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BIACORE INTERNATIONAL AB

Form 6-K

August 15, 2003

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 June and July 2003

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.

HALF-YEAR REPORT JANUARY - JUNE 2003

- * Whilst sales to the academic sector increased, Biacore's total sales in the second quarter of 2003 fell by 8% to SEK 142.5 million (154.6). In the first half of 2003, sales amounted to SEK 249.0 million (295.9), a reduction of 16% compared with the previous year. Excluding the impact of exchange rates, sales fell by 8% in the first half of 2003.
- * Biacore's earnings per share increased by 267% to SEK 2.75 (0.75) in the second quarter of 2003, primarily as a consequence of capitalization of product development expenses, tight cost control and lower tax. Earnings per share in the first half-year 2003 increased by 21% to SEK 3.52 (2.92).
- * Biacore entered a market segment with substantial growth potential with the recent introduction of its new GxP package to be used in conjunction with Biacore(r)3000. The key application of this combination will be in the clinical trials of the new wave of biological therapeutics, where it will be used to measure data such as the product's immunogenicity. The Company continued to invest in the development of its new SPR array technology with

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the first system based on this technology due to be introduced in the second half of 2004.

* Given current market conditions and the fact that sales in the second quarter recovered more slowly than anticipated, Biacore now expects its revenues for the full-year 2003 to be approximately 5% below last year's level. As a result of this changed sales outlook, earnings per share, positively affected by the capitalization of product development expenses and lower tax, are forecast to increase by approximately 40% in 2003. The previous outlook for the full-year 2003 was for sales to be approximately the same as last year and for earnings per share to increase by approximately 60%.

	January - June			April - June		
	2003	2002	Change	2003	2002	Change
Sales, SEK million	249.0	295.9	-16%	142.5	154.6	-8%
Operating income, SEK million	32.4	61.8	-48%	28.3	32.2	-12%
Operating margin, %	13	21		20	21	
Income after financial items, SEK million	40.5	50.7	-20%	31.5	19.5	62%
Earnings per share, SEK	3.52	2.92	21%	2.75	0.75	267%

This report contains certain forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 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. Accordingly, investors and shareholders are urged not to place undue reliance on these statements.

Operational Review January-June 2003

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

In the second quarter of 2003, Biacore experienced some improvement in its overall operating environment which was led by increased sales to academic customers. In contrast, demand from early discovery customers in pharmaceutical and biotechnology companies in the United States and Europe is still lower than anticipated. However, sales to this segment in Asia-Pacific showed good progress.

Sales in the applied segments of the market, which are addressed with Biacore(r)S51, Biacore(r)3000 with the GxP Package and Biacore(r)C, performed somewhat better than the early discovery segment in the second quarter. As a consequence of the continued slowdown in sales to early drug discovery customers in the United States and Europe, Biacore's sales fell by 8% in the second quarter of 2003 to SEK 142.5 million (154.6). This compares with the 25% decline seen in the first quarter. Sales in the first half-year 2003 decreased by 16% to SEK 249.0 million (295.9). Excluding currency effects sales in the first half of 2003 fell by 8%.

Biacore(r)3000 is Biacore's most important product offering to the basic life science research market in academia and early discovery in the biotech and pharma industry. In order to enhance significantly the utility of Biacore(r)3000 in the field of functional proteomics, the Company has introduced a new automated functionality to the system which will enable it to work seamlessly

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with mass spectrometry (MS) systems.

In addition, the second quarter saw the introduction of a new GxP package to be used in conjunction with Biacore(r)3000. 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, where it will be used to capture data such as the therapeutic product's immunogenicity. Since its launch, this new combination has shown good progress in both the United States and Europe. The introduction of these two new important applications of Biacore(r)3000 are expected to positively impact the sales of this system in the second half of 2003.

