

# **ARTIMPLANT INTERIM REPORT JANUARY 1 – SEPTEMBER 30, 2006**



- Net revenue of SEK 3.9 million (1.8)\*
- Net profit of SEK -46.5 million (-30.2)
- Net profit of SEK -29.4 (-30.2) if one time write-downs of capitalized R&D costs without cash effect are excluded
- Earnings per share of SEK -0.79 (SEK -0.61)
- Strong sales increase for Artelon<sup>®</sup> CMC Spacer close to 800 (100) units sold to end customers during the third quarter
- Three new Spacer products received CE-mark during the period
- Hans Rosén was appointed CEO
- The strategic direction of the Company is further developed
- Artimplant lowers revenue target of 2006 to "in parity with revenue of last year"

\* Numbers within brackets relate to the corresponding period last year.



#### **Upcoming information events**

Annual accounts 2006......February 20, 2007 Interim report Jan-Mar 2007......May 3, 2007 Interim report Jan-Jun 2007.....August 8, 2007 Interim report Jan-Jun 2007.....November 8, 2007

Financial reports are available at <u>www.artimplant.com</u> simultaneously as distributed to the media. For information regarding business model, technology and products see Artimplant's annual report 2005, which is available at the Company's website.

#### For more information

Hans Rosén, Chief Executive Officer Tel + 46 31 746 56 44, +46 708 583 470 hans.rosen@artimplant.com

Lars-Johan Cederbrant, Chief Financial Officer Tel. +46 31 746 5654, +46 703 016 854 lars-johan.cederbrant@artimplant.com

#### Artimplant

Artimplant is a biomaterials company focused on solutions to problems in orthopedic, odontological and reconstructive surgery. The Company is engaged in the development, production and marketing of degradable implants designed to restore active lifestyles and improve quality of life. The proprietary technology Artelon<sup>®</sup>, a longterm degradable biomaterial, offers new solutions to unmet clinical needs and opens new markets.

Artimplant's business model is that of licensing its products and technology to global partners. The Company currently has six licensing and one distribution agreement with three global partners.

Artimplant is a public company, listed on the Nordic Exchange in the Small Cap segment and in the healthcare sector.

#### Mission

Artimplant's mission is to develop, produce and market implants based on the biomaterial Artelon<sup>®</sup> that meet the needs of patients, physicians and healthcare providers in orthopedics and other therapy areas.

# Vision

Artimplant's vision is to become the partner of choice in biomaterials for hard and soft tissue repair in multiple therapy areas.

Financial result January – September 2006 Net sales increased by 117%, reaching SEK 3.9 million (1.8) and consisted mainly of product sales with associated license revenues (68%) as product smaller development well as a compensation. The sales increase of Artelon® CMC Spacer continues and sales to end customers increased considerably to close to 800 (100) sold units after a successful campaign during the third quarter in the United States. More than 2,000 Artelon<sup>®</sup> CMC Spacers have been sold to end customers since inception. Artimplant did not receive any license revenue from Small Bone Innovations (SBI) during the third quarter. The explanation is that SBI purchased a bigger stock of Artelon<sup>®</sup> CMC Spacers at the end of 2005. Payment including license revenue for 800 units was received and booked in 2005.

Six months after plan, at the end of September, Arthrotek Inc, a Biomet company, released the rotator cuff product on general sales.

The operating loss was SEK 47.7 million (31.0), including depreciation and one time amortization of capitalized product development costs of SEK 20.7 million (4.5). In Q3 the capitalized product development costs of the projects Reinforcement Bands and Artelon<sup>®</sup> Surgical Suture were written off completely. This added a one time amortization of SEK 5.5 million (-), which together with the second quarter's one time amortization of SEK 11.6 million relating to the Artelon<sup>®</sup> Augmentation Device ACL (ACL) amounted SEK 17.1 million. Those one time amortizations have no cash effect. Reinforcement Bands (has also been called Suture Tape) includes product for soft tissue reinforcement and is replaced by Artelon<sup>®</sup> Tissue Reinforcement (sold by Arthrotek as SportMesh<sup>TM</sup>), which is being used to similar indications.

Artelon<sup>®</sup> Surgical Suture requires additional market adaptations regarding dimension and strength to reach market penetration. The



Company does however, at present, prioritize Spacer and Tissue Reinforcement applications.

