Artimplant

Biomaterials for Tissue Engineering

Nine-month interim report 1999

- **During the third quarter 1999, Artimplant and the US biotech company Genzyme Tissue Repair (GTR) signed two agreements. Both agreements concern a further development of cartilage replacement, a method developed at Artimplant's subsidiary GMC, and include a clinical evaluation and a material transfer agreement which allows GTR to test Artimplant's patent pending biodegradable membranes.**
- **In April, Artimplant and Mölnlycke Health Care (MHC) signed a long-term collaboration agreement collaboration. The object is to create an additional technological platform for MHC's future product generations within advanced wound care. The goal is to initiate clinical trials of a first wound care product during year 2000. During the third quarter, Artimplant's revenues from MHC amounted to 0.4 MSEK and are expected to amount to 1.2 MSEK during the fourth quarter.**
- **Awaiting approval from ethics committee and the National Swedish Board of Health and Welfare clinical trials with resorbable bone fracture implants are expected to start after year-end 1999. This is one quarter later than earlier planned. However, the goal to certify and launch at least one product during year 2000 remains. The first product to be evaluated in clincial trials is a device for ankle fracture fixation.**
- **Artimplant's first larger scientific publication has been compiled and will be submitted to an international journal for review. The article includes innovative chemistry, material technology, cell biology, long term studies on animals as well as a preliminary follow-up on humans with Artimplant's biodegradable anterior crutiate ligament implant.**
- **A multicenter study including at least 200 patients with ACL-injury is proceeding and the surgery series is expected to be completed by the end of the first quarter 2000. In connection with the Annual General Meeting of the Swedish Society of Medicine, Artimplant will present an abstract concerning the pilot study including 20 patients with ACL-injuries that was initiated during the fourth quarter 1997. The results show that knee joint stability of the operated knee is in par with that of the undamaged knee.**
- **Revenues for the group amounted to 14.2 MSEK (6.7 MSEK). The operating result amounted to -8.8 MSEK (-5.9 MSEK). Result after financial items amounted to -8.5 MSEK (-1.7 MSEK). Earnings per share after taxes amounted to –1.31 SEK (-0,27 SEK).**

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Artimplant's result January-September 1999

Net sales for the Group during the first nine months amounted to 14.2 MSEK (6.7 MSEK). Operating result during the period amounted to –8.8 MSEK (-5.9 MSEK). The result includes marketing and sales expenses amounting to 0.7 MSEK, mainly concerning ongoing market surveys preceding the planned product launches. Result after financial items amounted to –8.5 MSEK (-1.7 MSEK). Goodwill relating to the acquisition of GMC amounted to 13.1 MSEK and is depreciated over 20 years.

The Parent company's net sales of 0.4 MSEK mainly relates to proceeds from Mölnlycke Health Care and is forecasted to amount to 1.6 MSEK for the full-year 1999.

Net sales for the subsidiary Gothenburg Medical Center (GMC), consolidated as of May 1st, 1998, amounted to 14.4 MSEK. During the same period the previous year, net sales amounted to 13.9 MSEK. Operating result during January-September amounted to 0.6 MSEK. An additional orthopedic surgery specialist has been employed at GMC.

Research and development activities

Artimplant is a biomaterial company focused on unmet medical needs in the field of orthopedic surgery. The company develops resorbable polymers, for use as 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 continuously 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.

Artimplant's first larger scientific publication has been compiled and will be submitted to an international journal for review. The article includes innovative chemistry, material technology, cell biology, long term studies on animals as well as a preliminary follow-up on humans with Artimplant's biodegradable anterior cruciate ligament implant. The publication is believed to be unique in its kind.

Ligaments

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. A first multicenter study at six centers including at least 200 patients with anterior crutiate ligament (ACL) injuries was initiated in Sweden during the first quarter 1999. The surgery series is expected to be completed by end of the first quarter 2000

In connection with the Annual General Meeting of the Swedish Society of Medicine the results from the pilot study, initiated during the fourth quarter 1997 and including 20 patients with ACL-injuries, will be presented by Associate Professor Lars Peterson. The patients included in the study have undergone surgery using augmentation technique with Artimplant's biodegradable implant in combination with tissue taken from the patient's patellar tendon. The results after a minimum of twelve months show that the knee joint stability of the operated knee is in par with that of the undamaged knee.

