Artimplant

Biomaterials for Tissue Engineering

Year-end report 1999

- **The certification process for ligament products has been intensified and applications could be filed earlier than previously planned. This increases the possibility to certify at least one ligament product already in year 2000. The market potential for Artimplant's ongoing development projects within the ligament area is estimated to SEK 20-30 billion.**
- **At the Annual General Meeting of the Swedish Society of Medicine in December 1999 a 12-month or more follow-up was presented on the results from the 20 patient pilot study initiated during the fourth quarter 1997. The follow-up shows that joint stability in the operated knee well equals that of the undamaged knee.**
- **A multicenter study, including at least 200 patients with damaged anterior crutiate ligament (ACL) in the knee is proceeding. The operation series is expected to be concluded towards the end of the first quarter year 2000. Early results from the ongoing thumb ligament study show that Artimplant's material functions well surgically and that the patients attain subjective as well as objective joint stability.**
- **During the first quarter year 2000 Artimplant received an approval from ethics committee as well as National Finnish Board of Health and Welfare to conduct a clinical study including 50 patients with damaged ACL's. This study will be part of a second ACL multicenter study.**
- **During year 2000 Artimplant is entering a market phase and plans to recruit to several key positions. The company plans to conclude the recruitment of a Sales and Marketing Director in the near future.**
- **Artimplant has initiated the incorporation of a subsidiary with the aim to exploit the carrier technology within the drug delivery area. Trial series made with a number of pharmaceutical compounds have shown promising results.**
- **During 1999 Artimplant signed agreements with Mölnlycke Health Care and Genzyme Tissue Repair.**
- **Revenues for the group amounted to 20.0 MSEK (11.4 MSEK). The operating result amounted to -14.7 MSEK (-8.5 MSEK). Result after financial items amounted to -14.2 MSEK (-3.5 MSEK). Earnings per share after taxes amounted to -1.72 SEK (-0.42 SEK).**

Artimplant's result 1999

Net sales for the Group during 1999 amounted to 20.0 MSEK (11.4 MSEK). Operating result during the period amounted to -14.7 MSEK (-8.5 MSEK). The result includes marketing expenses amounting to 1.9 MSEK,

mainly referring to ongoing market surveys preceeding the planned product launches. Result after financial items amounted to -14.2 MSEK (-3.5 MSEK). Goodwill relating to the acquisition of GMC amounted to 13.0 MSEK and is depreciated over 20 years.

The Parent company's net sales of 1.6 MSEK mainly refers to proceeds from Mölnlycke Health Care.

Net sales for the subsidiary Gothenburg Medical Center (GMC), consolidated as of May 1st, 1998, amounted to 19.0 MSEK. During the same period the previous year, net sales amounted to 18.8 MSEK. Operating result during 1999 amounted to 1.4 MSEK (2.4 MSEK). An additional orthopedic surgery specialist has been recruited during 1999.

Operations

Artimplant is a biomaterial company focused on unmet medical needs in the field of orthopedic surgery. The company develops biodegradable implants, in order to provide injured tissue with temporary relief and support the body's natural healing processes. Combinations of material make it possible to custom-tailor characteristics such as strength, elasticity and resorption rate in accordance with a vast number of specifications. The company has gradually expanded its development activities to include more than a dozen projects based on Artimplant's technology. The product portfolio includes fibers for production of ligaments, solid materials for production of bone fracture implants, and membranes for treatment of conditions such as chronic wounds and cartilage injuries.

During year 2000 Artimplant is entering a market phase and consequently plans to recruit to several key positions. The company plans for example to conclude the recruitment of a Sales and Marketing Director in the near future. In prospect of the planned market launch towards end off year 2000, in-depth quantitative and qualitative market research has been carried out regarding products estimated to be closest to market launch.

The certification process for ligament products has been intensified and applications could be filed earlier than previously planned. This increases the possibility to certify at least one ligament product certified already in year 2000. Considering the positive early follow-up results from the pilot study regarding ACL and thumb ligaments, and the large market potential for Artimplant's ligament products, increased priority has been given to this market segment. According to the company's assessment the market potential for Artimplant's ongoing development projects within the ligament market segment amounts to SEK 20-30 billion. Weak competition within the ligament market, as well as the relatively limited target groups within orthopedic surgery and hand surgery, makes the earnings potential, as well as the possibility to quickly attain a high market penetration, appear attractive for the different ligament products. For many of the ligament products under clinical trial there are currently no adequate treatment alternatives.

Artimplant has earlier patented a method to couple a growth factor to biodegradable polymer material. Artimplant has initiated the incorporation of a subsidiary in order to exploit the carrier technology within the drug delivery area. Trial series made during the latter part of 1999 have shown that the company's biodegradable polymer material, to which various pharmaceutical compounds have been coupled, can be well suited for controlled release of pharmaceuticals and other active substances over a long period of time.

