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BIACORE INTERNATIONAL AB

Form 6-K

March 17, 2004

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

For the months of January through February 2004

Commission File Number 000-28966

Biacore International AB (publ)

C/o Biacore International SA

Puits-Godet 12

CH-2000 Neuchatel

Switzerland

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ X

Form 40-F ☐

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐

No ☒ X

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): Not applicable.

YEAR-END REPORT 2003

* Biacore's sales in the fourth quarter of 2003 amounted to SEK 160.8 million (175.9), a decrease of 9% mostly due to currency effects. For the full-year 2003, sales decreased by 16% to SEK 515.5 million (614.2). Excluding currency effects, the sales decline was 9%.

* Biacore's earnings per share in the fourth quarter amounted to SEK 5.67 (4.15), an increase of 37%. For the full-year 2003, earnings per share decreased by 45% to SEK 4.53 (8.20). Lower sales and the cost associated with the discontinuation of Procel(tm) were the main reasons for this decrease.

* Biacore has decided to increase its investment, particularly in sales and marketing, to capture the significant business opportunities that exist for its core SPR technology. This investment is designed to further penetrate the late-stage drug discovery market and to underpin the successful launch of the Company's ground-breaking SPR array system in 2004.

* Biacore's Board has decided to take the initial steps needed to de-list the

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Company's ADRs from Nasdaq National Market in the United States. This decision is due to the increasing costs of maintaining this listing, the lack of advantages with a dual listing and the limited number of Biacore ADRs traded on Nasdaq.

- * The Board has decided to recommend to the Annual General Meeting an unchanged dividend payment for the financial year 2003 of SEK 3.00 per share.
- * The current market and currency conditions make an accurate sales forecast for 2004 difficult. However, Biacore expects sales and earnings per share for the full-year 2004 to increase. As always, sales and earnings are likely to vary substantially between the quarters.

	January-December			October-December		
	2003	2002	Change	2003	2002	Change
Sales, SEK million	515.5	614.2	-16%	160.8	175.9	-9%
Operating income, SEK million	29.5	140.6	-79%	54.7	48.5	13%
Operating margin, %	6	23		34	28	
Income after financial items, SEK million	41.4	120.2	-66%	57.0	49.6	15%
Net income, SEK million	44.3	80.8	-45%	55.4	40.6	36%
Diluted earnings per share, SEK	4.53	8.20	-45%	5.67	4.15	37%

Operational Review January - December 2003

Amounts stated in this report pertain to the Biacore Group, unless indicated otherwise. Figures in parentheses refer to the corresponding period in 2002.

Biacore's sales developed more satisfactorily during the fourth quarter than in prior quarters 2003. The sales volume was on the same level as the corresponding period in 2002, and the reported sales decline of 9% was due to currency effects. Sales to academic customers and late-stage drug discovery customers continued to increase in the fourth quarter. However, demand from early-stage drug discovery customers continued to be weak, and this trend was particularly apparent in Europe in the fourth quarter.

For the full-year 2003, sales declined by 16% to SEK 515.5 million (614.2). Excluding currency effects, the drop was 9%. Biacore(r)3000 continues to be the Company's best-selling product. This flexible system is Biacore's most important product offering to academic customers in its core basic life science research market. Biacore(r)3000 is used to solve a wide range of biological research problems, especially in the field of functional proteomics. Sales of Biacore(r)3000 with the new GxP package, which is used in the clinical trials of the growing number of bio-therapeutics under development, to capture important data including immunogenicity, has made good sales progress in all key markets. Sales of Biacore(r)S51 also continued to make an important contribution, as major customers in the pharmaceutical and biotech industries have increasingly recognized the benefits of this system in the field of lead optimization.

Consumables and service accounted for approximately 27% of total sales.