Hand surgery

Two pilot studies including a total of 15 patients for treatment of injured thumb ligament and osteoarthritis at the base of the thumb are proceding. Injuries to the ligaments that stabilize the base of the thumb is the most common hand injury in connection with skiing. Treatment alternatives are limited, which means that even young patients with joint instability and consequently arthritis may have to undergo arthrodesis. Thumb base osteoarthritis results in increasing pain and limited grasping strength and is one of the most common arthritis injuries in the hand, especially among older women.

Bone fractures
Artimplant has developed solid biodegradable materials similar to the fiber materials used in ligament implants. The solid materials are used in fixation systems for different types of surgical bone fracture treatments, with the purpose to eliminate the need for reoperation. Awaiting approval from ethics committee and the National Swedish Board of Health and Welfare clinical trials with resorbable bone fracture implants are expected to start after year year-end 1999. This is one quarter later than earlier planned. However, the goal to certify and launch at least one product during year 2000 remains. The first product to be evaluated in clinical trials is a device for ankle fracture fixation.

According to the National Swedish Board of Health and Welfare approximately 6,000 patients per year are hospital treated for ankle fracture in Sweden and the corrsponding figure in the US is approximately 440,000.

Genzyme Tissue Repair
In September 1999, a first development collaboration agreement was signed between Artimplant and 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 largest biotech companies in the world with revenues exceeding 670 MUSD in 1998. GTR 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 developed by researchers now employed at or tied to Artimplant. This method was approved by the FDA on the basis of clinical documentation from patients treated at Gothenburg Medical Center (GMC).

The object of the September agreement is to improve and shorten the time for the surgical procedure. With the current standard procedure, periost from the patient's own tibia is used to cover and fixate the cells during cartilage replacement.

In October, a new agreement was reached that will allow GTR to test Artimplant's biodegradable membranes in developing a second generation of Carticel™. The second generation Carticel™ product is based on the development of a pre-formed autologous cartilage graft which is intended to allow the procedure to be performed arthroscopically, as opposed to current standard with open surgery.

To date, more than 3,000 patients have been treated with the method (Carticel™) in the US. In Sweden more than 700 patients have been treated, of which 90 per cent at GMC. During the first six months of 1999 GTR's sales of Carticel™ increased by 30 per cent. Of the estimated half a million new cartilage injuries that occur annually in the US and Europe, roughly 40,000 are so severe that they require surgery.

Mölnlycke Health Care
In April, Artimplant and Mölnlycke Health Care (MHC) signed an agreement concerning a long term research and development collaboration. The object 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 initiate clinical trials of a first wound care product during year 2000.

Mölnlycke Health Care is a leading manufacturer and distributor of products for wound care and single-use products for surgical interventions. Wound care products account for approximately a third of the company's total revenues of SEK 2bn per year, and MHC has given increased priority to research and development in this area. It is estimated that more advanced products, that improve the wound healing environment, will account for almost half of wound care sales within 2-3 years. 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 the first nine months 1999 amounted to 13.3 MSEK (21.0 MSEK), whereof 11.9 MSEK (17.5 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. The total number of warrants amounted to 1,750,000 on June 30th 1999 with the right to subscribe for one series B share B each at a price of SEK 16 during the period July 1, 1999 - December 31, 1999, which is expected to provide proceeds of 28 MSEK during this period. In the event of full exercise, the warrants represent 21.2 per cent of the capital and 10.1 per cent of the votes. The new number of shares will then amount to 8,250,000, whereof 1,000,000 series A and 7,250,000 series B. If fully exercised, shareholders' equity will amount to 87 MSEK, or SEK 10.06 per share.

During the third quarter 838,000 shares have been exercised but not yet registered. This has provided the company proceeds of 13.4 MSEK. Equity per share after registration of exercised warrants amounts to SEK 9.32.

At the end of the reporting period liquid assets amounted to 31.4 MSEK (40.0 MSEK)

Employees

The number of employees at the end of the reporting period amounted to 45 (41), whereof 30 (32) were employed at GMC. The number of consultants tied to the parent company amounted to 10. During the first nine months the company has been further reinforced by recruitment of a Chief Financial Officer, additional researchers and clinical trial managers, as well as production personnel. Since the first products are expected to be launched in year 2000 resources for marketing activities will be expanded.

