



# Artimplant

Biomaterials for Tissue Engineering

## Six-month report

2000

- The operation series in the first randomized multicenter study with injured anterior crutiate ligament (ACL) has been finalized. EU certification is expected to take place during Q4 2000. A second multicenter study has been initiated in Finland and expanded in Sweden.
  - Preparatory work for market launch of the first ligament product continues. Michael Nordh from AstraZeneca has been recruited with responsibility for the build-up of Artimplant's global market organization. Artimplant expects to launch several products during the next two year period.
  - At an international hand surgery congress in Kuopio, Finland, short term follow-up results were presented on treatment of chronic thumb ligament injuries where Artimplant's augmentation ligament has been used. All five patients included in a pilot study had after six months regained normal joint stability and grasp strength in the operated joint.
  - The build-up of full scale production is ongoing and is expected to be completed during the second half of 2000.
  - In addition to earlier approved patents, the company received one additional patent approval during the second quarter. Artimplant plans to file further patent applications during 2000.
  - Artimplant Drug Delivery Systems AB, a wholly-owned subsidiary for the development and commercialization of Artimplant's carrier technology within the drug delivery area, is being incorporated.
  - A directed share issue, whereof the main share was subscribed by international institutional investors, provided the company with net proceeds of SEK 136m during the second quarter.
  - All employees and persons tied to the Artimplant Group were offered to participate in a warrant program whereof approximately 75 per cent chose to subscribe. Of persons in management position or with specialist competence, 28 of 30 chose to subscribe. In total 243,100 rights were subscribed.
  - Revenues for the Group during the first six months amounted to SEK 12.4m (10.0m). The operating result amounted to SEK -10.1m (-5.0m). Result after financial items amounted to SEK -6.1m (-4.6m). Earnings per share after taxes amounted to SEK -0.74 (SEK -0.70).
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### **Artimplant's result January-June 2000**

Net sales for the Group during January-June 2000 amounted to SEK 12.4m (10.0m). Operating result during the period amounted to SEK -10.1m (-5.0m). Result after financial items amounted to SEK -6.1m (-4.6m). Goodwill relating to the acquisition of GMC amounted to SEK 12.6m 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 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 spring 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 the financing items.

Net sales for the subsidiary Gothenburg Medical Center (GMC) amounted to SEK 10.9m (10.3m) during the first six months 2000. Operating result amounted to SEK 0.4m (0.5m).

### **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. 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. The product portfolio includes fibers for production of ligaments, solid materials for production of bone fracture implants as well as membranes for treatment of e.g. chronic wounds and damaged cartilage.

During year 2000 Artimplant enters a market phase and the company expects to launch several products during the next two year period. EU-certification for the first ligament product is expected to take place during the fourth quarter 2000. Artimplant's market organization is under expansion and in April the company recruited a Marketing & Sales Director, Michael Nordh from AstraZeneca, with responsibility for establishing a global market organization.

The preparatory work for market launch of the first ligament product, an implant for reconstruction of ACL, continues. As part of the pre-launch phase, establishment of sales channels in various European countries such as Germany, France, Spain, Italy and Great Britain are being planned for. The build-up of full scale production is ongoing and is expected to be completed during the second half of 2000.

Furthermore, additional clinical studies are planned for outside Sweden. A randomized clinical study including 50 patients, where tendons from the back of the patient's thigh (hamstrings) are used instead of parts of the patient's patellar tendon, was initiated during the first quarter 2000 in Finland. This study has been expanded to Sweden (GMC) and can gradually expand to include clinics in other countries.

Artimplant's orthopedic specialist clinic, Gothenburg Medical Center (GMC), is world leading within cartilage replacement. In April 2000 Artimplant participated in the International Cartilage Repair Society's congress in Gothenburg with over 600 participants from all over the world. Professor Lars Peterson, responsible for the clinical research at Artimplant, was elected new President for the International Cartilage Repair Society.