Sales were divided geographically as follows:

	January-December			October-December		
SEK million	2003	2002	Change	2003	2002	Change
Americas	228.6	270.5	-16%	69.4	63.8	9%
Europe	136.5	173.9	-22%	43.2	62.7	-31%
Asia-Pacific	150.4	169.8	-11%	48.2	49.4	-2%

Sales in the Americas were affected by a slowdown in orders from the pharmaceutical and biotechnology sector. A marked improvement occurred in the

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fourth quarter, but it is still too early to tell if this is a new market trend. In Europe, the sharp slowdown in sales to early-stage drug discovery customers, which started in the third quarter became more marked in the fourth quarter. Sales in Asia-Pacific - Japan being the most important market - varied strongly between the quarters during the course of 2003, a common phenomenon in Biacore's business.

The 82% gross margin achieved for the full-year 2003 was consistent with prior periods.

In the fourth quarter, costs for marketing amounted to SEK 45.2 million (53.4), a decrease of 15%. In the same period, administration costs increased by 26% to SEK 17.2 million (13.6), adjustment of pension plan assets to required levels being one factor. R&D expenses increased by 12% in the fourth quarter to SEK 34.2 million (30.4). Of these amounts, SEK 12.4 million (4.1) were capitalized.

Operating income in the fourth quarter increased by 13% to SEK 54.7 million (48.5), and the operating margin was 34% (28).

The Item affecting comparability in 2003 pertains to the discontinuation of Procel(tm).

Operating income for the full-year 2003 decreased by 79% to SEK 29.5 million (140.6), mainly as a result of lower sales and the discontinuation of Procel(tm). The operating margin was 6% (23). After adjustment for the item affecting comparability, SEK -58.5 million in 2003, and damages received for patent infringement, SEK 19.6 million, in 2002, operating income decreased by 27%. Currency differences during 2003 amounted to SEK -14.7 million (-16.6) in 'Other income and expenses'. These differences were mainly due to the depreciation of the U.S. dollar and the Japanese yen against the Swedish Krona.

As a result of deferred taxes and the geographical distribution of earnings, a tax gain of SEK 2.9 million is reported (-40.1). Taxes have been limited by deductible expenses for the discontinuation of Procel(tm), among other items.

Net income for 2003 was SEK 44.3 million (80.8), leading to a 45% decrease in diluted earnings per share to SEK 4.53 (8.20). Earnings per share in the fourth quarter was SEK 5.67 (4.15), an increase of 37%.

Investing Activities

During 2003, capital expenditures totaled SEK 16.4 million (31.7).

Personnel

At the end of December 2003, Biacore had 346 (325) permanent employees.

In May 2003, Biacore introduced a new incentive stock option program involving a maximum of 100,000 new Biacore shares.

In January 2004, Mr Erik Wallden assumed the new position of Head of Marketing and Business Development and Executive Vice President of Biacore.

Business Review

Biacore has a world-leading position in the commercialization of surface plasmon resonance (SPR) technology. SPR-based systems from Biacore are used world-wide for the real-time detection and monitoring of biomolecular binding interactions. The Company's key customers include academic life science researchers, the pharmaceutical and biotechnology industry as well as the food industry and government testing facilities.

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In 2003, Biacore's sales declined due to pharmaceutical companies, especially in the United States and Europe, focusing their R&D spending on late-stage drug discovery and development activities and limiting their purchases of equipment for early-stage applications. However, there is a high probability that this trend will cease within the next twelve to eighteen months. Bearing in mind the large potential for its systems in other market segments, Biacore remains very positive about its longer-term prospects. Increased investment in sales and marketing will also contribute to the Company's growth.

Academic Customers - Our Strong Core Business

Biacore's SPR based systems have a strong following from academic customers around the globe and are found in all leading life science institutions. This is evidenced by the fact that, as per year-end 2003, more than 3,200 peer-reviewed scientific papers had been published based on research using Biacore's systems. The strength of the Company's business has been reflected in the sales progress to this market segment that has been made over the course of 2003. During this period, the Company's marketing activities have continued to focus on the ability of its SPR technology based systems to help solve many of the important problems faced by academic scientists working on a better understanding of the molecular causes of disease.