Financial statements

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

KEY RATIOS, GROUP

	Jan-Sep 1999	Jan-Sep 1998	Jan-Dec 1998
Net result per share, SEK	-1,31	-0,27	-0,53
Net result per share fully diluted, SEK	-1,03	-0,21	-0,42
Equity per share, SEK	8,47	10,04	9,77
Equity per share fully diluted, SEK	10,06	11,30	11,09
Number of shares at end of reporting period	6 503 000	6 500 000	6 500 000
Number of shares fully diluted	8 250 000	8 250 000	8 250 000
Return on shareholders´ equity, %	neg	neg	neg
Return on capital employed, %	neg	neg	neg
Equity ratio, %	91	92	87

INCOME STATEMENT ARTIMPLANT

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	**Jan-Sep 1999**	**Jan-Sep 1998**	**Jan-Dec 1998**	**Jan-Sep 1999**	**Jan-Sep 1998**	**Jan-Dec 1998**

Net sales	14 163	6 705	11 426	418	136	144
Cost of goods & services sold	-11 753	-6 052	-10 051	-418	-136	-144
Gross profit	**2 410**	**653**	**1 375**	**0**	**0**	**0**
Research & development expenses	-5 764	-3 088	-5 127	-5 764	-3 088	-5 127
Marketing & sales expenses	-681	-	-	-681	-	-
Administrative expenses	-4 760	-3 505	-4 726	-2 435	-2 297	-3 579
Share in group results	-	-	-	691	0	2 589
Operating result	**-8 795**	**-5 940**	**-8 478**	**-8 189**	**-5 385**	**-6 117**
Interest income & other financial income	586	1 600	1 961	502	1 526	1 834
Interest expenses & other finan. expenses	-292	-31	-39	-290	-31	-39
Income from sale of warrants	-	2 631	3 063	-	2 631	3 063
Financial items net	**294**	**4 200**	**4 985**	**212**	**4 126**	**4 858**
Result after financial items	**-8 501**	**-1 740**	**-3 493**	**-7 977**	**-1 259**	**-1 259**
Taxes	-	-	26	-	-	-
Net result for reporting period	**-8 501**	**-1 740**	**-3 467**	**-7 977**	**-1 259**	**-1 259**

Note: Depreciation included in Income Statement

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	**Jan-Sep 1999**	**Jan-Sep 1998**	**Jan-Dec 1998**	**Jan-Sep 1999**	**Jan-Sep 1998**	**Jan-Dec 1998**
Capitalized R&D expenses	4 734	2388	3968	4 734	2388	3968
Patents	357	244	435	357	244	435
Goodwill	525	207	333	-	-	-
Machinery and equipment	1 167	804	1287	901	609	965
Total depreciation	**6 783**	**3 643**	**6 023**	**5 992**	**3 241**	**5 368**

BALANCE SHEET ARTIMPLANT

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	**Sep 30, 1999**	**Sep 30, 1998**	**Dec 31, 1998**	**Sep 30, 1999**	**Sep 30, 1998**	**Dec 31, 1998**
ASSETS						
Capitalized R&D expenses	20 004	10 666	13 002	20 004	10 666	13 002
Patents	1 163	961	1 320	1 163	961	1 320
Goodwill	13 128	9 733	13 653	-	-	-
Total intangible fixed assets	34 295	21 360	27 975	21 167	11 627	14 322
Machinery and equipment	4 159	3 701	4 035	3 539	2 846	3 266
Construction in progress	703	-	601	703	-	601
Total tangible fixed assets	4 862	3 701	4 636	4 242	2 846	3 867
Shares in subsidiary	-	-	-	17 996	14 050	17 996
Total financial fixed assets	-	-	-	17 996	14 050	17 996
Total fixed assets	**39 157**	**25 061**	**32 611**	**43 405**	**28 523**	**36 185**
Receivables	2 536	1 798	1 058	988	-	-
Receivables group companies	-	-	-	2 580	-	2 211
Other receivables	443	1 201	744	437	945	744
Prepaid expenses and accrued income	1 725	2 927	1 192	1 485	2 716	1 016
Total short term receivables	**4 704**	**5 926**	**2 994**	**5 490**	**3 661**	**3 971**
Cash and bank	31 359	40 019	37 524	26 893	36 956	33 236
Total current assets	**36 063**	**45 945**	**40 518**	**32 383**	**40 617**	**37 207**
TOTAL ASSETS	**75 220**	**71 006**	**73 129**	**75 788**	**69 140**	**73 392**

