



Artimplant

Biomaterials for Tissue Engineering

Six-month interim report

1999

- In April 1999, 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. The goal is to initiate clinical trials of a first wound care product during year 2000.
- Currently there are three clinical trials underway using Artimplants biodegradable implants: a multicenter study including at least 200 patients with anterior cruciate ligament (ACL) injuries in the knee, as well as two pilot studies within hand surgery for treatment of injured thumb ligament and arthrosis at the base of the thumb.
- Artimplant expects to initiate clinical trials with resorbable bone fracture implants during the second half of 1999, with the aim to have at least one product certified for market launch in year 2000. The first products are for fixation of ankle injuries and suture anchors to attach ligaments or tendons to bone.
- A scientific publication that includes innovative chemistry, material technology, cell biology and long term studies on animals with Artimplant's biodegradable anterior cruciate ligament implant is being compiled. This publication will be filed for publication during autumn 1999 and is believed to be unique in its kind.
- A report with preliminary 12-month follow-up data from the clinical pilot study of ACL-injuries will be presented during the second half of 1999.
- Revenues for the group amounted to 10.0 MSEK (3.1 MSEK). The operating result amounted to -5.0 MSEK (-3.6 MSEK). Result after financial items amounted to -4.6 MSEK (0.2 MSEK). Earnings per share after taxes amounted to -0.70 SEK (0,03 SEK).

Artimplant's result for the half year 1999

Net sales for the Group during the first half year amounted to 10.0 MSEK (3.1 MSEK). Operating result during the period amounted to -5.0 MSEK (-3.6 MSEK). Interest income amounted to 0.4 MSEK (1.4 MSEK). Result after financial items amounted to -4.6 MSEK (0.2 MSEK). Goodwill relating to the acquisition of GMC amounted to 13.3 MSEK at the end of the reporting period and is depreciated over 20 years.

Net sales for the subsidiary Gothenburg Medical Center (GMC) during the first quarter amounted to 10.3 MSEK. Operating result during the same period amounted to 0.5 MSEK.

During the second quarter 1998 Artimplant acquired Gothenburg Medical Center (GMC). GMC has been consolidated as of May 1st, 1998.

Research and development activities

Artimplant is a research based 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 during the year expanded its development activities to include more than a dozen projects based on Artimplant's technology.

The product portfolio includes fibers for production as ligaments as well as solid materials for production of bone fracture implants. The development of membrane products for treatment of conditions such as chronic wounds and damaged cartilage, which were filed for patent in 1998, has been intensified.

A scientific publication that includes innovative chemistry, material technology, cell biology and long term studies of animals with Artimplant's biodegradable anterior cruciate ligament implant is being compiled. This publication will be filed for publication during autumn 1999 and 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 cruciate ligament (ACL) injuries was initiated in Sweden during the first quarter. With the purpose to increase the possibility for an early market launch in the North American market, the trial protocols for the first multicenter study have been adapted to the regulations stipulated by Food & Drug Administration (FDA). The operation series is expected to continue during 1999.

Preliminary 12-month follow-up data from the clinical pilot study including 20 patients will be presented during autumn 1999 at selected seminars and conferences. 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 pilot study, with the purpose to optimize the surgical technique for the multicenter study, has shown that the knee joint stability of the operated knee is in par with the stability measured in 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 have been initiated.

Injuries to the ligaments that stabilize the base of the thumb is the most common hand injury in connection with skiing. If the diagnosis is improper, or if the re-attachment fails, the ligament degenerates. This leads to joint instability that over time leads to cartilage wear and the development of osteoarthritis. 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. A so called spacer, which is an approximately half inch pillow-like structure containing the same type of resorbable fiber material used in the company's other ligament implants, is developed to function as a joint implant for patients with osteoarthritis at the base of the thumb. Thumb base osteoarthritis 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. The aim is to have at least one product certified for market launch in year 2000.

The first products to be evaluated in clinical trials are fixation products for use in malleoli fractures (ankle fractures) and suture anchors used to attach ligaments and tendons to bone. Clinical trial with the first product is planned to start during the second half of 1999.

According to the National Swedish Board of Health and Welfare approximately 6,000 people per year are hospital treated for ankle fracture in Sweden and according to US statistics approximately 440,000 ankle fractures occur each year in the US. Suture anchors are since many years widely used in both hand surgery and orthopedics.