The research areas where Biacore believes that its technology is in the position to deliver the most value include Cancer, Neuroscience and Immunology and Infectious Diseases. In the latter area, the utility of SPR technology was highlighted when Biacore signed a collaborative deal with the Shanghai Institute of Materia Medica, the Chinese Academy of Sciences, which will involve the use of SPR technology to find new compounds which are active against the SARS virus.

In addition, Biacore has succeeded in building the profile of its technology in another key area of life science research, Proteomics, where the Company is increasingly being recognized as a global leader. In the field of functional proteomics, a rapidly growing market, there are three areas where Biacore's SPR systems have clear competitive advantages, namely ligand fishing, protein-protein interactions and integration with Mass Spectrometry through automated recovery and preparation of bound analytes. These areas are crucial to developing a clear understanding of disease processes and for identifying potential drug candidates.

Developing Our Pharmaceutical Industry Customer Base

A key element of Biacore's strategy is to increase the utilization of its SPR technology-based systems by pharmaceutical and biotechnology companies to discover and develop better drugs for the treatment of a wide range of diseases. In recent years, Biacore's ability to deliver to this customer base has been enhanced by the introduction of a number of systems focused on the specific needs of the drug development process.

Biacore(r)S51 - Building A Business in Lead Optimization

During the course of 2003, Biacore has continued to work to establish Biacore(r)S51 as a key tool for pharmaceutical and biotechnology customers, addressing critical bottlenecks in the drug discovery process downstream of high-throughput screening (HTS), particularly in the area of lead optimization. Biacore(r)S51 is gradually establishing its position in this segment of the market based on its ability to provide more relevant biological information on compound activity, in a single assay, than any other technology available today.

Given the progress that has been made with Biacore(r)S51 since its launch, Biacore is confident that it will become a major contributor to the Company's future sales growth. In the second quarter 2003, the utility of the system for

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small molecule analysis was enhanced with the introduction of a new software package and two new chip surfaces. This has led to further interest in the system from some of the world's leading drug discovery laboratories.

This confidence is also based on the growing appreciation of the product from the market as new customer-generated data highlighting the benefits of using Biacore(r)S51 become increasingly available. At the Society for Biomolecular Screening Conference in Portland, Biacore presented further data on the value of using Biacore(r)S51 for the detailed characterization of potential new therapeutics which are directed at kinases.

Biacore(r)3000 GxP Package - Important to the Bio-Therapeutics Revolution

Biacore's GxP package, which was launched in the spring of 2003 and which is used in conjunction with Biacore(r)3000, has been well received by pharmaceutical and biotechnology customers. This new combination has been designed to facilitate pharmaceutical companies' compliance with the regulatory requirements and will complement Biacore(r)C, launched in 2001 for rapid concentration analysis in drug development, manufacturing quality control and in-process control applications.

A key application of the Biacore(r)3000 GxP Package will be in the clinical trials of the new wave of biological therapeutics, including antibodies, which are a major source of growth for the pharmaceutical industry. The new combination will play a key role in capturing vital data during clinical trials such as the therapeutic product's immunogenicity.

This new application is expected to provide an important source of growth for Biacore, given the large number of new biological therapeutics, which are being developed by both pharmaceutical and biotechnology companies around the world. A major advantage of using an SPR assay to measure specific antibody levels in the blood of clinical trial patients is that no special purification is needed. This enhances both the speed and reproducibility of the results generated.

Food Analysis Business - Sales Continue to Build

Biacore's food analysis business has made good progress with rapid consecutive releases of its proprietary Qflex(r) kits for beta agonists, sulphonamides and chloramphenicol, all residues considered harmful in the food chain. These kits in conjunction with the dedicated food analysis platform, Biacore(r)Q, are gaining acceptance by food regulators and food production companies. This is further evidenced by the growing presence of the technology in markets such as Asia, where routine testing is now undertaken by one of the major poultry producers in Thailand, and Europe, where in the United Kingdom key independent and government facilities now routinely use Biacore(r)Q. Further advances also in the vitamin analysis segment, including adoption of Biacore(r)Q by some of the world's leading dairy product and vitamin producers, are further increasing the Company's presence in this sector.