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	**Sep 30, 1999**	**Sep 30, 1998**	**1998-12-31**	**Sep 30, 1999**	**Sep 30, 1998**	**Dec 31, 1998**
SHAREHOLDERS' EQUITY & LIABILITIES						

Equity						
Share capital	650	650	650	650	650	650
Paid-in, not registered new issue	13 360	-	-	13 360	-	-
Restricted reserves	65 113	66 324	66 324	65 113	66 324	66 324
Total restricted capital	79 123	66 974	66 974	79 123	66 974	66 974
Non-restricted reserves	-2 207	-	-	-	-	-
Net result for reporting period	-8 501	-1 740	-3 467	-7 977	-1 259	-1 259
Total non-restricted period	-10 708	-1 740	-3 467	-7 977	-1 259	-1 259
Total equity	**68 415**	**65 234**	**63 507**	**71 146**	**65 715**	**65 715**
Deferred tax	240	272	240	-	-	-
Other provisions	300	700	300	-	-	-
Total provisions	**540**	**972**	**540**	**-**	**-**	**-**
Other long term liabilities	200	300	300	200	300	300
Total long term liabilities	**200**	**300**	**300**	**200**	**300**	**300**
Accounts payable	1 318	1 473	1 130	1 072	1 114	993
Other short term liabilities	583	1 187	4 673	311	902	4 320
Accrued expenses and prepaid income	4 164	1 840	2 979	3 059	1 109	2 064
Total short term liabilities	**6 065**	**4 500**	**8 782**	**4 442**	**3 125**	**7 377**
TOTAL SHAREHOLDERS' EQUITY & LIABILITIES	**75 220**	**71 006**	**73 129**	**75 788**	**69 140**	**73 392**

STATEMENT OF CHANGES IN FINANCIAL POSITION	**Group**	**Group**	**Group**	**Parent**	**Parent**	**Parent**
Amounts in thousand SEK	**Jan-Sep 1999**	**Jan-Sep 1998**	**Jan-Dec 1998**	**Jan-Sep 1999**	**Jan-Sep 1998**	**Jan-Dec 1998**
Funds generated from operations	**-1 718**	**1 903**	**2 562**	**-1 985**	**1 982**	**4 116**
Increase(-), decrease(+) of short term receivables	-1 710	-4 454	-1 522	-1 519	-2 189	-2 499
Increase(+), decrease(-) of short term liabilities	-2 717	2 243	6 525	-2 935	868	5 120
Chgs in working cap. (exl. liquid assets)	**-4 427**	**-2 211**	**5 003**	**-4 454**	**-1 321**	**2 621**
New issue	13 408	**-**	**-**	13 408	**-**	**-**
Increase in long term liabilities	-	972	540	-	-	-
Total funds generated	**7 263**	**664**	**8 105**	**6 969**	**661**	**6 737**
Investments in intangible fixed assets	-11 936	-17 506	-26 017	-11 936	-7 566	-12 032
Investments in tangible fixed assets	-1 392	-3 485	-4 910	-1 276	-2 435	-3 819
Investments in financial fixed assets	-	-	-	-	-14 050	-17 996
Decrease in long term liabilities	-100	-100	-100	-100	-100	-100
Total funds used	**-13 428**	**-21 091**	**-31 027**	**-13 312**	**-24 151**	**-33 947**
CHANGES IN LIQUID FUNDS	**-6 165**	**-20 427**	**-22 922**	**-6 343**	**-23 490**	**-27 210**

Other financial information:

Full-year report: Feb. 18, 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 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 for treatment of injured anterior cruciate ligament (ACL). 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.

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. Cartilage replacement – a new method for treatment of damaged cartilage – was developed by researchers employed or tied to Artimplant. The clinical documentation of the patients who have undergone cartilage replacement at GMC, has formed the basis for the US authorities' approval.

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

Gothenburg, November 5, 1999
Artimplant AB (publ)

Anders Cedronius
Chief Executive Officer

This report has not been reviewed by Artimplant's auditors.

Artimplant's interim reports and press releases can be retrieved from: www.Artimplant.se

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