns 40% of LMA. Mr. Wallner is the settlor of a trust which owns a 10% interest in Arrow. In 2003, Novamedix purchased \$5.6 million from Arrow for the supply of impads.

Inter Medical Supplies, a wholly owned subsidiary of Orthofix, which manufactures Orthofix products, rents facilities in the Seychelles from LMA under a three year lease which started in 2002. The annual rent paid to LMA is approximately \$65,000.

In 2003, Verona Controllo Qualita provided quality control and logistics services to Orthofix S.r.l. and Inter Medical Supplies Limited (Seychelles), wholly owned subsidiaries of Orthofix. LMA owns a 50% interest in Verona Controllo Qualita. Mr. Gaines-Cooper is the Chairman of LMA and is the settlor of a trust that owns 40% of LMA. In 2003, Orthofix purchased \$0.3 million from Verona Controllo Qualita for quality control, goods and logistics services. In March 2004, Orthofix S.r.l terminated its relationship with Verona Controllo Qualita for quality control and logistics services.

#### Indebtedness of Management

On January 10, 2002 we entered into full-recourse loans with Charles Federico and Gary Henley, each with a principal amount of \$145,200. The loans were entered into to assist the executives in purchasing shares of OrthoRx Inc. common stock. Each loan has an annual interest rate of 3.97%, compounded annually and matures on the earlier of (1) January 10, 2007 and (2) the date that the executive ceases to be our employee, officer or director. The loans are secured by stock pledge agreements covering shares of OrthoRx Inc. common stock owned by Messrs. Federico and Henley. As of December 31, 2003, no payments had been made on either of the loans, and the aggregate amount outstanding under each of the loans was \$156,958 including accrued interest.

Item 14. Principal Accountant Fees and Services  
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Principal Accountant Fees and Services

The following table sets forth by category of service the total fees for services performed by Ernst & Young LLP during the fiscal years ended December 31, 2003 and December 31, 2002:

|                         | 2003        |
|-------------------------|-------------|
|                         | -----       |
| Audit Fees.....         | \$638,312   |
| Audit-Related Fees..... | 200,396     |
| Tax Fees.....           | 1,048,725   |
| All Other Fees.....     | 7,912       |
|                         | -----       |
| Total.....              | \$1,895,345 |

Audit Fees

Audit fees in 2003 and 2002 consisted of the aggregate fees, including expenses, billed in connection with the audit of our annual consolidated financial statements, quarterly reviews, statutory audits of our subsidiaries and accounting consultations on audit matters.

Audit-Related Fees

Audit-related fees in 2003 and 2002 were for acquisition-related due diligence services, employee benefit plan audits and accounting consultations. A substantial portion of the increase in audit-related fees in 2003 from 2002 was due to acquisition-related due diligence services in connection with our December 2003 acquisition of Breg, Inc.

Tax Fees

Tax fees in 2003 and 2002 related to services for tax compliance, tax planning and tax advice. The increase in tax fees in 2003 from 2002 was due to tax consulting services related to our acquisition of Breg, Inc.

All Other Fees

The remaining fees paid to Ernst & Young LLP in 2003 were related to access to professional reference materials and publications.

Pre-Approval Policies and Procedures

The Audit Committee approves all audit, audit-related services, tax services and other services provided by Ernst & Young LLP. Any services provided by Ernst & Young LLP that are not specifically included within the scope of the audit must be either (i) pre-approved by the entire Audit Committee in advance



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of any engagement or (ii) pre-approved by the Chairman of the Audit Committee pursuant to authority delegated to him by the other independent members of the Audit Committee, in which case the Audit Committee is then informed of his decision. Under the Sarbanes-Oxley Act of 2002, these pre-approval requirements are waived for non-audit services where (i) the aggregate of all such services is no more than 5% of the total amount paid to the external auditors during the fiscal year in which such services were provided, (ii) such services were not recognized at the time of the engagement to be non-audit services and (iii) such services are approved by the Audit Committee prior to the completion of the audit engagement. In 2003, less than 2% of the fees paid to Ernst & Young LLP for non-audit services were approved pursuant to the above exception.