Sales were divided geographically as follows:

SEK million	January-June			April-June		
	2003	2002	Change	2003	2002	Change
Americas	106.4	147.1	-28%	65.2	80.8	-19%
Europe	70.7	67.0	6%	39.8	36.5	9%
Asia-Pacific	71.9	81.8	-12%	37.5	37.3	1%

Although there was a slight improvement in the second quarter of 2003, sales in the Americas continued to be affected by a slowdown in orders from the U.S. pharmaceutical sector. Sales in Europe increased by 9% in the second quarter to SEK 39.8 million (36.5). Sales in Asia-Pacific in the second quarter were on the same level as in the previous year, SEK 37.5 million (37.3), as orders from pharmaceutical industry customers in Japan picked up.

The gross margin in the second quarter increased to 80% from 77% in the first quarter.

Given the uncertain sales development, the Company has continued to keep a tight control of its operating costs. Total costs for marketing, administration and research and development decreased by 24% in the second quarter of 2003 to SEK 81.2 million (107.4). During this period, marketing and sales costs decreased by 22% to SEK 43.1 million (55.6), while administration costs fell by 4% to SEK 18.8 million (19.5).

R&D spending in the second quarter amounted to SEK 31.5 million (32.3). Of this amount, SEK 12.2 million (0) was capitalized. During the first half-year 2003, Biacore has capitalized SEK 24.1 million. Since Biacore, due to new accounting standards, started to capitalize certain product development expenses in 2002, SEK 29.1 million have been capitalized.

Due to lower sales in 2003 and SEK 19.6 million in damages from Thermo BioAnalysis in the second quarter of 2002, operating income in the second quarter 2003 declined by 12% to SEK 28.3 million (32.2) despite the Company's tight control of costs. The operating margin in the second quarter was 20% (21). Currency differences during the period amounted to SEK -3.3 million (-8.4) in "Other income and expenses" and SEK 0.1 million (-0.1) in "Financial items."

The effective tax rate for the first half-year was 15% of income after financial items (44). The lower tax rate is due to a change in the geographical mix of income, one factor being the Swiss operations. The tax rate in the first half-year 2002 was affected by non-deductible write-downs of shares.

Net income for the second quarter of 2003 was SEK 26.9 million (7.4), giving diluted earnings per share of SEK 2.75 (0.75), an increase by 267%. For the first half-year 2003, diluted earnings per share increased by 21% to SEK 3.52 (2.92).

Capital Expenditures

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During the first half-year of 2003, capital expenditures totaled SEK 10.7 million (9.0).

Personnel

The 2003 Annual General Meeting of shareholders approved a five-year employee stock option program of a maximum of 100,000 Biacore shares with an exercise price of SEK 178.

At the end of June 2003, Biacore had 340 (316) permanent employees.

Business Review

The second quarter of 2003, Biacore has seen some improvement from the depressed first quarter in the demand for its world leading surface plasmon resonance (SPR) technology. Systems based on this technology are used for the real-time detection and monitoring of biomolecular binding interactions. This improvement appears to be based on the end of the Iraq war, which has removed some of the uncertainty from the global political and economic environment. While sales to early drug discovery customers in the United States and Europe remained difficult, the applied segments of the market, i.e. lead optimization, clinical trials and quality control, all showed progress.

Looking ahead, Biacore remains confident that its recently strengthened product offering and its well-balanced customer base, which includes world-leading life science research institutes, leading companies in the pharmaceutical and biotechnology industries and major food manufacturers, will enable it to resume a pattern of attractive growth once the macro-environment improves.

Academic Customers Focusing on Molecular Causes of Disease

Biacore's marketing activities continue 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.

Key areas where Biacore has focused its marketing include Cancer, Neuroscience and more recently Infectious Diseases, where a full scale disease area launch was undertaken. As part of this campaign, an article was published in 'Trends in Microbiology', highlighting the value of SPR technology in HIV research.

In addition, Biacore has placed a great deal of its on-going marketing effort 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, there are two areas where Biacore's SPR systems have clear competitive advantages, namely ligand fishing and protein interactions. These areas are both crucial to developing a clear understanding of disease and for identifying drug-like structures that may prove the basis of potential drug candidates.