This market segment also offers considerable longer-term recurrent revenues through kit sales.

SPR Array Technology - Expanding Our Commercial Opportunities

Biacore is determined to build on the strong SPR-based business that it has established over the last thirteen years. In order to achieve this, the Company is working on a number of important technological breakthroughs in SPR detection and micro-fluidics that form the basis for the development of its new SPR array system.

This system, which is on-track to reach the market in the second half of 2004, will be able to deliver a significant improvement in the speed with which

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information on protein interactions can be generated. Delivering the same high sensitivity and data quality that the Company's customers currently enjoy and require, this new platform will enable Biacore's SPR technology to be used across a broader range of applications in both basic life science research and drug discovery with a higher throughput and information content than is possible today.

To commercialize its SPR array technology, Biacore has utilized two collaborations to develop specific applications and gain access to reagent expertise. These collaborations with Millennium Pharmaceuticals and BD Biosciences Pharmingen have enabled Biacore to develop the critical elements of the system's specification so that it meets the demands of its targeted end-users. The fact that the collaboration with Millennium came to an end, as planned, in the summer of 2003, allows Biacore to extend the number of pharmaceutical customers with whom it can work to generate the applications data needed to ensure the successful launch of this ground-breaking new system.

Initially the SPR array system will be targeted at applications in two key areas:

- * Interaction proteomics, which is of significant interest to academic customers given the importance of understanding exactly how proteins interact as part of elucidating the causes of disease, and
- * post-HTS small molecule characterization areas, where its sensitivity, increased throughput and high information content will complement Biacore(r)S51 in lead optimization applications.

Over time, the Company expects the SPR array system to have applications across the spectrum of drug discovery and development activities and be a valuable tool in many proteomics applications.

Maximizing The Potential of Our SPR Business

Biacore has decided to re-focus and to increase its investment in the sales and marketing activities needed to support its SPR-based systems, especially towards the late-stage drug discovery customers. This decision has been made based on the attractive prospects that the Company sees for its current and developing product portfolio and in particular for the enhanced commercial opportunities that can be accessed via its new SPR array system that is due to be introduced in the second half of 2004.

Amongst the key areas in which Biacore expects higher sales are:

- * The Company's core life science research customers as Biacore's SPR technology gains even greater recognition in the field of functional proteomics.
- * The new applications of the Biacore(r)3000, including the new GxP package which has taken Biacore into the fast growing bio-therapeutics clinical trials market.
- * Its systems dedicated to late-stage customers in the pharmaceutical and biotechnology industry, Biacore(r)S51 for "hit to lead"-selection, and Biacore(r)C for quality control applications.
- * The significant commercial potential of the first system being developed based on Biacore's novel SPR array technology, which is due to reach the market in the second half of 2004 and which will be targeted initially at functional proteomics and post-HTS small molecule characterization by the pharmaceutical industry.

De-Listing From Nasdaq

Biacore's Board has decided to take the initial steps needed to de-list the Company's ADRs from Nasdaq National Market in the United States. This decision is due to the increasing costs of maintaining this listing, the lack of

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advantages with a dual listing and the limited number of Biacore ADRs traded on Nasdaq.

Nominations Committee

The Annual General Meeting has decided to establish a nominations committee with the task to propose to the Annual General Meeting:

1. The number of Board members to be elected.
2. The election of Board members.
3. Remuneration to the members of the Board.

Until the Annual General Meeting 2004, the nominations committee consists of the following: Lars-Goran Andren, chairman of the board, co-ordinator of the committee; Peter Bolte, Handelsbanken Fonder; Inger Brattne, Pfizer and Peter Rudman, Nordeas fonder.

Quarterly Sales Variations

Biacore's total sales during the period 2001-2003 were split between quarters as follows:

Quarter 1	23%	Quarter 3	22%
Quarter 2	25%	Quarter 4	30%

Dividend

The Board has decided to recommend to the Annual General Meeting an unchanged dividend payment for the financial year 2003 of SEK 3.00 per share.