Net profit amounted to SEK -46.5 million (-30.2) or -29.4 (-30.2) if one time write-offs of the capitalized R&D costs without cash effect are excluded. The result per share amounted to SEK -0.79 (-0.61) or SEK -0.50 (-0.61) if excluding the one time write-offs of the capitalized development costs. The net result was negatively affected by exchange rate differences of SEK 209 thousand.

The overall fixed cost level, excluding one time amortizations and depreciation, increased by SEK 2.8 million during the period compared to 2005. More resources are used on product and process development as well as marketing while less are used within administration compared to last year.

#### Investments and cash position

The investments during the period totaled SEK 1.8 million (2.0), whereas SEK 0.8 million (1.7) was attributable to investments in intangible fixed assets. Artimplant's production capacity is being increased to meet an increased demand of the company's products as of 2007. At the end of the period cash and cash equivalents amounted to SEK 78 million (109).

# Personnel

Hans Rosén was appointed to new CEO on August 29, 2006.

As at September 30, 2006, Artimplant employed 31 people (27), 14 women and 17 men.

# Approvals and product development

During Q3 the Artelon<sup>®</sup> MTP Spacer, Artelon<sup>®</sup> STT Spacer and Artelon<sup>®</sup> CMC Spacer Arthro for minimally invasive surgery received CE-mark. The products will be marketed together with the Artelon<sup>®</sup> CMC Spacer. Test sales were initiated in Europe during Q4.

Artimplant and SBI do, however, await clearance for marketing in the US before full launch. When the products receive clearance for marketing in the US, they have the potential to double the market of Artimplant's spacer products. This gives the spacer concept the potential to become the preferred therapy for treatment of osteoarthritis in small bones and joints. Artelon<sup>®</sup> Scaffold for odontology applications is currently being evaluated and developed in close cooperation with a selection of leading Swedish clinics. Clinical data from a small number of patients regarding soft tissue augmentation in the mouth is currently evaluated.

Product development to further develop Artelon<sup>®</sup> Scaffold for bone augmentation in the upper jaw for so called sinus lift is in progress.

# Increased use of Artelon® products

Both in the US and in Scandinavia surgeons show an increasing interest in treating osteoarthritis in the thumb base joint by using the Artelon<sup>®</sup> CMC Spacer (exclusively licensed to SBI, except in the Nordic countries). The investment in training and meetings with many physicians has started to pay off. At the end of Q3 more than 300 physicians had performed surgery with the Artelon<sup>®</sup> CMC Spacer. The customer base leads the way for an effective launch of Artimplant's new spacer products when they have received clearance for marketing in the US. Artelon<sup>®</sup> CMC Spacer is a first confirmation that Artimplant's degradable implants have a foothold in the market and is an important reference.

Artelon<sup>®</sup> Tissue Reinforcement (sold exclusively by Arthrotek as SportMesh<sup>™</sup> for the rotator cuff application) has so far been used by a number of selected key accounts. Six months after plan, at the end of September, Arthrotek released the rotator cuff product on general sale. Marketing is now underway in Europe and USA. The market potential for the rotator cuff application is according to Artimplant estimates several times bigger when compared with the Artelon<sup>®</sup> CMC Spacer.

Artimplant's products for cosmetic soft tissue applications and bone augmentation have triggered a strong interest from dentists in several European countries. The Company has ongoing discussions with European distributors regarding distribution of Artimplant's dental products with a planned start during the second half of 2007.



# **Refinement of strategy**

After 18 months, the sales of Artelon<sup>®</sup> CMC Spacer have begun to pick up which points towards the first commercial breakthrough of Artelon<sup>®</sup> and the Spacer concept. Artimplant would like to emphasize the importance of this reference for the technology Artelon<sup>®</sup>, medical, regulatory and business wise.

Artimplant's possibility to make money is based on the ability to develop new product applications and build on the market position of the brand Artelon<sup>®</sup> with its unique documented properties.

The license agreements signed so far represent an important base for the operations of the company. In order to enhance the marginal benefit, Artimplant are now developing operations to better meet the medical needs of patients, and licensees requests for clinical documentation, as well as product concepts ready for launch. This gives Artimplant a possibility to increase its profit margin.

