Artimplant

Biomaterials for Tissue Engineering

Nine–month report 2000

- **The intensive work with the build-up of the quality control system has been in progress during most of the year and used resources from all functions within Artimplant. The quality control system, which is a prerequisite for an EU-certification, is believed to be up and running in December 2000, which is approximately two months later than earlier expected. An audit of the company's quality control system is believed to take place during the same month by a Notified Body.**
- **The same Notified Body will also perform a technical audit related to the certification of Artimplant's first product. Depending on the time the Notified Body needs for the technical audit, certification of the product can take place at the earliest before year-end.**
- **The documentation for an EU-certification of Artimplant's augmentation implant for reconstruction of the anterior crutiate ligament injury (ACL injury) includes clinical data from a 30 month follow-up of the pilot study initiated in autumn 1997. Furthermore, the documentation includes safety data from the first randomized multicenter study including 200 patients.**
- **The first randomized multicenter study is proceeding according to plan. Interim follow-up shows no deviation from expectations or compared to earlier pilot study. This study is designed according to FDA's recommendations regarding long term follow-up of reconstruction of ACL injuries.**
- **As a support for the scientific documentation and Artimplant's launch strategy of various products, further clinical studies are planned within and outside the Nordic region. This includes an expansion of the second multicenter study for ACL injuries as well as initiation of a multicenter study with the spacer implant for treatment of osteoarthritis at the base of the thumb.**
- **Revenues for the Group during the first nine months amounted to SEK 16.5m (14.2m). The operating result amounted to SEK -16.7m (-8.8m). Result after financial items amounted to SEK -11.5m (-8.5m). Earnings per share after taxes amounted to SEK -1.32 (SEK -1.31).**

Artimplant's result January-September 2000

Net sales for the Group during January-September 2000 amounted to SEK 16.5m (14.2m). Operating result during the period amounted to SEK -16.7m (-8.8m). Result after financial items amounted to SEK -11.5m (-8.5m). Goodwill relating to the acquisition of GMC amounted to SEK 12.4m at the end of the reporting period and is depreciated over 20 years. The Parent company's net sales of SEK 2.4m refers mainly to proceeds from Mölnlycke Health Care.

Higher costs and investments for R&D operations, marketing and production had a negative effect on the operating result. Additional personnel was recruited to all these functions during the first nine months 2000.

Revenues from sales of warrants to personnel and persons tied to the Artimplant Group, as well as higher interest income from share issue proceeds received in April 2000, had a positive effect on financial items.

Net sales for the subsidiary Gothenburg Medical Center (GMC) amounted to SEK 15.5m (14.4m) during the first nine months 2000. Operating result amounted to SEK 0.3m (0.6m). The lower operating result is in its entirety due to an increase in costs for cultivation of cartilage cells in connection with cartilage replacement procedures. As of the fourth quarter, GMC will forward the entire cost increase to invoicing, which is not expected to have a negative effect on the demand for such surgical procedures.

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 recreate an active life. The implants provide injured or worn tissue with temporary relief and support the body's natural healing processes. The company's in-house developed biomaterials are based on a new patented technology that opens new market opportunities within orthopedic surgery and several other specialist areas where medical needs are significant.

An intensive work with the build-up of the quality control system has been in progress during most of 2000 and used resources from all functions within Artimplant. A Notified Body audits and approves the company's quality control system. An review is made of all functions such as R&D, production, marketing and administration. The quality control system is expected to be up and running in December 2000, which is approximately two months later than earlier expected. An audit of the company's quality control system is believed to take place the same month.

An approval of the quality control system is a prerequisite to receive a certification. Artimplant is aiming at an EU-certification of the first product, an augmentation device to use for anterior crutiate ligament reconstruction. The Notified Body performs an audit related to the certification of the product. Depending on the time the Notified Body needs for the technical audit, certification of the product can take place before year-end at the earliest.