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In making its recommendation to appoint Ernst & Young LLP as our independent auditor for the fiscal year ending December 31, 2004, the Audit Committee has considered whether the services provided by Ernst & Young LLP are compatible with maintaining the independence of Ernst & Young LLP and has determined that such services do not interfere with that firm's independence in the conduct of its auditing function.

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### PART IV

#### Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

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(a) Documents filed as part of report on Form 10-K

(3) Exhibits

| Exhibit<br>Number<br>----- | Description<br>-----  |
|----------------------------|---|
| 3.1*                       | Certificate of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F for the fiscal year ended December 31, 2000 and incorporated herein by reference).             |
| 3.2*                       | Articles of Incorporation of the Company (filed as an exhibit to the Company's annual report on Form 20-F for the fiscal year ended December 31, 2000 and incorporated herein by reference).                |
| 10.1*                      | Orthofix Inc. Employee Stock Purchase Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)          |
| 10.2*                      | Orthofix International N.V. Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1) |

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- 10.3\* Form of Performance Accelerated Stock Option under the Staff Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
- 10.4\* Orthofix International N.V. Executive Share Option Plan (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
- 10.5\* Form of Performance Accelerated Stock Option Inducement Agreement. (1)
- 10.6\* Employment Agreement, dated as of July 1, 2001, between Orthofix International N.V. and Charles W. Federico (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
- 10.7\* Employment Agreement, dated as of March 1, 2003, between the Company and Thomas Hein (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
- 10.8\* Employment Agreement, dated as of March 1, 2003, between the Company and Gary D. Henley (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
- 10.9\* Employment Agreement, dated as of July 1, 1999, between Orthofix International N.V. and Robert Gaines-Cooper (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
- 10.10\* Employment Agreement, dated as of July 1, 1999, between Orthofix International N.V. and Edgar Wallner (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference). (1)
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- 10.11\* Employment Agreement, dated as of November 20, 2003, between Orthofix International N.V. and Bradley R. Mason. (1)
- 10.12\* Full Recourse Promissory Note between Orthofix International N.V. and Charles W. Federico dated January 10, 2002 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).
- 10.13\* Full Recourse Promissory Note between Orthofix International N.V. and Gary D. Henley dated January 10, 2002 (filed as an exhibit to the Company's annual report on Form 10-K for the fiscal year ended December 31, 2002 and incorporated herein by reference).
- 10.14\* Share Purchase Agreement, dated as of March 20, 2003, between

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Orthofix International N.V. and Intavent Limited (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference).

- 10.15\* Acquisition Agreement dated as of November 20, 2003, among Orthofix International N.V., Trevor Acquisition, Inc., Breg, Inc. and Bradley R. Mason, as shareholders' representative (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
- 10.16\* Voting and Subscription Agreement dated as of November 20, 2003, among Orthofix International N.V. and the significant shareholders of Breg, Inc. identified on the signature pages thereto (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
- 10.17\* Credit Agreement dated as of December 30, 2003, among Colgate Medical Limited, as borrower, and Orthofix International N.V. and certain subsidiaries of the borrower, as guarantors, certain limited guarantors party thereto, the lenders parties thereto, Wachovia Bank, National Association, as administrative agent, and Wachovia Capital Markets, LLC, as sole lead arranger and book manager (filed as an exhibit to the Company's current report on Form 8-K filed January 8, 2004 and incorporated herein by reference).
- 14.1\* Code of Ethics of the Company.
- 21.1\* Subsidiaries of the Company.
- 23.1\* Consent of Ernst & Young, independent auditors.
- 23.2\* Consent of PricewaterhouseCoopers, independent accountants.
- 31.1\*\* Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
- 31.2\*\* Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
- 32.1\* Section 1350 Certification of Chief Executive Officer.
- 32.2\* Section 1350 Certification of Chief Financial Officer.

\* Previously filed as an exhibit to this Annual Report on Form 10-K.

\*\* Filed herewith.

(1) Management Contract or Compensatory Plan or Arrangement.

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities

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Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORTHOFIX INTERNATIONAL N.V.

Dated: April 29, 2004

By: /s/ Thomas Hein

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Name: Thomas Hein  
Title: Chief Financial Officer