EDWARDS LIFESCIENCES CORP
Form 8-K
May 13, 2003

QuickLinks -- Click here to rapidly navigate through this document

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 13, 2003

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**1-15525**	**36-4316614**
(State or other jurisdiction of incorporation)	(Commission file number)	(IRS Employer Identification No.)

One Edwards Way, Irvine, California	**92614**
(Address of principal executive offices)	(Zip Code)

(949) 250-2500
Registrant's telephone number, including area code

Item 5. Other Events.

Set forth below is a description of the material risks related to Edwards Lifesciences Corporation, a Delaware corporation, and an investment in its securities. This description replaces and supersedes prior descriptions of the material risks included in previous filings with the Securities and Exchange Commission to the extent that they are inconsistent with the description contained in this Current Report on Form 8-K.

Risk Factors

You should carefully consider the risks described below, as well as other information contained in our filings with the Securities and Exchange Commission. If any of the events described below occurs, our business, financial condition or results of operations could be materially harmed. In that case, the value our securities could decline and you may lose part or all of your investment. Unless otherwise indicated or the context

otherwise requires, the terms "we," "our," "us" and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

If we do not introduce new products in a timely manner, our products may become obsolete, and our operating results may suffer.

The cardiovascular products industry is characterized by rapid technological changes, frequent new product introductions and evolving industry standards. Without the timely introduction of new products and enhancements, our products will likely become technologically obsolete over time, in which case our revenue and operating results would suffer. Even if we are able to develop new technologies, these technologies may not be accepted quickly because of industry specific factors, such as the need for regulatory clearance, unanticipated restrictions imposed on approved indications, entrenched patterns of clinical practice and uncertainty over third party reimbursement

Moreover, significant technical innovations generally will require a substantial investment before we can determine the commercial viability of these innovations. We may not have the financial resources necessary to fund these technical innovations. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development, and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

We may incur product liability losses that could adversely affect our operating results.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture and marketing of medical devices. Our products are often used in surgical and intensive care settings with seriously ill patients. In addition, some of the medical devices manufactured and sold by us are designed to be implanted in the human body for long periods of time. We could be the subject of product liability suits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information could result in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers.

We may experience supply interruptions that could harm our ability to manufacture products.

We use a diverse and broad range of raw and organic materials and other items in the design and manufacture of our products. Our non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metals. Our heart valve therapy products are manufactured from treated natural animal tissue and man-made materials. We purchase certain of the materials and components used in the manufacture of our products from external suppliers. In addition, we purchase certain supplies from single sources for reasons of quality assurance, cost-effectiveness or constraints resulting from regulatory requirements. We work closely with our

---

suppliers to assure continuity of supply while maintaining high quality and reliability. Alternative supplier options are generally considered and identified, although we do not typically pursue regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with this regulatory process. Although a change in suppliers could require significant effort or investment by us in circumstances where the items supplied are integral to the performance of our products or incorporate unique technology, management does not believe that the loss of any existing supply contract would have a material adverse effect on us.

In an effort to reduce potential product liability exposure, in the past certain suppliers have announced that they might limit or terminate sales of certain materials and parts to companies that manufacture implantable medical devices. In some cases, we have been required to indemnify suppliers for product liability expenses in order to continue to receive materials or parts. There can be no assurance that an indemnity from us will be satisfactory to these suppliers in the future. If we are unable to obtain these raw materials or there is a significant increase in the price of materials or components, our business could be harmed.

We may be required to recognize additional charges in connection with the write-down of some of our investments, the disposition of some of our businesses or for other reasons.

We have made investments in the equity instruments of other companies, and may make further such investments in the future. To the extent that the value of any such investment declines, we may be required to recognize charges to write down the value of that investment. For example, in September 2002, we recorded a $67.4 million pretax charge related to the impairment of our investment in the preferred stock of World Heart Corporation. See "Disposition of assets and other non-recurring charges, net" under "Management's discussion and analysis of financial condition and results of operations" in our Annual Report on Form 10-K for the year ended December 31, 2002.

In the case of some of the companies in which we have invested, the value of their equity securities has declined since the time of our original investment. As a result, we may be required to recognize additional charges, which could be substantial, to write down our investments.

At December 31, 2002, in addition to our investment in World Heart, which was $6.1 million, we had approximately $17.4 million of investments in equity instruments of other companies and had recorded unrealized losses on these investments of approximately $6.8 million on our balance sheet under "accumulated other comprehensive income," net of tax.