The documentation for an EU-certification of Artimplant's augmentation device for reconstruction of anterior cruciate ligament injury (ACL injury) includes clinical data from a 30 month follow-up of the pilot study initiated in autumn 1997. Furthermore, the documentation includes safety data from the first randomized multicenter study including 200 patients.

Artimplant expects to have several products certified during the coming years and has therefor initiated an extensive pre-launch program. This includes mapping of the larger markets in Europe with the purpose of establishing own sales channels over time in countries such as Germany, France, Spain, Italy and Great Britain. The market organization is under continued build-up. A Sales Director for the Nordic region has recently been recruited.

As a support for the scientific documentation and Artimplant's launch strategy of various products, further clinical studies are planned within and outside the Nordic region. This includes an expansion of the second multicenter study for ACL injuries initiated during the first half of 2000 in Finland and expanded into Sweden. Planning of an international multicenter study with the spacer implant for treatment of thumb-base osteoarthritis is ongoing.

The first project of the Mölnlycke Health Care cooperation has been completed. The biological evaluation of the new material variations within the wound care area will take place under Mölnlycke's management. Artimplant will parallelly continue biological evaluation of the new materials within other medical application areas, which are not included in the agreement. Discussions are ongoing regarding a second project within the collaboration agreement. Mölnlycke has per July paid in full for the first project.

Anterior Crutiate 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 first product for certification is an implant for reinforcement during ACL-injury reconstruction. The application refers to reinforcement (augmentation) of tissue taken from the patient (so called autograft).

Artimplant has so far intiated three clinical studies for this application:

1. a pilot study initiated in autumn 1997 including 20 patients where a part of the patient's patellar tendon has been reinforced with Artimplant's implant,
2. a first randomized multicenter study including 200 patients initiated in spring 1999, where half of the group was surgically treated with the same technique as in the pilot study and the other half with patellar tendon without reinforcement. This study is designed according to FDA's recommendations regarding long term follow-up of reconstruction of ACL-injuries (minimum 24 months follow-up),
3. a second randomized multicenter study including 100 patients initiated in spring 2000. Half the group was surgically treated with tendon taken from the back side of the patient's thigh (so called hamstring) reinforced with Artimplant's implant and half of the group with hamstring tissue without reinforcement.

One of the potential advantages with the hamstring method is less complications at the donor site compared to if the patellar tendon is used. In the study, which takes place in Finland and Sweden, 75 patients have been treated. The operation series includes a total of 100 patients. Currently the company is planning for studies in other Nordic countries based on the same protocol.

The first randomized multicenter study is proceeding according to plan. Interim follow-up shows no deviations from expectations or compared to earlier pilot study. Clinical data from this multicenter study can according to the protocol be used to show clinical stability after a 24 month follow-up.

Spacer

Artimplant is carrying out a hand surgery study on ten patients with osteoarthritis at the base of the thumb. The injury causes increasing pain and limited grasping ability. Osteoarthritis at the base of the thumb is one of the most common forms of arthritis in the hand, especially among older women. Approximately one million people in the western world are diagnosed with thumb-base osteoarthritis each year and satisfying treatment alternatives are not avaliable. The market potential is estimated at SEK 5-12bn.

Preliminary follow-up results show that treatment with Artimplant's biodegradable implant (spacer) leads to significant pain relief already within six months. The six month results will be presented at an international forum as soon as an adequate patent protection for the product is secured, which is expected to be possible during the first quarter 2001. Furthermore, Artimplant plans to initiate an international clinical multicenter study during 2001 for treatment of thumb-base osteoarthritis.

Thumb ligament

At an international hand surgery congress during August in Kuopio, Finland, Artimplant presented promising short term follow-up results on a new method for treatment of chronic thumb ligament injuries. All five patients included in a pilot study had after six months regained normal joint stability and grasp strength in the operated joint. Today these patients are normally offered arthodesis as the only remaining treatment alternative.

In the pilot study a so called augmentation technique was used, which means that joint tissue from the patient's wrist was reinforced with Artimplant's biodegradable implant. Using the augmentation principle is new within the hand surgery area and created considerable interest at the congress in Kuopio. The surgeon who has performed the operation program has received approval from the ethical committee to include additional patients in the pilot study.