Biacore(r)3000 - Additional Utility in Functional Proteomics

Biacore has recently introduced a new module for Biacore(r)3000 which marks an important step forward in the integration of SPR-MS. This new module enhances the functionality of Biacore(r)3000 by allowing automated and increased capacity recovery functionality as well as direct MALDI target deposition for further analysis by a number of mass spectrometry systems. This new functionality is the result of Biacore's collaboration with Bruker Daltonics. The combination of these two technologies is designed to:

- generate functional information on proteins, receptors and ligands of

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- interest,
- isolate and purify these molecules, and
- characterize and identify these proteins or other molecules.

Biacore is confident that this new SPR-MS linkage will provide researchers with a radical new approach to functional proteomics studies and strengthen its already strong competitive position in the rapidly growing proteomics market. Early customer response to this new module has increased Biacore's confidence in the long-term sales potential of this technology combination.

Developing High Quality Drug Candidates

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.

Lead Optimization - A New Market Opportunity

Biacore(r)S51 - New Customer Data to Support Marketing Activities

Biacore(r)S51 is the first Biacore system introduced specifically for the pharmaceutical and biotechnology industry. This system addresses critical bottlenecks in the drug discovery process downstream of high-throughput screening (HTS). Biacore(r)S51 is able to achieve this by providing 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 its future sales growth. In the second quarter, the utility of the system for small molecule analysis was enhanced with the introduction of a new software package and two new chip surfaces.

This confidence is also based on the growing appreciation of the product from the market as well as new customer-generated data highlighting the benefits of using Biacore(r)S51. In the last few months, more data supporting the value of the Biacore(r)S51 in lead optimization has been made public. Amongst these data are the results of small molecule screening studies, which were conducted in conjunction with GlaxoSmithKline.

Procel(tm) - Building Awareness

Procel(tm) is designed to complement Biacore(r)S51 and provide a highly competitive offering in the field of lead optimization. By using Procel(tm), researchers have access to an easy-to-use cell-based fluorescent analytical system which has been designed to characterize compounds that interact with both G protein coupled receptors (GPCRs) and ion channels. These are two main classes of drug targets under evaluation today.

Since this system is based on a new technology for Biacore, sales of Procel(tm) are expected to build more slowly than has been the case with Biacore(r)S51.

Biacore(r)3000 GxP Package - Accessing The Clinical Trials Market

In line with its strategy of developing new solutions which are tailored to the needs of its customers, Biacore has recently introduced a new GxP package to be used in conjunction with Biacore(r)3000. This new package has been designed to facilitate pharmaceutical companies' compliance with worldwide regulatory expectations and will complement Biacore(r)C, launched in 2001 for rapid concentration analysis in drug development, manufacturing quality control and in-process control applications.

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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, where this new product will be used to capture vital data 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 purification of the blood samples is needed. This enhances both the speed and reproducibility of the measurement. The major benefits of Biacore(r)3000 GxP Package in this segment of the pharmaceutical development market will be a key factor in driving Biacore's overall sales for the remainder of 2003.

Food Business Unit - Sales Continue to Build

Biacore's food business unit had a very successful second quarter with sales of Biacore(r)Q being particularly strong in Europe with some customers ordering their second systems. This demand for second systems was due to these food manufacturers incorporating Biacore's SPR technology into the routine analysis of their manufacturing process, a positive sign for the development of the Company's food business unit.

The second quarter also saw the introduction of a number of new Qflex kits which have extended the range of antibiotics which can be analyzed using Biacore(r)Q.

SPR Array Technology - Meeting the Need for Higher Information Content

Biacore is determined to build on the strong SPR-based business that it has established over the last decade. 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 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 and development 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 SPR array system is designed for applications in the interaction proteomics and post-HTS small molecule characterization areas, where its sensitivity, increased throughput and high information content will complement Biacore's existing systems. 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.

Future Growth Prospects Remain Positive

Despite the slowdown in sales seen during the first half of 2003, Biacore remains confident that it is in a strong position to build the value of its business over the next several years. This positive view is based on:

- The growth expected from the Company's core life science research customers as

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Biacore's SPR technology gains even greater recognition in the field of functional proteomics.