Artimplant's prioritized business projects for the upcoming three years are built on the following three product groups:

- **Spacer**: New indications to exploit within orthopedics exist. The brand Artelon<sup>®</sup> is well positioned thanks to the current sales of Spacer products.
- **Tissue Reinforcement**: New indications within Achilles, collapsed arches, and shoulder joints. Artimplant benefits from building the brand Artelon<sup>®</sup> for the rotator cuff application.
- **Scaffold**: Artelon<sup>®</sup> is used for two applications for bone augmentation and soft tissue augmentation within odontology.

There are numerous potential application areas for Artelon<sup>®</sup> with its unique property to help the body to heal. All cannot be exploited by Artimplant. In 2007 Artimplant plans to license Artelon<sup>®</sup> for some single application areas. The Company will in these cases abandon the principle of developing and documenting its products in-house.

# Prospects for the remainder of the year

Artimplant has declared the following operational goals for 2006:

- Increase revenue significantly
- Launch at least three new products
- Sign new development and license or distribution agreements for at least three products
- Increase manufacturing capacity to meet increased demand
- Continue reinforcing and expanding product and process development

The new management adjusts the first bullet to "in parity with revenue of last year". The other goals remain.

# Parent company

The majority of the operations are run through the parent company Artimplant AB. Artimplant USA, Inc. is the only subsidiary and is at present fully funded by the parent. During January – September only the parent had external revenue so the revenue of the parent equals the revenue of the group. Result before balance sheet allocations and tax amounts SEK -45.1 million, whereof SEK -21.7 was for depreciation and one time write offs, including the above mentioned one time write offs of SEK -17.1 million. Investments in the parent do in all material aspects equal the group. As at September 30, 2006 the parent had SEK 77.5 million in cash. In September, 2006 91,750 A-shares were converted to B-shares.

#### Merger and deregistration of subsidiaries

The dormant subsidiary Artimplant Ortopedisk Klinik AB will be absorbed by Artimplant AB. Fusion has been initiated and will probably be finalized before year end. The merger will not materially affect the net loss. The dormant subsidiary KB Artimplant Ortopedisk Klinik has been deregistered.

# Accounting principles

Artimplant applies IFRS. This interim report has been prepared in accordance with IAS 34 and the Swedish Annual Report Act. As of January 2006 Artimplant prepares consolidated financial statements. Artimplant AB (parent) and Artimplant USA, Inc. are consolidated while the



dormant company Artimplant Ortopedisk Klinik AB is accounted for as a shareholding of the parent. The operation in Artimplant USA, Inc. was earlier part of the parent, so the consolidated accounts of 2006 is in all material aspects comparable with 2005.

License income from product sales is, according to the agreements with SBI and Biomet, due four to six weeks after calendar quarter end. Accrued license income for one quarter is, as at January 2006 recognized the following quarter, hence no license income from product sales are recorded in Q1 2006.

Depreciation of capitalized product development costs is, as of January 2006 part of research and development costs, instead of part of cost of goods sold. When Artimplant receives product development contributions from third parties during a development project the research and development costs are not capitalized according to IAS 38.



#### **INCOME STATEMENT**

	Gro	Group		Parent		
Amounts in SEK thousands	jul-sep	jan-sep	jul-sep	jan-sep	jan-dec	
	2006	2006	2005	2005	2005	
Net sales	878	3 891	478	1 797	8 229	
Cost of goods & services sold*	-106	-235	-1 557	-4 961	-6 535	
Gross profit/loss	772	3 656	-1 079	-3 164	1 694	
Research and development costs (1,2)	-11 636	-37 232	-4 973	-14 189	-20 906	
Marketing costs	-3 303	-8 929	-2 773	-7 165	-9 608	
Administrative costs	-2 168	-5 209	-2 360	-6 523	-8 613	
Operating loss	-16 335	-47 714	-11 185	-31 041	-37 433	
Interest income and other financial income	484	1 358	421	840	1 211	
Interest expenses and other financial expenses	-9	-171	-2	-13	-22	
Net financial items	475	1 187	419	827	1 189	
Loss after financial items	-15 860	-46 527	-10 766	-30 214	-36 244	
Taxes	-	-	-	-	-	
Loss for the period	-15 860	-46 527	-10 766	-30 214	-36 244	

\* 2005 includes depreciation of capitalized R&D costs as specified under (1) below

# The income statements include depreciation on tangible and amortization on intangible fixed assets as shown in the following table.