An estimated half a million people in the western world are diagnosed with thumb ligament injury each year. It is one of the most common skiing injuries in the hand. When early diagnosed, the injury is treated surgically shortly after occurrence whereby the ligament is reattached to its original location. However, an improper diagnosis, or reattachment failure, will eventually lead to joint instability, cartilage weardown and arthrosis development. The market potential for Artimplant's biodegradable implant for treatment of chronic thumb ligament injuries is estimated at approximately SEK 500m.

Investments and financial position

During January-September 2000 investments amounted to SEK 25.5m (17.3m), whereof SEK 20.1m (11.9m) were made in immaterial assets. At the end of the reporting period liquid assets amounted to SEK 148.9m (31.4m).

After authorization from an extraordinary General Meeting on March 27, 2000, Artimplant effected a directed issue of 1,000,000 B shares at a price of SEK 143 per share. The main share of the issue was subscribed by international institutions. During April, the company received proceeds amounting to SEK 136m after deduction of issue related costs.

Artimplant's ordinary Annual General Meeting on May 3, 2000 approved a warrant program for employees and persons tied to the Artimplant Group. The program includes 512,500 warrants and each warrant entitles to subscription of one B share at a price of SEK 300. The warrants are to be exercised no later than March 30, 2004. If fully exercised the warrant program will provide the company with proceeds of SEK 154m and have a dilutionary effect of 5.5% for the capital and 2.8% for the votes. At the end of the period, 243,100 rights had been subscribed.

Personnel

The number of employees at the end of the reporting period amounted to 60 (45), whereof 33 (30) were employed at GMC. The number of consultants tied to the parent company amounted to 11 (10).

Patents

As of October 31, 2000, Artimplant has five patents approved in Sweden whereof three are approved in a number of other countries. Another seven patents are being prepared for filing at the Swedish Patent Office (PRV).

Financial statements

The financial statements for January-September and full-year 2000 are compared with the corresponding period in 1999.

INCOME STATEMENT ARTIMPLANT

Amounts in thousand SEK	Group Jan-Sept 2000	Group Jan-Sept 1999	Group Jan-Dec 1999	Parent Jan-Sept 2000	Parent Jan-Sept 1999	Parent Jan-Dec 1999
Net sales	16 542	14 163	20 032	2 392	418	1 613
Cost of goods & services sold	-14 455	-11 753	-16 267	-2 392	-418	-1 613
Gross profit	**2 087**	**2 410**	**3 765**	**0**	**0**	**0**
Research & development expenses	-10 051	-5 764	-9 187	-10 051	-5 764	-9 187
Marketing expenses	-3 019	-681	-1 892	-3 019	-681	-1 892

Administrative expenses	-5 766	-4 760	-7 338	-3 418	-2 435	-4 239
Share in group results	-	-	-	307	691	1 691
Operating result	**-16 749**	**-8 795**	**-14 652**	**-16 181**	**-8 189**	**-13 627**
Interest income & other financial income	2 850	586	753	2 793	502	640
Interest expenses & other financial expenses	-36	-292	-314	-36	-290	-310
Income from sale of warrants	2 431	-	-	-	-	-
New share issue expenses	-	-	-	-6 797	-	-
Financial items net	**5 245**	**294**	**439**	**-4 040**	**212**	**330**
Result after financial items	**-11 504**	**-8 501**	**-14 213**	**-20 221**	**-7 977**	**-13 297**
Taxes	-687	-	60	-	-	-
Net result for reporting period	**-12 191**	**-8 501**	**-14 153**	**-20 221**	**-7 977**	**-13 297**

Note: Depreciations included in Income Statement

Amounts in thousand SEK	**Group Jan-Sept 2000**	**Group Jan-Sept 1999**	**Group Jan-Dec 1999**	**Parent Jan-Sept 2000**	**Parent Jan-Sept 1999**	**Parent Jan-Dec 1999**
Capitalized R&D expenses	8 184	4 734	7 600	8 184	4 734	7 600
Patents	586	357	544	586	357	544
Goodwill	525	525	699	-	-	-
Machinery and equipment	2 009	1 167	1 750	1 708	901	1 391
Total depreciation	**11 304**	**6 783**	**10 593**	**10 478**	**5 992**	**9 535**

