

## **Q-MED'S TURNOVER UP 87 PERCENT**

### **Key ratios 2000**

- **Turnover increased by 87 percent for comparable units, to SEK 237.2 (126.9\*) million. During the fourth quarter turnover increased by 103 percent and amounted to SEK 81.9 (40.3\*) million.**
- **Income after financial items increased by 252 percent, to SEK 44.0 (12.5\*) million. Income for the fourth quarter was SEK 17.6 (2.6) million. Increased focus on research and development, 25 (18\*) percent of turnover.**

Amounts in SEK millions	2000	1999*	%
Turnover	237.2	126.9	+87
Gross income	212.1	111.1	+91
Gross income, % of turnover	89.4	87.5	
Operating income	33.7	13.6	+148
Operating income, % of turnover	14.2	10.7	
Operating income exclusive of Ixion	42.3	13.6	+211
Operating income exclusive of Ixion, % of turnover	17.8	10.7	
Income after financial items	44.0	12.5	+252
Net income for the year	39.3	11.1	+254
Number of employees at year-end	197	110	+79
Earnings per share, SEK	1.64	0.61	+169
Share price at year-end, SEK	192	67	+187
Market value	4,713	1,528	+208

\*Income statement items excluding Venofer, an intravenous iron preparation which Q-Med had a licencing agreement for in the Nordic countries up until December 31, 1999.

**Per Olof Wallström, President and CEO, comments as follows:**

"Q-Med showed continued high and stable growth during the financial year 2000. It was also the first whole year as a company listed on the stock exchange. The share price tripled compared to the introduction price in December 1999. We are happy with the market's confidence in the company and its development.

The company stands stronger than ever, works with a high gross margin and has good momentum. The new share issue in connection with the introduction on to the stock exchange and our positive cash flow give us the financial strength necessary to make investments in new markets and new products. The listing has also markedly increased the exposure of the company in the media, which contributes to the company's strong position in the recruitment of highly competent personnel.

Q-Med intends to continue to actively develop its potential and we believe in continued strong development."

Attached: Report on operations 2000

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## **REPORT ON OPERATIONS 2000**

### **THE YEAR 2000 IN BRIEF**

**March: Two new products for facial esthetics, PERLANE and RESTYLANE Fine Lines, are launched.**

**June: An application is submitted in USA for the registration of DEFLUX for the treatment of children with a malformation of the urinary bladder, so-called reflux. The application is given priority treatment.**

**July: A patent application for an injection device used in the treatment with DEFLUX for stress urinary incontinence is submitted.**

**July: A new business unit is formed, Cell Therapy and Encapsulation. Ownership in the American company Ixion Biotechnology, Inc. is increased to 59 percent of the shares.**

**August: The application to start clinical trials in USA with RESTYLANE for facial esthetics is approved.**

**October: An application for the European approval of DUROLANE, intended for the treatment of worn out knee joints, is submitted.**

**October: The Gastroenterology and Urology Devices Advisory Panel to USA's regulatory authority recommends approval of DEFLUX for the indication reflux in children.**

**December: A decision is taken to build further office and laboratory premises in Uppsala covering an area of 11,000 sq.m., an investment of SEK 130 million.**

*Q-Med is a rapidly growing and profitable biotechnology and medical device company that develops, produces and markets medical implants. All products are based on the company's patented technology for the production of NASHA - Non-Animal Stabilized Hyaluronic Acid. Q-Med's operations focus on four areas, Esthetics, Orthopedics, Uro-Gynecology, and Cell Therapy and Encapsulation. The products RESTYLANE, RESTYLANE Fine Lines and PERLANE are used for the filling out of lips and facial wrinkles and today account for the majority of sales. The development of MACROLANE for breast augmentation is ongoing. DUROLANE, Q-Med's product for the treatment of osteoarthritis in the knee-joint, is in the clinical documentation phase. DEFLUX is a product which has been approved in Europe for the treatment of vesicoureteral reflux (malformation of the urinary bladder) in children and stress urinary incontinence in women. Since July 2000 Q-Med has held a majority interest in the American biotechnology company Ixion Biotechnology, Inc., which carries out research within cell therapy for diabetes. Q-Med today has 200 employees, with 145 at the company's production facility and head office in Uppsala, 15 at Ixion and the remainder in wholly owned foreign subsidiaries. The Q-Med share has been listed on the O-list of the OM Stockholm Stock Exchange since December 1999.*