Lars Peterson has been appointed Professor at Gothenburg University, as well as Anders Lindahl, one of Artimplant's consultants and specialist physician in clinical chemistry at Sahlgrenska University Hospital.

Artimplant Drug Delivery Systems AB, a wholly owned subsidiary for development and commercialization of Artimplant's carrier technology within the drug delivery area, is being incorporated. Trials have shown that the company's biodegradable polymer material, to which various pharmaceutical compounds have been coupled, is well suited for controlled release of pharmaceuticals or other active substances over a long period of time. Possible indication areas are for example local application of antibiotics or pain relief compounds, systemic release of hormones in low doses as well as coupling of growth factors for stimulation of local tissue growth.

### ***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. The operation series in the first multicenter study at centers in Sweden including 200 patients with ACL injuries has been completed. With over two year follow-up data from the pilot study which was initiated in 1997, as well as early observations from the multicenter study, Artimplant seeks EU-certification for the ACL implant, which is expected to take place during the fourth quarter 2000.

During the first quarter 2000 Artimplant received an approval from the ethics committee as well as the National Finnish Board of Health and Welfare to conduct a clinical study including 50 patients with damaged ACL's. This study has been initiated and is part of a second ACL multicenter study. At GMC an operation series following the same protocol has also been initiated. 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 are used. One of the potential advantages is less complications at the donor site compared to if the patellar tendon is used.

### ***Hand surgery***

At an international hand surgery congress during August in Kuopio, Finland, Artimplant presented for the first time and in a scientific forum the short term follow-up results on a new method for treatment of chronic thumb ligament injuries where Artimplant's augmentation ligament has been used. All five patients included in a pilot study had after six months regained normal joint stability and grasp strength in the operated joint.

A so called augmentation technique was used, which means that joint tissue from the patient's wrist was reinforced with Artimplant's biodegradable implant and surgically inserted for repair of chronic (>6 months) the thumb ligament injury. Using the augmentation principle is new in the hand surgery area.

The surgeon who performed the surgeries has received approval from ethics committee to include additional patients in the study. This in order to avoid arthrodesis (surgery resulting in a stiff joint) as the only alternative for patients, while awaiting EU-certification of Artimplant's augmentation ligament. Artimplant is following up on the possibilities for an EU-certification of the thumb ligament implant partly on the basis of the pilot study recently presented in Kuopio.

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 wear and arthrosis development. The market size for Artimplant's biodegradable implant for treatment of chronic thumb ligament injuries is estimated to approximately SEK 500m.

Artimplant is also carrying out a hand surgery study on ten patients with osteoarthritis at the base of the thumb. Early follow-up results show that the treatment with Artimplant's biodegradable implant (spacer) leads to significant pain reduction. A longer follow-up period is needed to ascertain long term results. Approximately one million people are diagnosed with thumb-base osteoarthritis each year in the western world and satisfying treatment alternatives are not available. The market size for a functioning implant is estimated at SEK 5-12bn.

### ***Bone fracture***

Artimplant has developed solid biodegradable materials related to the fiber materials in the ligament products. The aim is to use the solid materials in fixation systems for various types of surgical bone fracture treatments, thereby eliminating the need for re-operation.

Due to the positive observations with Artimplant's ligament products, along with the significantly larger market and earnings potential for these implants in comparison to bone fracture implants, priorities were changed during the first quarter 2000 in order to focus on development and EU-certification of ligament products. A comprehensive quality control program is ongoing with the purpose to obtain an EU-certification, which includes

all functions at Artimplant that are related to development, production and follow-up of clinical trials. Therefore, the work of initiating clinical trials using bone fracture implants has been postponed.

### ***Genzyme Tissue Repair (GTR)***

During 1999, an agreement was reached that will allow GTR to test Artimplant's biodegradable membranes in developing a second generation of Carticel™ for cartilage replacement. The second generation Carticel™ product is based on development of cartilage cell tissue (pre-formed graft) which will make arthroscopic cartilage replacement possible, as opposed to the current standard procedure with open surgery. Tests with Artimplant's material are ongoing and GTR wishes to expand the testing of new membranes.