As part of the ongoing evaluation of our various businesses and products, we from time to time identify businesses or products that are not performing at a level commensurate with the rest of our business. We may from time to time seek to dispose of these underperforming businesses or product lines, and may also seek to dispose of businesses or product lines from time to time for strategic or other business reasons. If we are unable to dispose of a business or product line on terms we consider acceptable, we may voluntarily terminate that business or cease providing that product. Any of these events may result in charges, which could be substantial and which could adversely affect our results of operations.

We have entered into interest rate swap agreements in connection with some of our indebtedness, and expect that we will continue to do so from time to time in the future. In the event that we elect to terminate a swap agreement prior to its maturity, we may be required to make cash payments to the counterparty and to recognize a charge in connection with that termination, which could adversely affect our results of operations.

We may not successfully identify and complete acquisitions or strategic alliances on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances.

As part of our growth strategy, we regularly review potential acquisitions of complementary businesses, technologies, services or products and potential strategic alliances. We may be unable to find suitable acquisition candidates or appropriate partners with which to form partnerships or strategic alliances. Even if we identify appropriate acquisition or alliance candidates, we may be unable to complete such acquisitions or alliances on favorable terms, if at all. In addition, the process of integrating an acquired business, technology, service or product into our existing business and operations may result in unforeseen operating difficulties and expenditures. Integration of an acquired company also may require significant management resources that otherwise would be available for ongoing development of our business. Moreover, we may not realize the anticipated benefits of any acquisition or strategic alliance, and such transactions may not generate anticipated financial results. In addition, we may be required to take charges or write-downs in connection with acquisitions we have made or may make in the future. Future acquisitions could also require issuances of equity securities, the incurrence of debt, contingent liabilities or amortization expenses related to other intangible assets, any of which could harm our business.

Our business is subject to economic, political and other risks associated with international sales and operations.

Because we sell our products in a number of foreign countries, our business is subject to risks associated with doing business internationally. Our net sales originating outside of the United States, as a percentage of total net sales, were 45.6% in 2002. We anticipate that sales from international operations will continue to represent a substantial portion of our total sales. In addition, many of our manufacturing facilities and suppliers are located outside of the United States. Our management expects to increase our sales efforts internationally, which could expose us to greater risks associated with international sales and operations. Accordingly, our future results could be harmed by a variety of factors, including:

changes in foreign medical reimbursement policies and programs;

unexpected changes in foreign regulatory requirements;

changes in foreign currency exchange rates;

changes in a specific country's or region's political or economic conditions, particularly in emerging regions;

trade protection measures and import or export licensing requirements;

potentially negative consequences from changes in tax laws;

difficulty in staffing and managing foreign operations;

changes in the international political situation;

differing labor regulations; and

differing protection of intellectual property.

We are subject to risks arising from currency exchange rate fluctuations.

We generated 45.6% of our 2002 net sales outside of the United States. Substantially all of our sales outside of the United States are denominated in local currencies. Measured in local currency, a substantial portion of our foreign generated sales were generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our foreign generated sales

varies with currency exchange rate fluctuations. Significant increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, could have a material adverse effect on our results of operations. We have a hedging policy that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity and cost; however, this hedging policy does not completely eliminate the effects of currency exchange rate fluctuations.

Fluctuations in our quarterly operating results may cause our stock price to decline.

Our sales and operating results may vary significantly from quarter to quarter. A high proportion of our costs are fixed, due in part to significant sales, research and development and manufacturing costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter, and the price of our common stock may fall. Other factors that could affect quarterly operating results include:

demand for and clinical acceptance of products;

the timing and execution of customer contracts, particularly large contracts that would materially affect our operating results in a given quarter;

the timing of sales of products;

changes in foreign currency exchange rates;

unanticipated delays or problems in introducing new products;

competitors' announcements of new products, services or technological innovations;

changes in our pricing policies or the pricing policies of our competitors;

increased expenses, whether related to sales and marketing, raw materials or supplies, product development or administration;

adverse changes in the level of economic activity in the United States and other major regions in which we do business;

costs related to possible acquisitions of technologies or businesses;

our ability to expand our operations; and

the amount and timing of expenditures related to expansion of our operations.

Our inability to protect our intellectual property could have a material adverse effect on our business.