## REVENUES

Q-Med increased its sales by 87 percent during 2000, to SEK 237.2 (126.9\*) million. In the fourth quarter turnover amounted to SEK 81.9 (40.3\*) million, an increase of 103 percent. Exchange rate fluctuations have affected sales positively by SEK 1.0 million compared with the previous year.

Net turnover (SEK millions)	Jan – Dec			Oct – Dec		
	2000	1999	+/- %	2000	1999	+/- %
Esthetics	233.8	124.8	+87%	80.8	39.8	+103%
Uro-Gynecology	3.1	2.1	+48%	1.2	0.5	+140%
Other	0.3	-	-	-0.1	-	-
Total	237.2	126.9	+87%	81.9	40.3	+103%

\*Note: Q-Med previously had a licencing agreement with regard to Venofer, an intravenous iron preparation, for sales in the Nordic countries. The agreement was terminated as from January 1, 2000. For the sake of comparability all income statement items attributable to Venofer for 1999 have been excluded in this report. The legal income statement for 1999 is also included on page 8.

### Esthetics

- **Sales: SEK 233.8 (124.8) million, an increase by 87 percent.**
- **Two complementary products within facial esthetics were launched in March: RESTYLANE Fine Lines and PERLANE.**
- **An application to start clinical trials with RESTYLANE in USA was approved in August. Final approval by the ethical committee was obtained in January 2001.**

The business unit Esthetics' sales development during the year has to a considerable extent been strengthened by the launch in March of the new products PERLANE and RESTYLANE Fine Lines. Demand is increasing in existing markets and operations are being established in new markets. Further distributors have been established during the year in seven countries. Q-Med's facial esthetic products are now sold in almost 50 countries, where Brazil, Italy, Germany and France dominate. Among the newer markets growth was greatest in South Korea, Japan and Mexico.

The very high sales of PERLANE in the second quarter led to supply problems during the third and parts of the fourth quarter. However, the demand could be met during the fourth quarter as the work on scaling up the production batches took effect.

In August Q-Med was informed by the FDA, the American regulatory authority, that the company's application to begin clinical trials within facial esthetics with RESTYLANE had been approved. Final approval by the ethical committee was obtained in January 2001, after which the study can begin. The application for registration in USA is estimated to be submitted at the beginning of 2002.

Q-Med submitted an application for the registration of RESTYLANE in Japan in May 1999. Approval was expected during 2000, but it has been delayed and the planned launch is now in 2003. Q-Med has contracted a new advisor in Japan and during 2001 will carry out a study for supplementary clinical documentation. The effect of the delay on sales is limited. Q-Med has been selling RESTYLANE in Japan for just over one year and sales and the number of customers are increasing according to plan. In accordance with the regulations, the doctors are able to directly import RESTYLANE and Q-Med has the right to give certain medical information. The difference compared to a registration is that Q-Med can then proceed to actively market the product in the country.

Net turnover (SEK millions)	Jan – Dec			Oct – Dec		
	2000	1999	+/- %	2000	1999	+/- %
RESTYLANE	156.6	122.3	+28%	47.2	37.3	+27%
PERLANE	64.5	2.5	+2.480%	29.2	2.5	+1.068%
RESTYLANE F.L.	12.7	-	-	4.4	-	-
Total	233.8	124.8	+87%	80.8	39.8	+103%

## **Orthopedics**

- **An application for European approval of DUROLANE was submitted to the Swedish Medical Products Agency in October. Approval is expected during the first half of 2001.**

Q-Med carried out a safety study on just over 100 patients as a basis for the application for CE-marking of DUROLANE. This study was completed in June. During 2001 a major study will be carried out, which will focus on the effect of treatment with DUROLANE in comparison with a placebo (sodium chloride injection). The study will be carried out in USA, Sweden and Canada on 300 patients with 6 months' follow-up. These study results will also form the basis of Q-Med's application for registration of the product in USA, which is estimated to be able to be submitted at the beginning of 2002.