BALANCE SHEET ARTIMPLANT

Amounts in thousand SEK	Group 2000-09-30	Group 1999-09-30	Group 1999-12-31	Parent 2000-09-30	Parent 1999-09-30	Parent 1999-12-31
ASSETS						
Capitalized R&D expenses	32 855	20 004	22 287	32 855	20 004	22 287
Patents	2 000	1 163	1 199	2 000	1 163	1 199
Goodwill	12 429	13 128	12 954	-	-	-
Total intangible fixed assets	47 284	34 295	36 440	34 855	21 167	23 486
Machinery and equipment	7 807	4 159	4 556	6 947	3 539	4 023
Construction in progress	-	703	-	-	703	-
Total tangible fixed assets	7 807	4 862	4 556	6 947	4 242	4 023
Shares in subsidiary	-	-	-	18 096	17 996	17 996
Total financial fixed assets	-	-	-	18 096	17 996	17 996
Total fixed assets	**55 091**	**39 157**	**40 996**	**59 898**	**43 405**	**45 505**
Receivables	1 718	2 536	2 408	-	988	988
Receivables group companies	-	-	-	-	2 580	602
Other receivables	1 249	443	681	1 128	437	679
Prepaid expenses and accrued income	4 208	1 725	2 037	3 965	1 485	1 846
Total short term receivables	7 175	4 704	5 126	5 093	5 490	4 115
Cash and bank	148 940	31 359	39 660	145 267	26 893	37 153
Total current assets	**156 115**	**36 063**	**44 786**	**150 360**	**32 383**	**41 268**
TOTAL ASSETS	**211 206**	**75 220**	**85 782**	**210 258**	**75 788**	**86 773**

Amounts in thousand SEK	Group 2000-09-30	Group 1999-09-30	Group 1999-12-31	Parent 2000-09-30	Parent 1999-09-30	Parent 1999-12-31
SHAREHOLDERS' EQUITY & LIABILITIES						
Equity						
Share capital	925	650	763	925	650	763
Paid-in, not registered new issue	-	13 360	9 936	-	13 360	9 936
Restricted reserves	215 696	65 113	83 016	222 493	65 113	83 016
Total restricted capital	216 621	79 123	93 715	223 418	79 123	93 715
Non-restricted reserves	-3 064	-2 207	-2 208	-	-	-
Net result for reporting period	-12 191	-8 501	-14 153	-20 221	-7 977	-13 297
Total non-restricted period	-15 255	-10 708	-16 361	-20 221	-7 977	-13 297
Total equity	**201 366**	**68 415**	**77 354**	**203 197**	**71 146**	**80 418**
Deferred tax	179	240	179	-	-	-
Other provisions	200	300	200	-	-	-
Total provisions	**379**	**540**	**379**	**-**	**-**	**-**
Other long term liabilities	100	200	200	100	200	200
Total long term liabilities	**100**	**200**	**200**	**100**	**200**	**200**
Accounts payable	2 826	1 318	2 640	2 014	1 072	2 334
Liabilities group companies	-	-	-	989	-	-
Tax liabilities	687	-	2	-	-	-
Other short term liabilities	736	583	894	421	311	544
Accrued expenses and prepaid income	5 112	4 164	4 313	3 537	3 059	3 277
Total short term liabilities	**9 361**	**6 065**	**7 849**	**6 961**	**4 442**	**6 155**
TOTAL SHAREHOLDERS' EQUITY & LIABILITIES	**211 206**	**75 220**	**85 782**	**210 258**	**75 788**	**86 773**