Production

The build-up of Artimplant's production facilities in Gothenburg for manufacture of biodegradable implants is running according to plan. Routine production of fiber materials currently used in clinical trials have started and other clean room production can be scaled up according to needs.

Gothenburg Medical Center (GMC)

In May 1998, Gothenburg Medical Center AB (GMC) was acquired. GMC is one of the leading sportstrauma clinics in Sweden within orthopedic surgery. Lars Peterson, founder of GMC, has together with other researchers developed a new method for cartilage replacement. Since the introduction of the cartilage replacement method in 1987, nine out of ten patients in Sweden have received their treatment at GMC.

One main purpose of the acquisition is that Artimplant can more effectively conduct early clinical evaluations and test new methods, which shortens time to market for new products. GMC will be a forum for advanced clinical research, application and education within orthopedic surgery.

Net sales for the subsidiary GMC during the first half year amounted to 10.3 MSEK. Operating result during the same period amounted to 0.5 MSEK.

During the first quarter a third orthopedic surgeon has been recruited. GMC plans to further strengthen the orthopedic surgical operation by recruiting another orthopedic specialist. The limited operations within general practice at GMC will be closed down.

Artimplant and 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. The development of a new material platform has started. The goal is to initiate clinical trials of a first wound care product during year 2000. The planning regarding other product projects within chronic wounds has started.

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. Conventional products, surgical dressings and similar, presently account for approximately 75 percent of total wound care sales. However, 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.

Artimplant's primary market focus is orthopedic surgery. At year-end 1998 the company had defined a dozen separate product projects with substantial market potential. Since the company's technology for biodegradable polymer materials is well suited for a number of other medical applications, of which some are outside Artimplant's primary focus, the company sees broadened possibilities for research and development collaboration with other partners.

Investments and financial position

Investments during the first half year 1999 amounted to 8.6 MSEK (16.2 MSEK), whereof 7.9 MSEK (14.4 MSEK) were made in immaterial assets. At the end of the reporting period liquid assets amounted to 23.4 MSEK. An additional earnings-based payment of 4.0 MSEK referring to the acquisition of GMC has been made.

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 amounts to 1,750,000 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 would then amount to 8,250,000, whereof 1,000,000 series A and 7,250,000 series B. If fully exercised, the equity will amount to 87 MSEK, or SEK 10.54 per share.

Employees

The number of employees at the end of the reporting period amounted to 49 (41), whereof 34 (32) were employed at GMC. The number of consultants tied to the parent company Artimplant has decreased from 13 to 10 as they have been employed at Artimplant. During the first half year the company has been further reinforced by recruitment of a Chief Financial Officer, additional researchers, and personnel within production. Since the first products are expected to be launched already in year 2000 resources for clinical trial and marketing activities will be expanded.

Financial statements

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

KEY RATIOS, GROUP

	Jan-Jun 1999	Jan-Jun 1998
<i>Net result per share, SEK</i>	-0.70	0.03
<i>Net result per share fully diluted, SEK</i>	-0.55	0.02
<i>Equity per share, SEK</i>	9.07	10.33
<i>Equity per share fully diluted, SEK</i>	10.54	11.53
<i>Number of shares at end of reporting period</i>	6 500 000	6 500 000
<i>Number of shares fully diluted</i>	8 250 000	8 250 000
<i>Return on shareholders' equity, %</i>	neg	1
<i>Return on capital employed, %</i>	neg	1
<i>Equity ratio, %</i>	91	92

INCOME STATEMENT ARTIMPLANT

	Group	Group	Parent	Parent
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Amounts in thousand SEK	Jan-Jun 1999	Jan-Jun 1998	Jan-Jun 1999	Jan-Jun 1998
Net sales	10 011	3 086	23	136
Cost of goods & services sold	-8 305	-2 937	-23	-136
Gross profit	1 706	149	0	0
Research & development expenses	-3 392	-1 638	-3 392	-1 638
Administrative expenses	-3 285	-2 085	-1 735	-1 685
Share in group results	-	-	560	0
Operating result	-4 971	-3 574	-4 567	-3 323
Interest income & other financial income	448	1 369	393	1 368
Interest expenses & other financial expenses	-34	-256	-34	-256
Income from sale of warrants	0	2 631	0	2631
Financial items net	414	3 744	359	3 743
Result after financial items	-4 557	170	-4 208	420
Net result for reporting period	-4 557	170	-4 208	420