Q-Med plans to sign a partnership agreement(s) during 2001 for the distribution of DUROLANE in both Europe and USA, and possibly in Japan.

## **Uro-Gynecology**

- **Sales: SEK 3.1 (2.1) million.**
- **An application for the registration of DEFLUX for the treatment of children with reflux was submitted in July. The application was given priority treatment and in October approval was recommended by the Gastroenterology and Urology Devices Advisory Panel to the FDA, the American regulatory authority.**
- **A patent application was submitted in July for a new injection device for treatment with DEFLUX for stress urinary incontinence.**

In July Q-Med submitted an application in USA for the registration of DEFLUX for the treatment of vesicoureteral reflux (VUR) in children. The product has been given priority treatment by the FDA, the American regulatory authority, so-called "expedited review" status. At a meeting in Washington in October FDA's Gastroenterology and Urology Devices Advisory Panel, consisting of clinical experts, decided to recommend that the FDA approve the product.

This decision constitutes a recommendation, that is the FDA can still decide not to follow the opinion of its advisory body. However, Q-Med sees the decision as very positive news, which strengthens the company's opinion that approval can be expected during 2001. This presupposes that Q-Med meets the FDA's quality requirements in accordance with GMP, Good Manufacturing Practice.

USA is a market where today there is no approved endoscopic treatment for children with reflux. Q-Med estimates that the market in USA will be worth approximately SEK 300 million per year.

In July a patent application was also submitted for a new injection device for the administration of DEFLUX for stress urinary incontinence. During 2001 clinical trials will be started, which amongst other things will form the basis of the application in USA.

During the third and to a certain extent during the fourth quarter as well Q-Med had supply problems with DEFLUX. The production method has been upgraded and automatized and will be introduced during spring 2001.

## **Cell Therapy and Encapsulation**

- **The business unit was formed in July.**
- **59 percent of Ixion Biotechnology, Inc., with business activities within cell therapy for diabetes, amongst other things, was acquired for USD 7.8 million (SEK 70.1 million).**

In July a new business unit was formed within Q-Med, Cell Therapy and Encapsulation. At the same time ownership in Ixion Biotechnology, Inc., a Florida-based research company with business activities within diabetes, amongst other things, was increased to 59 percent. It is estimated that the capital that Ixion received through Q-Med's investment in the company will finance Ixion's research until some way into 2002. In March 2000 the first experiments on mice were published in the journal Nature Medicine.

## EXPENSES AND INCOME\*

- **Gross margin 89 (87) percent.**
- **Large investments in research and development, SEK 58.5 (22.3) million.**
- **Operating income was SEK 33.7 (13.6) million. Ixion's share was SEK -8.6 (-) million.**

\*The figures for the previous year are exclusive of Venofer.

Q-Med's gross margin amounted to 89 percent during 2000, an improvement of 2 percentage points compared with the previous year. For the fourth quarter the gross margin amounted to 90 (89) percent. The improvement in the gross margin is due above all to the increase in volumes and the full effect of the new production facility which was started up during the second quarter of 1999.

Selling expenses increased as a result of continued international expansion. All subsidiaries except Ixion are sales companies. The costs for research and development increased by 162 percent compared with the previous year and amounted to just under 25 (18) percent of the net turnover. For the fourth quarter the increase was 135 percent or 23 (20) percent of the net turnover. Ixion is consolidated according to the purchase accounting method as from July 2000. Research and development costs in Ixion amounted to SEK 11.1 (-) million for the period July-December, of which SEK 5.5 (-) million was in quarter four. Furthermore, the increase in costs for research and development is due to an increased number of projects and increased costs for external studies and analyses of DUROLANE and RESTYLANE. There have also been additional costs for scaling up and developing the manufacturing process for all products compared to the previous year.