Anterior Crutiate Ligament (ACL)

At the Annual General Meeting of the Swedish Society of Medicine in December 1999 Associate Professor Lars Peterson presented results from the pilot study including 20 patients with ACL injuries, which was initiated during the fourth quarter 1997. The patients in the study have undergone so called augmentation with Artimplant's biodegradable implant in combination with the patient's own patellar tendon. The results show that after 12 months or more all patients included in the pilot study had gained joint stability in the operated knee equal to that of the undamaged knee. Artimplant's implant made possible earlier mobility training, stress and functional training after surgery with maintained stability compared to the surgical technique today most frequently used.

A first multicenter study at six centers including at least 200 patients with damaged ACL's was initiated in Sweden during 1999. The clinical study complies with the current FDA recommendations for a PMA-

application procedure (Pre-market Approval). The operation series is expected to be concluded by the end of the first quarter year 2000.

During the first quarter year 2000 Artimplant received an approval from ethics committee as well as National Finnish Board of Health and Welfare to conduct a clinical study including 50 patients with damaged ACL's. This study will be part of a second ACL multicenter study. Instead of using parts of the patient's patellar tendon as done in the pilot and multicenter studies, tendons from the back of the patient's thigh (hamstrings) will be used. One of the potential advantages is less complications at donor site compared to if the patellar tendon is used.

Hand surgery

During 1999 Artimplant initiated two pilot studies within hand surgery for treatment of injured thumb ligaments and osteoarthritis at the base of the thumb. The operation series regarding treatment of damaged thumb ligaments was concluded in December 1999. Early follow-up results for the limited number of treated patients show that Artimplant's biodegradable thumb ligament implant functions well surgically and the patients attain subjective as well as objective joint stability. Provided that continued follow-up results continue to be positive, Artimplant plans to file for certification based on a six months follow-up, in order to launch the thumb ligament implant in Europe.

The operation series in the second hand surgery study for treatment of osteoarthritis at the base of the thumb with a so called spacer is expected to be completed during the first quarter year 2000. The early follow-up results for the limited number of patients show that treatment with Artimplant's biodegradable spacer leads to significant pain reduction. The company's assessment is that a six months follow-up is adequate in order to ascertain adequate pain reduction, however, a longer follow-up period is needed in order to establish lasting and satisfactory results with regards to joint stability and grasp strength.

Bone fracture

Artimplant has developed solid biodegradable materials for use in fixation systems for various types of surgical bone fracture treatment. The aim with the biodegradable bone fracture implants is to eliminate the need for re-operation. Artimplant has received approval from ethical committee to perform clinical studies with biodegradable bone fracture implants. The company plans to launch a first bone fracture implant during year 2000, assuming the remaining required authority approvals are received in time.

One of the first bone fracture applications is a product for fixation of ankle fracture. According to the National Swedish Board of Health and Welfare approximately 6,000 patients per year are hospital treated for ankle fractures in Sweden and the corresponding figure in the US is approximately 440,000.

Genzyme Tissue Repair

In September 1999, a first development collaboration agreement was signed between Artimplant and Genzyme Tissue Repair (GTR), which states that Artimplant's subsidiary GMC shall carry out a clinical trial for GTR to evaluate alternative fixation systems during cartilage replacement procedures.

Genzyme Corporation is one of the five largest biotech companies in the world and is a leading developer of biological products for injuries such as cartilage damage and severe burns. In 1997 GTR recieved FDA approval for Carticel™, autologous cultured chondrocytes for the repair of articular cartilage defects in the knee joint. Autologous chondrocyte transplantation (cartilage replacement) was approved by the FDA on the basis of clinical documentation from patients treated at Gothenburg Medical Center (GMC).

In October 1999, a new agreement was reached that will allow GTR to test Artimplant's biodegradable membranes in developing a second generation of Carticel™.

Mölnlycke Health Care

In April 1999, Artimplant and Mölnlycke Health Care (MHC) signed an agreement concerning a long term research and development collaboration. The objective is to create an additional technological platform for MHC's future product generations within the area of advanced wound care, in this case based on Artimplant's

patented technology of biodegradable polymer materials. Specification of the first product for post-surgical wounds is ongoing and the goal is to reach a clinical phase during year 2000.

MHC is a leading manufacturer and distributor of products for wound care and single-use products for surgical interventions, with revenues amounting to approximately SEK 2bn per year. The market growth for advanced wound care products is 15-20 per cent per year.

The research and development within the framework of the agreement is paid for by MHC. For products that are developed within the collaboration, Artimplant will receive licensing fees. Results from the research within wound care can also be applied within Artimplant's core market area orthopedic surgery.