### ***Mölnlycke Health Care***

A collaboration agreement was signed with Mölnlycke Health Care (MHC) in 1999. In accordance with the agreement, Artimplant has developed a material for a future generation of wound care products. The material is under evaluation while new material variations are being tested. MHC pays Artimplant for the joint research and the revenues amounted to SEK 2.4m during the first half year 2000.

### **Investments and financial position**

During January-June 2000 investments amounted to SEK 16.4m (12.5m), whereof SEK 12.7m (7.9m) were made in immaterial assets. At the end of the reporting period liquid assets amounted to SEK 158.3m (23.4m).

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 purpose is to increase the possibilities to recruit and retain qualified personnel, and increase the motivation and interest for the company's earnings development.

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. The subscription time includes the period October 1, 2003 until March 30, 2004. The premium for the warrants is calculated according to the so called Black & Scholes model and is set, taking share price fluctuations into consideration, at the time of transfer. 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.

All employees and persons tied to the Artimplant Group were offered to participate in the warrant program whereof approximately 75 per cent chose to subscribe. Of persons in management position or with specialist competence, 28 of 30 chose to subscribe. In total 243,100 rights were subscribed.

### **Personnel**

The number of employees at the end of the reporting period amounted to 53 (49), whereof 33 (34) were employed at GMC. The number of consultants tied to the parent company amounted to 11 (10).

### **Other**

Artimplant strives to build a solid patent protection around products that are commercially interesting, which includes everything from material synthesis and production processes to clinical applications. In addition to earlier approved patents, the company received a Swedish patent concerning the construction of ligament implants during the second quarter. Artimplant plans to apply for at least five new patents during 2000.

## Financial statements

The financial statements for January-June 2000 are compared with the corresponding period in 1999.

### INCOME STATEMENT ARTIMPLANT

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	Jan-June 2000	Jan-June 1999	Jan-Dec 1999	Jan-June 2000	Jan-June 1999	Jan-Dec 1999
Net sales	12 352	10 011	20 032	2 385	23	1 613
Cost of goods & services sold	-10 782	-8 305	-16 267	-2 385	-23	-1 613
<b>Gross profit</b>	<b>1 570</b>	<b>1 706</b>	<b>3 765</b>	<b>0</b>	<b>0</b>	<b>0</b>
Research & development expenses	-5 961	-3 392	-9 187	-5 961	-3 392	-9 187
Marketing expenses	-1 756	-	-1 892	-1 756	-	-1 892
Administrative expenses	-3 912	-3 285	-7 338	-2 362	-1 735	-4 239
Share in group results	-	-	-	394	560	1 691
<b>Operating result</b>	<b>-10 059</b>	<b>-4 971</b>	<b>-14 652</b>	<b>-9 685</b>	<b>-4 567</b>	<b>-13 627</b>
Interest income & other financial income	1 521	448	753	1 496	393	640
Interest expenses & other financial expenses	-11	-34	-314	-11	-34	-310
Income from sale of warrants	2 431	-	-	-	-	-
New share issue expenses	-	-	-	-6 797	-	-
<b>Financial items net</b>	<b>3 941</b>	<b>414</b>	<b>439</b>	<b>-5 312</b>	<b>359</b>	<b>330</b>
<b>Result after financial items</b>	<b>-6 118</b>	<b>-4 557</b>	<b>-14 213</b>	<b>-14 997</b>	<b>-4 208</b>	<b>-13 297</b>
Taxes	-681	-	60	-	-	-
<b>Net result for reporting period</b>	<b>-6 799</b>	<b>-4 557</b>	<b>-14 153</b>	<b>-14 997</b>	<b>-4 208</b>	<b>-13 297</b>