- The anticipated success of the new applications of the Biacore(r)3000 which include the new interface with MS systems which will extend the system's value in functional proteomics, and the new GxP package which will take Biacore into the fast growing bio-therapeutics clinical trials market.
- The continued growth of the three new systems recently introduced to meet the specific needs of customers in the pharmaceutical and biotechnology industry, Biacore(r)S51 and Procel(tm) for "hit to lead"-selection, and Biacore(r)C for quality control applications.
- The significant commercial potential of the new system being developed based on Biacore's novel SPR array technology.

These opportunities allied to the strength of the overall Biacore organization should enable the Company to continue to deliver attractive returns to its shareholders over the next several years.

Accounting principles

This interim report has been prepared in accordance with the Swedish Financial Accounting Standards Council's Statement No. 20 (RR 20), Interim Financial Reporting.

Parent Company

Biacore International AB handles group-wide functions and provides certain intercompany services but has no other business of its own. Sales during the first half-year 2003 amounted to SEK 12 million (1) and income after financial items was SEK 1 million (-11).

Quarterly Sales Variations

Biacore's total sales during the period 2000-2002 were split between quarters as follows:

Quarter 1	23%	Quarter 3	22%
Quarter 2	23%	Quarter 4	32%

Outlook For The Full-Year 2003

Given current market conditions and the fact that sales in the second quarter recovered more slowly than anticipated, Biacore now expects its revenues for the full-year 2003 to be approximately 5% below last year's level. As a result of this changed sales outlook, earnings per share, positively affected by the capitalization of product development expenses and lower tax, are forecast to increase by approximately 40% in 2003. The previous outlook for the full-year 2003 was for sales to be approximately the same as last year and for earnings per share to increase by approximately 60%.

Uppsala, Sweden, July 18, 2003
Biacore International AB (publ)

Ulf Jonsson
President and Chief Executive Officer

This interim report has not been subject to examination by the Company's auditor.

Financial Information

Biacore plans to release its interim report for January-September 2003 on

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Wednesday, October 22, 2003.

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.

More information on Biacore is available at the Company's website:
www.biacore.com

Biacore Consolidated Income Statements

SEK million	January-June			April-June			Full year 2002
	2003	2002	Change	2003	2002	Change	
Sales	249.0	295.9	-16%	142.5	154.6	-8%	614.2
Cost of goods sold	-53.1	-49.5	7%	-28.8	-25.1	15%	-100.9
Marketing	-81.7	-98.5	-17%	-43.1	-55.6	-22%	-199.8
Administration	-34.2	-35.5	-4%	-18.8	-19.5	-4%	-68.3
Research and development	-37.8	-54.6	-31%	-19.3	-32.3	-40%	-104.4
Other income and expenses	-7.8	6.3		-3.2	11.2		4.3
Amortization of goodwill	-2.0	-2.3		-1.0	-1.1		-4.5
Operating income	32.4	61.8	-48%	28.3	32.2	-12%	140.6
Financial items, net	8.1	-11.1		3.2	-12.7		-20.4
Income after financial items	40.5	50.7	-20%	31.5	19.5	62%	120.2
Income taxes	-6.2	-22.3		-4.6	-12.2		-40.1
Minority interest	0.1	0.5		-	0.1		0.7
Net income	34.4	28.9		26.9	7.4		80.8
Basic earnings per share, SEK	3.53	2.96		2.76	0.75		8.28
Diluted earnings per share, SEK	3.52	2.92		2.75	0.75		8.20
No. of shares, average, diluted, thousands	9,774	9,909		9,773	9,896		9,851
Net income	34.4	28.9		26.9	7.4		80.8
Stock options issued	0.5	-		0.5	-		-
Dividend	-29.3	-		-29.3	-		-
Currency translation differences	-15.8	-13.6		-11.4	-11.5		-15.3
Change in shareholders' equity	-10.2	15.3		-13.3	-4.1		65.5