Our success and competitive position are dependent, in part, upon our proprietary intellectual property. We rely on a combination of patents, trade secrets and nondisclosure agreements to protect our proprietary intellectual property, and will continue to do so. Although we seek to protect our proprietary rights through a variety of means, we cannot guarantee that the protective steps we have taken are adequate to protect these rights. Patents issued to or licensed by us in the past or in the future may be challenged and held invalid or not infringed by third parties. Competitors may also challenge our patents. In addition, certain of our patents are due to expire within the next six years and we may be unsuccessful in our efforts to extend these patents through improvement patents, modifications or line extensions. The failure to maintain our patents could have a material adverse effect on us.

We also rely on confidentiality agreements with certain employees, consultants and other parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached and we may not have adequate remedies for any breach. In addition, others may independently develop

substantially equivalent proprietary information or gain access to our trade secrets or proprietary information. We spend significant resources to monitor and enforce our intellectual property rights. However, we may not be able to detect infringement and may lose our competitive position in the industry. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture increased market position.

Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling products.

During recent years, our competitors have been involved in substantial litigation regarding patent and other intellectual property rights in the medical device industry generally. In the future, we may be forced to defend ourselves against other claims and legal actions alleging infringement of the intellectual property rights of others. Because intellectual property litigation can be costly and time consuming, our intellectual property litigation expenses could be significant. Adverse determinations in any such litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could, if such licenses are not available, prevent us from manufacturing, selling or using certain of our products, any one of which could have a material adverse effect on us.

Third parties could also obtain patents that may require us to either redesign our products or, if possible, negotiate licenses to conduct our business. If we are unable to redesign our products or obtain a license, we may have to exit a particular product offering.

We face intense competition and consolidation within our industry, and if we do not compete effectively, our business will be harmed.

The cardiovascular medical device industry is highly competitive. We compete with many companies, some of which have longer operating histories, better brand or name recognition and greater access to financial and other resources than us. Furthermore, the industry is characterized by intensive development efforts and rapidly advancing technology. Our present and future products could be rendered obsolete or uneconomical by technological advances by one or more of our current or future competitors or by alternative therapies, including drug therapies. See "Business Competition" in our Annual Report of Form 10-K for the year ended December 31, 2002. Our future success will

depend, in large part, on our ability to develop and acquire new products and technologies, anticipate technology advances and keep pace with other developers of cardiovascular therapies and technologies.

The medical device industry has been consolidating and as a result, transactions with customers are larger, more complex and tend to involve more long-term contracts. The enhanced purchasing power of these larger customers may also increase downward pressure on product pricing. In addition, many existing and potential domestic customers for our products have combined to form group purchasing organizations, or "GPOs." GPOs negotiate pricing arrangements with medical supply manufacturers and distributors and these negotiated prices are made available to members of GPOs. If we are not one of the providers selected by a GPO, we may be precluded from making sales to members of a GPO for several years. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our sales and profit margins, business, financial condition and results of operations.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with these regulations and develop our products to be compatible with these regulations.

The medical devices manufactured and marketed by us are subject to rigorous regulation by the U.S. Food and Drug Administration, or "FDA," and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time consuming, and approvals might not be granted for future products on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products could result in delayed realization of product revenues or in substantial additional costs, which could have material adverse effects on our business or results of operations. In addition, there can be no assurance that we will be or will continue to be in compliance with applicable FDA and other material regulatory requirements. If the FDA were to conclude that we were not in compliance with applicable laws or regulations, it could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us, our officers or our employees and could recommend criminal prosecution to the Department of Justice. Moreover, the FDA could proceed to ban, or request recall, repair, replacement or refund of the cost of, any device or product manufactured or distributed by us. Furthermore, both the FDA and foreign government regulators have become increasingly stringent, and we may be subject to more rigorous regulation by governmental authorities in the future.

We are subject to risks arising from concerns and/or regulatory actions relating to "mad cow disease."

Certain of our products, including pericardial tissue valve products, are manufactured using bovine tissue. Concerns relating to the potential transmission of bovine spongiform encephalopathy, or "BSE," commonly known as "mad cow disease," from cows to humans may result in reduced acceptance in certain geographies of bovine products. In addition, various governmental bodies are considering stricter regulation of such products. We obtain our bovine tissue only from sources within the United States, where strong control measures and surveillance programs exist and where no BSE cases have been reported. In addition, the bovine tissue used in our pericardial tissue valve products are from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. We have not experienced any adverse impact on our sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.

If third-party payors decline to reimburse our customers for our products or reduce reimbursement levels, our ability to profitably sell our products will be harmed.