### Note: Depreciation included in Income Statement

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	Jan-June 2000	Jan-June 1999	Jan-Dec 1999	Jan-June 2000	Jan-June 1999	Jan-Dec 1999
Capitalized R&D expenses	4 836	2 755	7 600	4 836	2 755	7 600
Patents	358	234	544	358	234	544
Goodwill	350	350	699	-	-	-
Machinery and equipment	1 210	712	1 750	1 025	536	1 391
<b>Total depreciation</b>	<b>6 754</b>	<b>4 051</b>	<b>10 593</b>	<b>6 219</b>	<b>3 525</b>	<b>9 535</b>

## BALANCE SHEET ARTIMPLANT

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	2000-06-30	1999-06-30	1999-12-31	2000-06-30	1999-06-30	1999-12-31
<b>ASSETS</b>						
Capitalized R&D expenses	29 159	17 975	22 287	29 159	17 975	22 287
Patents	1 817	1 254	1 199	1 817	1 254	1 199
Goodwill	12 604	13 303	12 954	-	-	-
Total intangible fixed assets	43 580	32 532	36 440	30 976	19 229	23 486
Machinery and equipment	7 034	3 923	4 556	6 312	3 259	4 023
Construction in progress	-	703	-	-	703	-
Total tangible fixed assets	7 034	4 626	4 556	6 312	3 962	4 023
Shares in subsidiary	-	-	-	17 996	17 996	17 996
Total financial fixed assets	-	-	-	17 996	17 996	17 996
<b>Total fixed assets</b>	<b>50 614</b>	<b>37 158</b>	<b>40 996</b>	<b>55 284</b>	<b>41 187</b>	<b>45 505</b>
Receivables	1 841	1 586	2 408	-	28	988
Receivables group companies	-	-	-	-	2 844	602
Other receivables	1 465	1 113	681	1 405	1 108	679
Prepaid expenses and accrued income	3 713	1 512	2 037	3 578	1 321	1 846
Total short term receivables	7 019	4 211	5 126	4 983	5 301	4 115
Cash and bank	158 316	23 423	39 660	154 452	18 344	37 153
<b>Total current assets</b>	<b>165 335</b>	<b>27 634</b>	<b>44 786</b>	<b>159 435</b>	<b>23 645</b>	<b>41 268</b>
<b>TOTAL ASSETS</b>	<b>215 949</b>	<b>64 792</b>	<b>85 782</b>	<b>214 719</b>	<b>64 832</b>	<b>86 773</b>

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	2000-06-30	1999-06-30	1999-12-31	2000-06-30	1999-06-30	1999-12-31
<b>SHAREHOLDERS' EQUITY &amp; LIABILITIES</b>						
Equity						
Share capital	925	650	763	925	650	763
Paid-in, not registered new issue	-	-	9 936	-	-	9 936
Restricted reserves	215 696	65 065	83 016	222 493	65 065	83 016
Total restricted capital	216 621	65 715	93 715	223 418	65 715	93 715
Non-restricted reserves	-3 064	-2 207	-2 208	-	-	-
Net result for reporting period	-6 799	-4 557	-14 153	-14 997	-4 208	-13 297
Total non-restricted period	-9 863	-6 764	-16 361	-14 997	-4 208	-13 297
<b>Total equity</b>	<b>206 758</b>	<b>58 951</b>	<b>77 354</b>	<b>208 421</b>	<b>61 507</b>	<b>80 418</b>
Deferred tax	179	240	179	-	-	-
Other provisions	200	300	200	-	-	-
<b>Total provisions</b>	<b>379</b>	<b>540</b>	<b>379</b>	<b>-</b>	<b>-</b>	<b>-</b>
Other long term liabilities	200	300	200	200	300	200
<b>Total long term liabilities</b>	<b>200</b>	<b>300</b>	<b>200</b>	<b>200</b>	<b>300</b>	<b>200</b>
Accounts payable	2 932	965	2 640	2 660	640	2 334
Liabilities group companies	-	-	-	307	-	-
Tax liabilities	681	-	2	-	-	-
Other short term liabilities	701	912	894	400	551	544
Accrued expenses and prepaid income	4 298	3 124	4 313	2 731	1 834	3 277
<b>Total short term liabilities</b>	<b>8 612</b>	<b>5 001</b>	<b>7 849</b>	<b>6 098</b>	<b>3 025</b>	<b>6 155</b>
<b>TOTAL SHAREHOLDERS' EQUITY &amp; LIABILITIES</b>	<b>215 949</b>	<b>64 792</b>	<b>85 782</b>	<b>214 719</b>	<b>64 832</b>	<b>86 773</b>