BALANCE SHEET ARTIMPLANT

Amounts in thousand SEK	Group June 30, 1999	Group June 30, 1998	Parent June 30, 1999	Parent June 30, 1998
ASSETS				
Capitalized R&D expenses	17 975	8 876	17 975	8 876
Patents	1 254	844	1 254	844
Goodwill	13 303	9 857	-	-
Total intangible fixed assets	32 532	19 577	19 229	9 720
Machinery and equipment	3 923	2 533	3 259	1 529
Construction in progress	703	0	703	0
Total tangible fixed assets	4 626	2 533	3 962	1 529
Shares in subsidiary	-	-	17 996	14 050
Total financial fixed assets	0	0	17 996	14 050
Total fixed assets	37 158	22 110	41 187	25 299
Receivables	1 586	1 330	28	0
Receivables group companies	-	-	2 844	0
Other receivables	1 113	691	1 108	571
Prepaid expenses and accrued income	1 512	1 524	1 321	1 419
Total short term receivables	4 211	3 545	5 301	1 990
Cash and bank	23 423	47 619	18 344	43 612
Total current assets	27 634	51 164	23 645	45 602
TOTAL ASSETS	64 792	73 274	64 832	70 901

Amounts in thousand SEK	Group June 30, 1999	Group June 30, 1998	Parent June 30, 1999	Parent June 30, 1998
SHAREHOLDERS' EQUITY & LIABILITIES				
Equity				
Share capital	650	650	650	650
Restricted reserves	65 065	66 324	65 065	66 324
Total restricted capital	65 715	66 974	65 715	66 974
Non-restricted reserves	-2 207	0	0	0
Income/loss for reporting period	-4 557	170	-4 208	420
Total non-restricted period	-6 764	170	-4 208	420
Total equity	58 951	67 144	61 507	67 394

<i>Deferred tax</i>	240	236	-	-
<i>Other provisions</i>	300	700	-	-
Total provisions	540	936	-	-
<i>Other long term liabilities</i>	300	400	300	400
Total long term liabilities	300	400	300	400
<i>Accounts payable</i>	965	1 487	640	1 240
<i>Tax liabilities</i>	0	66	0	0
<i>Other short term liabilities</i>	912	1 199	551	917
<i>Accrued expenses and prepaid income</i>	3 124	2 042	1 834	950
Total short term liabilities	5 001	4 794	3 025	3 107
TOTAL SHAREHOLDERS' EQUITY & LIABILITIES	64 792	73 274	64 832	70 901

STATEMENT OF CHANGES IN FINANCIAL POSITION

	Group	Group	Parent	Parent
Amounts in thousand SEK	Jan-Jun 1999	Jan-Jun 1998	Jan-Jun 1999	Jan-Jun 1998
<i>Funds generated from operations</i>	-506	2 016	-683	2 117
<i>Increase(-), decrease(+) of short term receivables</i>	-1 217	-2 073	-1 330	-518
<i>Increase(+), decrease(-) of short term liabilities</i>	-3 781	2 537	-4 352	850
Changes in working capital (excl. liquid assets)	-4 998	464	-5 682	332
<i>Increase in long term liabilities</i>	-	936	-	-
Total funds generated	-5 504	3 416	-6 365	2 449
<i>Investments in intangible fixed assets</i>	-7 896	-14 428	-7 896	-4 487
<i>Investments in tangible fixed assets</i>	-701	-1 815	-631	-746
<i>Investments in financial fixed assets</i>	-	-	-	-14 050
<i>Decrease in long term liabilities</i>	-	-	-	-
Total funds used	-8 597	-16 243	-8 527	-19 283
CHANGES IN LIQUID FUNDS	-14 101	-12 827	-14 892	-16 834

Note: Depreciation of tangible and intangible fixed assets included in Income Statement

	Group	Group	Parent	Parent
Amounts in thousand SEK	Jan-Jun 1999	Jan-Jun 1998	Jan-Jun 1999	Jan-Jun 1998
<i>Capitalized R&D expenses</i>	2 755	1 320	2 755	1 320
<i>Patents</i>	234	141	234	141
<i>Goodwill</i>	350	83	-	-
<i>Machinery and equipment</i>	712	302	536	237
Total depreciation	4 051	1 846	3 525	1 698

Other financial information:

Nine-month interim report: Nov. 5, 1999

Artimplant is a research based 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.

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Artimplant AB (publ)

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Chief Executive Officer

This report has been reviewed by Artimplant's auditors.

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

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