We sell our products and technologies to hospitals, doctors and other health care providers, all of which receive reimbursement for the health care services provided to their patients from third-party payors, such as government programs (both domestic and international), private insurance plans and managed care programs. These third-party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods as determined by such third-party payor, or was used for an unapproved indication. Third-party payors may also decline to reimburse for experimental procedures and devices. We believe that many of our existing and future products are cost-effective because they are intended to reduce overall health care costs over a long period of time. We cannot be certain whether these third-party payors will recognize these cost savings or will merely focus on the lower initial costs associated with competing therapies. If our products are not considered cost-effective by third-party payors, our customers may not be reimbursed for our products.

In addition, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. There can be no

assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation or reimbursement policies of third-party payors will not otherwise adversely affect the demand for and price levels of our products. In Japan, customers are reimbursed for our products under a government-operated insurance system. Under this system, the Japanese government annually reviews the reimbursement levels for products. The Japanese government is also considering other reimbursement regulation. If the Japanese government decides to reduce reimbursement levels for our products, our product pricing may be adversely affected.

We are, or may be, subject to lawsuits related to products or services manufactured or performed by us.

We are, or may be, a party to, or may be otherwise responsible for, pending or threatened lawsuits or other claims related to products and services currently or formerly manufactured or performed, as applicable, by us or other matters. Such cases and claims may raise difficult and complex factual and legal issues and may be subject to many uncertainties and complexities, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any pending legal matters or other claims, we may incur charges in excess of presently established reserves. While such a charge could have a material adverse impact on our net income or net cash flows in the period in which it is recorded or paid, management believes that no such charge relating to any currently pending lawsuit would have a material adverse effect on our consolidated financial position.

The market price for our common stock may be volatile.

The market price of our common stock could fluctuate substantially in the future in response to a number of factors, including the following:

- quarterly variations in operating results, as discussed above under " Fluctuations in our quarterly operating results may cause our stock price to decline,"
- announcements of innovations, new products, strategic developments or business combinations by us or our competitors,
- changes in our expected operating expense levels or income and losses,
- changes in financial estimates and recommendations of securities analysts,
- the operating and securities price performance of other companies that investors may deem comparable to us, and
- changes in general conditions in the economy, the financial markets, the domestic or international political situation, particularly in light of the conflict in Iraq, or the medical device industry.

In addition, in recent years the stock market has experienced extreme price and volume fluctuations. This volatility has had a significant effect on the market prices of securities issued by many companies for reasons unrelated to their operating performance. These broad market fluctuations may materially adversely affect our stock price, regardless of our operating results.

Our stockholder rights plan, charter and bylaws, as well as provisions of Delaware law, could make it difficult for a third party to acquire our company.

We have a stockholder rights plan that may have the effect of discouraging unsolicited takeover proposals. The rights issued under the stockholder rights plan would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our board of directors. In addition, Delaware corporate law and our charter and bylaws contain provisions that could

delay, deter or prevent a change in control of our company or our management. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors and take other corporate actions without the concurrence of our management or board of directors. These provisions:

- authorize our board of directors to issue "blank check" preferred stock, which is preferred stock that can be created and issued by our board of directors, without stockholder approval, with rights senior to those of common stock;
- provide for a staggered board of directors and three-year terms for directors, so that no more than one-third of our directors could be replaced at any annual meeting;
- provide that directors may be removed only for cause;
- provide that stockholder action may be taken only at a special or regular meeting and not by written consent;
- provide for super-majority voting requirements for some provisions of our charter; and
- establish advance notice requirements for submitting nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at a meeting.

We are also subject to anti-takeover provisions under Delaware law, which could also delay or prevent a change of control. Together, these provisions of our charter and bylaws, Delaware law and our stockholder rights plan may discourage transactions that otherwise could provide for the payment of a premium over prevailing market prices of our common stock, and also could limit the price that investors are willing to pay in the future for shares of our common stock.

Our issuance of preferred stock could adversely affect holders of our common stock and discourage a takeover.

Our board of directors is authorized to issue up to 50,000,000 shares of preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, including voting rights, dividend rights, preferences over our common stock with respect to dividends or in the event of a dissolution, liquidation or winding up and other terms. In the event that we issue preferred stock in the future that has preference over our common stock with respect to payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the rights of the holders of our common stock or the market price of our common stock could be adversely affected. In addition, the ability of our board of directors to issue shares of preferred stock without any action on the part of our stockholders may impede a takeover of us and prevent a transaction favorable to the holders of our common stock.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 13, 2003

EDWARDS LIFESCIENCES CORPORATION

By: /s/ BRUCE P. GARREN

Bruce P. Garren
Corporate Vice President,
General Counsel and Secretary

QuickLinks