**CASH FLOW ANALYSIS**

	Group	Group	Group	Parent	Parent	Parent
Amounts in thousand SEK	Jan-June 2000	Jan-June 1999	Jan-Dec 1999	Jan-June 2000	Jan-June 1999	Jan-Dec 1999
<b>Current operations</b>						
Result after financial items	-6 118	-4 557	-14 213	-14 997	-4 208	-13 297
Adjustment for items not effecting cash flow	6 754	4 051	10 517	6 219	3 525	9 559
Taxes Paid	-681	-	-1	-	-	-
<b>Cash flow from current operations before changes in working capital</b>	<b>-45</b>	<b>-506</b>	<b>-3 697</b>	<b>-8 778</b>	<b>-683</b>	<b>-3 738</b>
Cash flow from changes in working capital						
Increase(-), decrease(+) in receivables	-1 893	-1 217	-2 132	-868	-1 330	-144
Increase(+), decrease(-) in liabilities	763	219	3 067	-57	-352	2 778
<b>Cash flow from current operations</b>	<b>-1 175</b>	<b>-1 504</b>	<b>-2 762</b>	<b>-9 703</b>	<b>-2 365</b>	<b>-1 104</b>
<b>Investments</b>						
Aquisition of subsidiaries	-	-4 000	-4 000	-	-4 000	-4 000
Aquisition of intangible fixed assets	-12 684	-7 896	-17 308	-12 684	-7 896	-17 308
Aquisition of tangible fixed assets	-3 688	-701	-1 694	-3 314	-631	-1 571
<b>Cash flow from investments</b>	<b>-16 372</b>	<b>-12 597</b>	<b>-23 002</b>	<b>-15 998</b>	<b>-12 527</b>	<b>-22 879</b>
<b>Financing</b>						
New share issue	136 203	-	28 000	143 000	-	28 000
Repayment of loans	-	-	-100	-	-	-100
<b>Cash flow from financing</b>	<b>136 203</b>	<b>0</b>	<b>27 900</b>	<b>143 000</b>	<b>0</b>	<b>27 900</b>
<b>Cash flow for reporting period</b>	<b>118 656</b>	<b>-14 101</b>	<b>2 136</b>	<b>117 299</b>	<b>-14 892</b>	<b>3 917</b>
<b>Liquid funds at beginning of period</b>	<b>39 660</b>	<b>37 524</b>	<b>37 524</b>	<b>37 153</b>	<b>33 236</b>	<b>33 236</b>
<b>Liquid funds at end of period</b>	<b>158 316</b>	<b>23 423</b>	<b>39 660</b>	<b>154 452</b>	<b>18 344</b>	<b>37 153</b>

**KEY RATIOS, GROUP**

	Jan-June 2000	Jan-June 1999	Jan-Dec 1999
Net result per share, SEK	-0,74	-0,70	-1,72
Net result per share fully diluted, SEK	-0,70	-0,55	-
Equity per share, SEK	22,35	9,07	9,38
Equity per share fully diluted, SEK	36,93	10,54	-
Number of shares at end of reporting period	9 250 000	6 500 000	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, %	96	91	90

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

**Other financial information:**

Nine-month report: Nov. 1, 2000

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*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.*

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

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Gothenburg, August 24, 2000  
Artimplant AB (publ)

Anders Cedronius  
Chief Executive Officer

This report has been reviewed by Artimplant's auditors.

Artimplant's annual report, interim reports and press releases are available at [www.Artimplant.se](http://www.Artimplant.se)

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