Investments and financial position

Investments during 1999 amounted to 19.0 MSEK (30.9 MSEK), whereof 17.3 MSEK (26,0 MSEK) were made in immaterial assets. An additional earnings-based payment of 4.0 MSEK referring to the acquisition of GMC has been made during the second quarter.

In connection with the financing of Artimplant's early explorative research, warrants were issued during the period 1995 to 1997. On June 30th 1999, the total number of warrants amounted to 1,750,000 with the right to subscribe for one series B share each at a price of SEK 16 during the period July 1, 1999 - December 31, 1999. All warrants were subscribed and the new issue was paid in full at year-end. At year-end 621,000 subscribed shares, corresponding to 9.9 MSEK in equity, had not been registered. After full subscription of the warrants the number of shares amounts to 8,250,000, whereof 1,000,000 series A and 7,250,000 series B. Shareholders' equity amounts to 77.4 MSEK, or SEK 9.38 per share.

At the end of the reporting period liquid assets increased by 2.2 MSEK amounting to 39.7 MSEK (37.5 MSEK).

Employees

The number of employees at the end of the reporting period amounted to 41 (46), whereof 25 (35) were employed at GMC. The reduction in personnel at GMC is due to the planned focus on orthopedic surgery and outsourcing of physiotherapy. The number of consultants tied to the parent company amounted to 11 (11).

Dividend

The Board of Directors proposes that no dividend be paid for the financial year 1999.

Financial statements

The income statement for 1999 is compared with the corresponding period in 1998. GMC has been consolidated as of May 1st, 1998.

KEY RATIOS, GROUP

	1999	1998
Net result per share, SEK	-1,72	-0,53
Net result per share fully diluted, SEK	-	-0,42
Equity per share, SEK	9,38	9,77
Equity per share fully diluted, SEK	-	11,09
Number of shares at end of reporting period	7 629 000	6 500 000
Number of shares fully diluted	8 250 000	8 250 000
Return on shareholders´ equity, %	neg	neg
Return on capital employed, %	neg	neg
Equity ratio, %	90	87

Paid-in, not registered new issue included when calculating per share ratios for 1999.

INCOME STATEMENT ARTIMPLANT

	Group	Group	Parent	Parent
Amounts in thousand SEK	**1999**	**1998**	**1999**	**1998**
Net sales	20 032	11 426	1 613	144
Cost of goods & services sold	-16 267	-10 051	-1 613	-144
Gross profit	**3 765**	**1 375**	**0**	**0**
Research & development expenses	-9 187	-5 127	-9 187	-5 127
Marketing expenses	-1 892	-	-1 892	-
Administrative expenses	-7 338	-4 726	-4 239	-3 579
Share in group results	-	-	1 691	2 589
Operating result	**-14 652**	**-8 478**	**-13 627**	**-6 117**
Interest income & other financial income	753	1 961	640	1 834
Interest expenses & other financial expenses	-314	-39	-310	-39
Income from sale of warrants	-	3 063	-	3 063
Financial items net	**439**	**4 985**	**330**	**4 858**
Result after financial items	**-14 213**	**-3 493**	**-13 297**	**-1 259**
Taxes	60	26	-	-
Net result for reporting period	**-14 153**	**-3 467**	**-13 297**	**-1 259**

Note: Depreciation included in Income Statement

	Group	Group	Parent	Parent
Amounts in thousand SEK	**1999**	**1998**	**1999**	**1998**
Capitalized R&D expenses	7 600	3 968	7 600	3 968
Patents	544	435	544	435
Goodwill	699	333	-	-
Machinery and equipment	1 750	1 287	1 391	965
Total depreciation	**10 593**	**6 023**	**9 535**	**5 368**

BALANCE SHEET ARTIMPLANT

Amounts in thousand SEK	Group Dec 31, 1999	Group Dec 31, 1998	Parent Dec 31, 1999	Parent Dec 31, 1998
ASSETS				
Capitalized R&D expenses	22 287	13 002	22 287	13 002
Patents	1 199	1 320	1 199	1 320
Goodwill	12 954	13 653	-	-
Total intangible fixed assets	**36 440**	**27 975**	**23 486**	**14 322**
Machinery and equipment	4 556	4 035	4 023	3 266
Construction in progress	0	601	0	601
Total tangible fixed assets	**4 556**	**4 636**	**4 023**	**3 867**
Shares in subsidiary	-	-	17 996	17 996
Total financial fixed assets	**-**	**-**	**17 996**	**17 996**
Total fixed assets	**40 996**	**32 611**	**45 505**	**36 185**
Receivables	2 408	1 058	988	-
Receivables group companies	-	-	602	2 211
Other receivables	681	744	679	744
Prepaid expenses and accrued income	2 037	1 192	1 846	1 016
Total short term receivables	**5 126**	**2 994**	**4 115**	**3 971**
Cash and bank	39 660	37 524	37 153	33 236
Total current assets	**44 786**	**40 518**	**41 268**	**37 207**
TOTAL ASSETS	**85 782**	**73 129**	**86 773**	**73 392**