CASH FLOW ANALYSIS ARTIMPLANT

Amounts in thousand SEK	Group Jan-Sept 2000	Group Jan-Sept 1999	Group Jan-Dec 1999	Parent Jan-Sept 2000	Parent Jan-Sept 1999	Parent Jan-Dec 1999
Current operations						
Result after financial items	-11 504	-8 501	-14 213	-20 221	-7 977	-13 297
Adjustment for items not effecting cash flow	11 448	6 783	10 517	10 478	5 992	9 559
Taxes Paid	-687	-	-1	-	-	-
Cash flow from current operations before changes in working capital	**-743**	**-1 718**	**-3 697**	**-9 743**	**-1 985**	**-3 738**
Cash flow from changes in working capital						
Increase(-), decrease(+) in receivables	-2 049	-1 710	-2 132	-978	-1 519	-144
Increase(+), decrease(-) in liabilities	1 512	1 283	3 067	806	1 065	2 778
Cash flow from current operations	**-1 280**	**-2 145**	**-2 762**	**-9 915**	**-2 439**	**-1 104**
Investments						
Aquisition of subsidiaries	-	-4 000	-4 000	-100	-4 000	-4 000
Aquisition of intangible fixed assets	-20 139	-11 936	-17 308	-20 139	-11 936	-17 308
Aquisition of tangible fixed assets	-5 404	-1 392	-1 694	-4 632	-1 276	-1 571
Cash flow from investments	**-25 543**	**-17 328**	**-23 002**	**-24 871**	**-17 212**	**-22 879**
Financing						
New share issue	136 203	13 408	28 000	143 000	13 408	28 000
Repayment of loans	-100	-100	-100	-100	-100	-100
Cash flow from financing	**136 103**	**13 308**	**27 900**	**142 900**	**13 308**	**27 900**
Cash flow for reporting period	**109 280**	**-6 165**	**2 136**	**108 114**	**-6 343**	**3 917**
Liquid funds at beginning of period	**39 660**	**37 524**	**37 524**	**37 153**	**33 236**	**33 236**
Liquid funds at end of period	**148 940**	**31 359**	**39 660**	**145 267**	**26 893**	**37 153**

KEY RATIOS, GROUP

	Jan-Sept 2000	Jan-Sept 1999	Jan-Dec 1999
Net result per share, SEK	-1.32	-1.31	-1.72
Net result per share fully diluted, SEK	-1.25	-1.03	-
Equity per share, SEK	21.77	10.52	9.38
Equity per share fully diluted, SEK	36.38	11.69	-
Number of shares at end of reporting period	9 250 000	6 503 000	8 250 000
Number of shares fully diluted	9 762 500	8 250 000	8 250 000
Return on shareholders´ equity, %	neg	neg	neg
Return on capital employed, %	neg	neg	neg
Equity ratio, %	95	91	90

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

Other financial information:
Year-end report: February 20, 2001

Artimplant is a biomaterial company focused on unmet needs in the field of orthopedic surgery. Artimplant develops, manufactures and markets biodegradable implants with the aim of recreating an active life. The company's in-house developed biomaterials are based on a new patented technology that opens new market opportunities within orthopedic surgery and numerous other specialist areas where medical needs are significant. After more than ten years of development work Artimplant is now entering a market phase.

Artimplant has developed and patented a number of biodegradable ligament implants currently undergoing clinical studies. Early observations from a pilot study using Artimplant's anterior crutiate ligament (ACL) implant show subjective as well as objective knee stability. The technique enables 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. The market potential for Artimplant's ongoing development projects amounts to approximately SEK 30 bn. Furthermore, the market potential for Artimplant's carrier technology is estimated at more than SEK 50 bn.

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.*

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

Gothenburg, November 1, 2000
Artimplant AB (publ)

Anders Cedronius
Chief Executive Officer

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

Artimplant's annual report, interim reports and press releases are available at www.artimplant.se

For further information, please contact:
Anders Cedronius, CEO tel: +46 - 31 - 746 5600
Lars-Erik Nygren, CFO tel: +46 - 31 - 746 5600
Kari Odhnoff, Investor Relations tel: +46 - 708 - 639 341