Outlook For The Full-Year 2004

The current market and currency conditions make an accurate sales forecast for 2004 difficult. However, Biacore expects sales and earnings per share for the full-year 2004 to increase. As always, sales and earnings are expected to vary substantially between the quarters.

The Annual General Meeting will be held on Wednesday, April 28, 2004 at 4.30 p.m. in Uppsala.

Uppsala, Sweden, February 25, 2004
Biacore International AB (publ)
The Board of Directors

Financial Information

Biacore's Annual Report will be distributed to the shareholders in mid April. The Annual Report will also be available from that time on Biacore's website. During 2004, Biacore plans to release its interim reports as follows:

January - March	Wednesday, April 28
January - June	Monday, July 19
January - September	Thursday, October 21

Biacore is a global market leader in Surface Plasmon Resonance (SPR) technology based systems with its own sales operations in the U.S., across Europe, Japan, Australia and New Zealand. A strong patent portfolio protects Biacore's SPR technology. Target groups for the Company's products consist primarily of medical and life science research laboratories and pharmaceutical and biotechnology companies around the world. Biacore is focusing on drug discovery and development as its prime areas for future growth. Based in Uppsala, Sweden, the Company is listed on the Stockholm Stock Exchange and Nasdaq in the U.S.

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This report contains certain forward-looking statements which, by their nature, involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements.

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Biacore Consolidated Income Statements

SEK million	January-December			October-December		
	2003	2002	Change	2003	2002	Change
Sales	515.5	614.2	-16%	160.8	175.9	-9%
Cost of sales	-94.0	-100.9	-7%	-22.5	-28.5	-21%
Marketing	-165.4	-199.8	-17%	-45.2	-53.4	-15%
Administration	-71.1	-68.3	4%	-17.2	-13.6	26%
Research and development	-78.6	-104.4	-25%	-21.9	-26.3	-17%
Other income and expenses	-14.4	4.3		-4.5	-4.5	
Amortization of goodwill	-4.0	-4.5		-1.0	-1.1	
Items affecting comparability	-58.5	-		6.2	-	
Operating income	29.5	140.6	-79%	54.7	48.5	13%
Financial items, net	11.9	-20.4		2.3	1.1	
Income after financial items	41.4	120.2	-66%	57.0	49.6	15%
Income taxes	2.9	-40.1		-1.5	-9.1	
Minority interest	-	0.7		-0.1	0.1	
Net income	44.3	80.8		55.4	40.6	
Basic earnings per share, SEK	4.55	8.28		5.68	4.16	
Diluted earnings per share, SEK	4.53	8.20		5.67	4.15	
No. of shares, average, diluted, thousands	9,787	9,851		9,767	9,786	
Net income	44.3	80.8		55.4	40.6	
Stock options issued	1.1	-		0.6	-	
Dividend	-29.3	-		-	-	
Currency translation differences	-20.6	-15.3		-1.4	-2.7	
Change in shareholders' equity	-4.5	65.5		54.6	37.9	

Quarterly Income Statements

SEK million	4Q	3Q	2Q	1Q	4Q	3Q	2Q	1Q
	2003	2003	2003	2003	2002	2002	2002	2002
Sales	160.8	105.7	142.5	106.5	175.9	142.4	154.6	141.3
Cost of sales	-22.5	-18.4	-28.8	-24.3	-28.5	-22.9	-25.1	-24.4
Marketing	-45.2	-38.5	-43.1	-38.6	-53.4	-47.9	-55.6	-42.9
Administration	-17.2	-19.7	-18.8	-15.4	-13.6	-19.2	-19.5	-16.0
Research and development	-21.9	-18.9	-19.3	-18.5	-26.3	-23.5	-32.3	-22.3
Other income and expenses	-4.5	-2.1	-3.2	-4.6	-4.5	2.5	11.2	-4.9
Amortization of goodwill	-1.0	-1.0	-1.0	-1.0	-1.1	-1.1	-1.1	-1.2
Items affecting comparability	6.2	-64.7	-	-	-	-	-	-