Amortization and depreciation of SEK 9.1 (6.7) million, of which SEK 0.7 (0.8) million is comprised of goodwill, has been charged against income. Amortization and depreciation for the fourth quarter was SEK 3.3 (2.1) million, of which SEK 0.2 (0.2) million was goodwill. The amortization of goodwill is recorded in the row for research costs.

Other operating revenues and expenses consist of the effects of exchange rates on accounts receivable and payable and Ixion's research grant and revenues from research agreements. For the period these grants and revenues amounted to SEK 2.5 (-) million. The previous year there was a revenue of a one-off nature due to the writing off of a loan of SEK 2.2 million from the Swedish National Board for Industrial and Technical Development, NUTEK.

Operating income for 2000 amounted to SEK 33.7 (13.6) million, which gives an operating margin of 14.2 (10.7) percent. For comparable units (excluding NUTEK 1999 and Ixion 2000) operating income amounted to SEK 42.3 (11.4) million, which gives an operating margin of 17.8 (9.0) percent. Due to the strong sales operating income for the fourth quarter was SEK 14.6 (2.4) million and the margin 17.8 (6.0) percent. For comparable units (excluding Ixion 2000) operating income for the fourth quarter amounted to SEK 18.5 (2.4) million, which corresponds to an operating margin of 22.6 (6.0) percent.

The new share issue which Q-Med carried out in December 1999 in connection with the listing on the O-list of the OM Stockholm Stock Exchange generated for the company SEK 258 million net. This meant that net financial income improved and amounted to SEK 10.3 (-1.1) million for the year, SEK 3.0 (0.2) million for the fourth quarter. Ixion's net financial income of SEK 0.4 (-) million is included for the period July-December, SEK 0.2 (-) million for quarter four.

Tax costs amounted to SEK -7.0 (-1.4) million, of which SEK -3.8 (1.4) was for quarter four. Loss carry-forward has been taken into account, mainly in the Parent Company where SEK 15 million was still unused of the loss carry-forward which arose in 1999, consisting of costs in connection with the new share issue and listing on the stock exchange. A net sum of SEK 3.0 (-) million, SEK 0.5 (-) million for quarter four, has been charged to the year's income on account of Ixion.

Note: The accounting principles for division of the functions in the income statement have been changed for 2000 compared with 1999. The figures for 1999 have been corrected to be in line with the new division. The net effect on the cost of goods sold is an increase of SEK 0.8 million for 1999, which includes a decrease of SEK 0.2 million for the fourth quarter.

## **INVESTMENTS AND CASH FLOW**

- **59 percent of Ixion Biotechnology acquired for SEK 70.1 million.**

In July Q-Med increased its holding in the American biotechnology company Ixion Biotechnology, Inc. to 59 percent. Ixion has been cooperating with Q-Med since April 1999 and makes use of Q-Med's NASHA technology to carry out research around the culture and transplantation of insulin-producing islet cells with a view to treating insulin-dependent diabetes.

Since April 1999 Q-Med has financed a large part of Ixion's research in exchange for newly issued shares in the company. Up until June 30, 2000 Q-Med had acquired 562,500 newly issued shares for approximately SEK 9.5 million, corresponding to a participating interest of 17.5 percent. During the first half of the year 2000 SEK 3.9 (2.6) million was invested. Through its wholly owned subsidiary Qvestor LLC, Q-Med acquired in July 2000 a further 3,337,500 newly issued shares for approximately SEK 60.6 million. Half of the purchase price was paid upon the signing of the agreement and the remainder will be paid 12 months later. Q-Med's participating interest in Ixion thereby amounted to 59 percent. The redemption of outstanding options meant that at December 31, 2000 the participating interest amounted to 57 percent. Q-Med's interest can be diluted to 52 percent at the most.

Investments in buildings and equipment amounted to SEK 28.9 (28.4) million, including SEK 8.1 (15.2) million for the fourth quarter. The investments are largely attributable to the high store adjacent to the production facility and to furniture and computers for new employees.