Amounts in thousand SEK	Group Dec 31, 1999	Group Dec 31, 1998	Parent Dec 31, 1999	Parent Dec 31, 1998
SHAREHOLDERS' EQUITY & LIABILITIES				
Equity				
Share capital	763	650	763	650
Paid-in, not registered new issue	9 936	-	9 936	-
Restricted reserves	83 016	66 324	83 016	66 324
Total restricted capital	**93 715**	**66 974**	**93 715**	**66 974**
Non-restricted reserves	-2 208	-	-	-
Net result for reporting period	-14 153	-3 467	-13 297	-1 259
Total non-restricted period	**-16 361**	**-3 467**	**-13 297**	**-1 259**
Total equity	**77 354**	**63 507**	**80 418**	**65 715**
Deferred tax	179	240	-	-
Other provisions	200	300	-	-
Total provisions	**379**	**540**	**-**	**-**
Other long term liabilities	200	300	200	300
Total long term liabilities	**200**	**300**	**200**	**300**
Accounts payable	2 640	1 130	2 334	993
Tax liabilities	2	-	-	-
Other short term liabilities	894	4 673	544	4 320
Accrued expenses and prepaid income	4 313	2 979	3 277	2 064
Total short term liabilities	**7 849**	**8 782**	**6 155**	**7 377**
TOTAL SHAREHOLDERS' EQUITY & LIABILITIES	**85 782**	**73 129**	**86 773**	**73 392**

CASH FLOW ANALYSIS	Group	Group	Parent	Parent
Amounts in thousand SEK	**1999**	**1998**	**1999**	**1998**

CURRENT OPERATIONS				
Result after financial items	-14 213	-3 493	-13 297	-1 259
Adjustment for items not effecting cash flow	10 517	5 629	9 559	5 375
Taxes paid	-1	-5	-	-
Cash flow from current operations before changes in working capital	**-3 697**	**2 131**	**-3 738**	**4 116**
Cash flow from changes in working capital				
Increase(-) decrease(+) in receivables	-2 132	893	-144	-2 499
Increase(+) decrease(-) in liabilities	3 067	196	2 778	1 120
Cash flow from current operations	**-2 762**	**3 220**	**-1 104**	**2 737**
INVESTMENTS				
Acquisition of subsidiaries	-4 000	-10 144	-4 000	-13 996
Acquisition of intangible fixed assets	-17 308	-12 032	-17 308	-12 032
Acquisition of tangible fixed assets	-1 694	-3 866	-1 571	-3 819
Cash flow from investments	**-23 002**	**-26 042**	**-22 879**	**-29 847**
FINANCING				
New share issue	28 000	-	28 000	-
Repayment of loans	-100	-100	-100	-100
Cash flow from financing	**27 900**	**-100**	**27 900**	**-100**
Cash flow for the year	**2 136**	**-22 922**	**3 917**	**-27 210**
Liquid funds at beginning of year	**37 524**	**60 446**	**33 236**	**60 446**
Liquid funds at end of year	**39 660**	**37 524**	**37 153**	**33 236**

Other financial information:

Annual General Meeting:	May 3, 2000	Six-month report:	Aug. 25, 2000
Three-month report:	May, 3 2000	Nine-month report:	Nov. 1, 2000

Artimplant is a biomaterial company focused on unmet needs in the field of orthopedic surgery. Artimplant's business concept is to develop, manufacture and market biodegradable implants that provide the injured tissue with temporary relief and support the body's natural healing process. The vision is to be world-leading within biologically degradable implants that stimulate self-healing and re-create an active life. The Company's researchers, which represent a unique combination of interdisciplinary competence, have synthesized a vast number of biodegradable polymers, that can be tailored for use in a number of different medical-treatment areas.

Artimplant has developed and patented a resorbable ligament implant that currently is undergoing clinical trial including 200 patients for treatment of injured anterior cruciate ligament (ACL). Early follow-up results from the pilot study using Artimplant's ACL implant show both subjective and objective joint stability in the operated knee, and the technique made possible relatively early rehabilitation. A ruptured ACL in the knee is one of the most frequent ligament injuries and often leads to lifelong detrimental effects for the injured, and substantial costs to society. Artimplant's technology can be applied in numerous other areas, and the development activities have expanded to include more than a dozen projects.

Artimplant's goal is to launch at least one product year 2000. As part of Artimplant's market strategy Gothenburg Medical Center (GMC) was acquired with the purpose of establishing Swedish headquarters for ***Artimplant Academy*** *– a forum for advanced clinical research, application and education within orthopedic surgery.*

Artimplant is listed on the OM Stockholm Stock Exchange O-list.

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Artimplant AB (publ)

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