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Operating income	54.7	-57.6	28.3	4.1	48.5	30.3	32.2	29.6
Financial items, net	2.3	1.5	3.2	4.9	1.1	-10.4	-12.7	1.6
Income after financial items	57.0	-56.1	31.5	9.0	49.6	19.9	19.5	31.2
Income taxes	-1.5	10.6	-4.6	-1.6	-9.1	-8.7	-12.2	-10.1
Minority interest	-0.1	-	-	0.1	0.1	0.1	0.1	0.4
Net income	55.4	-45.5	26.9	7.5	40.6	11.3	7.4	21.5

Basic earnings per share, SEK	5.68	-4.67	2.76	0.77	4.16	1.16	0.75	2.21
Diluted earnings per share, SEK	5.67	-4.67	2.75	0.77	4.15	1.16	0.75	2.17
No. of shares, average, diluted, thousands	9,767	9,750	9,773	9,770	9,786	9,750	9,896	9,918

Sales by region

	Jan.-Dec.		4Q	3Q	2Q	1Q	4Q	3Q	2Q	1Q
SEK million	2003	2002	2003	2003	2003	2003	2002	2002	2002	2002
Americas	228.6	270.5	69.4	52.8	65.2	41.2	63.8	59.6	80.8	66.3
Europe	136.5	173.9	43.2	22.6	39.8	30.9	62.7	44.2	36.5	30.5
Asia-Pacific	150.4	169.8	48.2	30.3	37.5	34.4	49.4	38.6	37.3	44.5
Total sales	515.5	614.2	160.8	105.7	142.5	106.5	175.9	142.4	154.6	141.3

Biacore Consolidated Balance Sheets

SEK million	December 31	
	2003	2002
Intangible assets	70.0	84.8
Property, plant and equipment	111.9	117.1
Long-term investments	1.0	7.9
Other long-term assets	23.8	27.7
Other current assets	260.2	242.3
Liquid funds	352.5	351.6
Total assets	819.4	831.4
Shareholders' equity	630.2	634.7
Minority interest	0.8	0.9
Provisions	80.6	83.4
Liabilities	107.8	112.4
Total shareholders' equity and liabilities	819.4	831.4

Financial structure

Operating capital	306.0	327.4
Long-term investments	1.0	7.9
Net interest-bearing assets	312.3	313.9
Net payable and deferred income tax asset	11.7	-13.6
Minority interest	-0.8	-0.9
Shareholders' equity	630.2	634.7

Biacore Consolidated Statements of Cash Flows

SEK million	January-December	
	2003	2002
Net income	44.3	80.8
Less: Depreciation and amortization	31.8	23.7
Less: Write-downs of intangible and tangible assets	48.7	-
Less: Income from long-term investments	-4.0	28.7

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Change in working capital	-19.2	37.1
Other	-14.9	-6.6
Cash flows from operating activities	86.7	163.7
Acquisition of business, net of cash acquired	-	1.6
Purchase of intangible assets	-50.1	-7.0
Purchase of property, plant and equipment	-16.4	-31.7
Sales of long-term investments	11.0	-
Cash flows from investing activities	-55.5	-37.1
Change in financial liabilities	-1.0	4.2
Dividend	-29.3	-
Cash flows from financing activities	-30.3	4.2
Net change in liquid funds	0.9	130.8

Key figures

Operating margin	5.7%	22.9%
Return on operating capital	9.3%	42.4%
Return on equity	7.0%	13.4%
Equity ratio	77%	76%
Shareholders' equity per share, diluted, SEK	64.34	64.44
No. of shares, thousands	9,750	9,750
No. of shares, end of period, diluted, thousands	9,794	9,849
No. of shares, average, diluted, thousands	9,787	9,851

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, thereunto duly authorized.

Dated: March 12, 2004
 Biacore International AB (publ)
 By: Lars-Olov Forslund
 Name: Lars-Olov Forslund
 Title: Chief Financial Officer