Q-Med's cash flow from operating activities amounted to SEK 30.3 (14.1) million for 2000, SEK 12.3 (16.2) million for quarter four. The total cash flow was positive, SEK 0.1 (247.8) million (SEK -7.0 and 245.7 million respectively for October-December this year and the previous year). The reason for the positive flow is the strong income in combination with the fact that Q-Med's next largest owner, HealthCap, utilized outstanding subscription options during the first quarter. Furthermore, during mainly the fourth quarter subscription options for the benefit of the personnel were redeemed and new option premiums were paid.

Due to the fact that DEFLUX has received so-called expedited review status for its application for approval in USA, Q-Med is at present investing in a new quality system. As Q-Med may be able to sell its first product on the American market during 2001, this investment has been brought forward. The FDA, the American regulatory authority, will inspect the Uppsala facility to certify it in accordance with GMP, Good Manufacturing Practice, probably during the first half of 2001. SEK 15.8 million had been invested at December 31, 2000. It is estimated that the remaining part of the investment, approximately SEK 4 million, will be taken during the first half of 2001.

## **PERSONNEL**

At the end of 2000 the organization consisted of 197 people, an increase of 87 people during the year. Personnel were mainly employed within production and research and development but also within marketing. The subsidiaries incl. Ixion more than doubled their number of employees during the year, from 24 to 59. At the end of 2001 it is estimated that the number of employees will be approximately 240. Recruiting during the coming year will be focused on production, research and development and on beginning to build up a market organization in USA.

## **PROPOSED DISPOSITION OF EARNINGS**

The Group's non-restricted equity amounted to SEK 50.7 million on December 31, 2000. No allocation to restricted equity is proposed. The Board and the President propose that the earnings at the disposal of the Annual General Meeting, consisting of retained earnings of SEK 11.4 million and a net profit of SEK 39.3 million, in total SEK 50.7 million, be carried forward. Thus, no dividend will be proposed.

## **PROSPECTS**

Sales 2001 should considerably exceed those for the year 2000. The gross margin should continue to be around 90 percent. The strong focus on new products and markets will continue, which will mean that the costs for above all clinical trials will increase markedly. Research costs attributable to Ixion will also increase. The expansion will take place under continued profitability, even though the operating margin might drop temporarily.

## **ANNUAL GENERAL MEETING AND ANNUAL REPORT**

The Annual General Meeting will be held on Thursday May 3, 2001 at 5 p.m. in Uppsala. Shareholders will be invited to attend through an announcement in the Swedish Official Gazette and in a national daily newspaper at the earliest six weeks and at the latest four weeks before the Meeting.

It is estimated that Q-Med's annual report will be distributed to the shareholders at the end of March, and from this time on it can be ordered from Q-Med AB (publ), Seminariegatan 21, 752 28 Uppsala, Sweden.

February 8, 2001  
Uppsala, Sweden

### **Q-Med AB (publ)**

Per Olof Wallström, President and CEO

Queries should be addressed to Per Olof Wallström, President and CEO, on +46(0)18-474 90 00 or +46(0)70-974 90 70.

## Consolidated income statement

(SEK millions)	January – December				October – December		
	2000	1999*	+/- %	1999**	2000	1999*	+/- %
Net turnover NASHA products	237.2	126.9	87	143.7	81.9	40.3	103
Cost of goods sold	-25.1	-15.8	59	-23.3	-8.3	-4.5	84
<b>Gross income</b>	<b>212.1</b>	<b>111.1</b>	<b>91</b>	<b>120.4</b>	<b>73.6</b>	<b>35.8</b>	<b>106</b>
Selling expenses	-97.8	-59.6	64	-65.1	-34.8	-20.7	68
Administrative expenses	-25.5	-17.7	44	-16.9	-6.0	-5.0	20
Research and development costs	-58.5	-22.3	162	-22.3	-18.8	-8.0	135
Other operating revenues	6.7	2.9	131	2.9	2.3	0.0	
Other operating expenses	-3.3	-0.8	313	-0.8	-1.7	0.3	
<b>Operating income</b>	<b>33.7</b>	<b>13.6</b>	<b>148</b>	<b>18.2</b>	<b>14.6</b>	<b>2.4</b>	<b>508</b>
Result from financial items	10.3	-1.1		-1.1	3.0	0.2	
<b>Income after financial items</b>	<b>44.0</b>	<b>12.5</b>	<b>252</b>	<b>17.1</b>	<b>17.6</b>	<b>2.6</b>	<b>577</b>
Tax on income for the period	-7.0	-1.4		-1.4	-3.8	1.4	
Minority interest lxion	2.3	-		-	0.4	-	
<b>Net income for the period</b>	<b>39.3</b>	<b>11.1</b>	<b>254</b>	<b>15.7</b>	<b>14.2</b>	<b>4.0</b>	<b>255</b>