Quarterly Income Statements

SEK million	2Q 2003	1Q 2003	4Q 2002	3Q 2002	2Q 2002	1Q 2002
	2003	2003	2002	2002	2002	2002
Sales	142.5	106.5	175.9	142.4	154.6	141.3
Cost of goods sold	-28.8	-24.3	-28.5	-22.9	-25.1	-24.4
Marketing	-43.1	-38.6	-53.4	-47.9	-55.6	-42.9
Administration	-18.8	-15.4	-13.6	-19.2	-19.5	-16.0
Research and development	-19.3	-18.5	-26.3	-23.5	-32.3	-22.3
Other income and expenses	-3.2	-4.6	-4.5	2.5	11.2	-4.9
Amortization of goodwill	-1.0	-1.0	-1.1	-1.1	-1.1	-1.2
Operating income	28.3	4.1	48.5	30.3	32.2	29.6
Financial items, net	3.2	4.9	1.1	-10.4	-12.7	1.6
Income after financial items	31.5	9.0	49.6	19.9	19.5	31.2

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Income taxes	-4.6	-1.6	-9.1	-8.7	-12.2	-10.1
Minority interest	-	0.1	0.1	0.1	0.1	0.4
Net income	26.9	7.5	40.6	11.3	7.4	21.5

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

Sales by region

	January-June		2Q	1Q	4Q	3Q	2Q	1Q
SEK million	2003	2002	2003	2003	2002	2002	2002	2002
Americas	106.4	147.1	65.2	41.2	63.8	59.6	80.8	66.3
Europe	70.7	67.0	39.8	30.9	62.7	44.2	36.5	30.5
Asia-Pacific	71.9	81.8	37.5	34.4	49.4	38.6	37.3	44.5
	249.0	295.9	142.5	106.5	175.9	142.4	154.6	141.3

Biacore Consolidated Balance Sheets

SEK million	June 30		Dec. 31
	2003	2002	2002
Intangible assets	105.2	80.9	84.8
Property, plant and equipment	116.1	105.6	117.1
Long-term investments	1.0	22.4	7.9
Other long-term assets	28.1	25.4	27.7
Other current assets	229.7	245.3	242.3
Liquid funds	339.1	285.0	351.6
Total assets	819.2	764.6	831.4
Shareholders' equity	624.5	584.5	634.7
Minority interest	0.7	0.9	0.9
Provisions	83.4	66.6	83.4
Liabilities	110.6	112.6	112.4
Total shareholders' equity and liabilities	819.2	764.6	831.4

Financial structure

Operating capital	324.3	311.6	327.4
Long-term investments	1.0	22.4	7.9
Net interest-bearing assets	301.1	251.0	313.9
Net payable and deferred income tax liability	-1.2	0.4	-13.6
Minority interest	-0.7	-0.9	-0.9
Shareholders' equity	624.5	584.5	634.7

Biacore Consolidated Statements of Cash Flows

SEK million	January-June		Full year
	2003	2002	2002
Net income	34.4	28.9	80.8
Less: Depreciation and amortization	15.7	12.0	23.7
Less: Income from long-term investments	-4.0	14.2	28.7
Change in working capital	9.2	17.3	37.1
Other	-9.4	-3.1	-6.6
Cash flows from operating activities	45.9	69.3	163.7
Acquisition of business, net of cash acquired	-	-	1.6
Purchase of intangible assets	-28.9	-1.0	-7.0
Purchase of property, plant and equipment	-10.7	-9.0	-31.7

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Sales of long-term investments	11.0	-	-
Cash flows from investing activities	-28.6	-10.0	-37.1
Dividend	-29.3	-	-
Change in financial liabilities	-0.5	4.9	4.2
Cash flows from financing activities	-29.8	4.9	4.2
Net change in liquid funds	-12.5	64.2	130.8

Key figures

Operating margin	13.0%	20.9%	22.9%
Return on operating capital	19.9%	38.1%	42.4%
Return on equity	10.9%	10.0%	13.4%
Equity ratio	76%	77%	76%
Shareholders' equity per share, diluted, SEK	63.89	59.00	64.44
No. of shares, thousands	9,750	9,750	9,750
No. of shares, end of period, diluted, thousands	9,774	9,906	9,849
No. of shares, average, diluted, thousands	9,774	9,909	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.

Biacore International AB (publ)
 By: Lars-Olov Forslund
 Name: Lars-Olov Forslund
 Title: Chief Financial Officer
 Dated: August 11, 2003