\* Exclusive of Venofor.

\*\* Including Venofor; legal report.

Note: The accounting principles for division of the functions in the income statement have been changed for 2000 compared with 1999. The figures for 1999 have been corrected to be in line with the new division. The net effect on the cost of goods sold is an increase of SEK 0.8 million for 1999, which includes a decrease of SEK 0.2 million for the fourth quarter.

## Consolidated cash flow analysis

(SEK millions)	2000	1999
Cash flow from operating activities*	30.3	14.1
Cash flow from investing activities	-47.9	-34.9
Cash flow from financing activities	17.7	268.6
<b>Cash flow for the period</b>	<b>0.1</b>	<b>247.8</b>
Liquid funds at beginning of period	250.6	2.8
Exchange rate difference in liquid funds	2.1	-
Liquid funds at end of period	252.8	250.6
* Of which change in working capital	-23.6	-5.8



## Consolidated balance sheet

(SEK millions)	Dec 31, 2000	Dec 31, 1999
<b>Fixed assets</b>		
<i>Intangible assets</i>		
Patents and other intellectual property	62.6	1.0
Goodwill	4.7	5.3
<i>Tangible assets</i>	98.0	76.0
<i>Financial assets</i>	1.0	6.4
<b>Current assets</b>		
<i>Inventories</i>	17.6	9.7
<i>Current receivables</i>		
Accounts receivable	53.8	26.0
Other current receivables	4.3	4.7
Prepaid expenses and accrued revenues	7.6	1.3
<i>Liquid funds</i>	252.8	250.6
<b>Total assets</b>	<b>502.4</b>	<b>381.0</b>
<b>Shareholders' equity</b>	392.0	314.9
<b>Minority interest</b>	22.7	-
<b>Provisions</b>	7.4	5.2
<b>Long-term interest-bearing liabilities</b>	13.6	26.9
<b>Current liabilities</b>		
Interest-bearing current liabilities	12.7	6.0
Accounts payable	14.7	12.3
Other interest-free current liabilities	13.5	4.0
Accrued expenses and prepaid revenues	25.8	11.7
<b>Total liabilities and shareholders' equity</b>	<b>502.4</b>	<b>381.0</b>

## Key ratios

	2000	1999
Gross margin, %	89,4	83,7
Gross margin exclusive of Venofer, %	89,4	87,5
Operating margin, %	14,2	12,7
Operating margin exclusive of Venofer, %	14,2	10,7
Operating margin exclusive of Venofer and before R&D costs, %	38,9	28,3
Number of employees	197	110
Equity/assets ratio, %	82,5	82,6
Average number of outstanding shares (thousands)	24.030	18.222
Earnings per share, SEK	1:64	0:86
Earnings per share exclusive of Venofer, SEK	1:64	0:61
Earnings per share after full dilution, SEK	1:55	0:77
Earnings per share after full dilution, exclusive of Venofer, SEK	1:55	0:55
Shareholders' equity per share, SEK	15:97	13:81
Shareholders' equity per share after full dilution, SEK	15:38	12:50

Note: Earnings per share is defined as the earnings for the period in relation to the average number of outstanding shares for the period. At December 31, 2000 there were 932,500 outstanding subscription options and 24,547,500 shares.