	Group				
Amounts in SEK thousands	jul-sep	jan-sep	jul-sep	jan-sep	jan-dec
	2006	2006	2005	2005	2005
(1) Capitalized R&D cost*	6 056	20 690	1 513	4 539	6 053
(2) Patents	215	567	286	781	790
Machinery and equipment	194	467	329	955	1 447
Total depreciation	6 464	21 724	2 128	6 275	8 290

\* In Q3 2006 a write-down of Capitalized R&D cost of SEK 5,510 thousand was charged against R&D costs



KEY RATIOS	Gro	Group		
	jul-sep	jan-sep	jan-dec	
	2006	2006	2005	
Earnings per share, SEK	-0,27	-0,79	-0,73	
Earnings per share after full dilution SEK	-0,27	-0,79	-0,73	
Equity per share, SEK	1,46	1,46	2,24	
Equity per share after full dilution SEK	1,46	1,46	2,24	
No. of shares at end of period	59 244 790	59 244 790	59 244 790	
Average n. of shares	59 244 790	59 244 790	49 370 659	
No. of shares after full dilution	60 997 792	60 997 792	61 107 012	
Yield on equity, %	neg	neg	neg	
Yield on capital employed, %	neg	neg	neg	
Equity/assets ratio, %	91	91	95	

ALLOCATION OF NET SALES	Group		Parent			
Amounts in SEK thousands	jul-sep	jan-sep	jul-sep	jan-sep	jan-dec	
Source of revenue	2006	2006	2005	2005	2005	
Licensing of product applications	-	446	129	129	1 841	
Product sales	878	2 184	92	829	1 529	
Milestone payments for product development projects	-	1 261	169	839	4 859	
	878	3 891	390	1 797	8 229	
Geographic areas	jul-sep 2006	jan-sep 2006	jul-sep 2005	jan-sep 2005	jan-dec 2005	
Scandinavia	164	559	40	301	350	
USA	714	3 332	350	1 496	7 879	
	878	3 891	390	1 797	8 229	



#### **BALANCE SHEET**

	Group	Parent	
Amounts in SEK thousands	2006-09-30	2005-09-30	2005-12-31
ASSETS			
Capitalized product development	7 568	29 125	27 949
Patents	1 226	1 714	1 264
Total intangible fixed assets	8 794	30 839	29 213
Machinery and equipment	1 856	1 022	1 394
Total tangible fixed assets	1 856	1 022	1 394
Stock and participation in subsidiaries*	1 707	1 807	1 707
Total financial fixed assets	1 707	1 807	1 707
Total fixed assets	12 357	33 667	32 314
Raw materials, semimanufactures and finished goods	992	778	944
Total inventories etc	992	778	944
Accounts receivable	105	297	204
Other receivables	1 656	1 671	1 093
Prepaid expenses and accrued income	2 467	2 011	1 275
Total short-term receivables	4 227	3 979	2 572
Cash and bank accounts	77 670	108 811	104 186
Total current assets	82 889	113 567	107 702
TOTAL ASSETS	95 245	147 234	140 016

	Group	Pare	nt
Amounts in SEK thousands	2006-09-30	2005-09-30	2005-12-31
SHAREHOLDERS' EQUITY & LIABILITIES			
Equity			
Share capital	5 924	5 924	5 924
Premium reserve	126 922	162 618	162 618
Total restricted equity	132 846	168 542	168 542
Retained earnings	362	-	548
Loss for the period	-46 527	-30 214	-36 244
Total retained loss	-46 165	-30 214	-35 696
Total equity	86 681	138 328	132 846
Provisions	343	-	245
Accounts payable	2 053	2 087	919
Liabilities, subsidiaries*	1 822	1 738	1 822
Other current liabilities	591	516	718
Accrued expenses and prepaid income	3 755	4 565	3 466
Total current liabilities	8 221	8 906	6 925
TOTAL SHAREHOLDERS' EQUITY & LIABILITIES	95 245	147 234	140 016

\* Only for dormant companies, not Artimplant USA

# Changes in shareholders' equity during the period

	Group	Parer	it
Amounts in SEK thousands	jan-sep	jan-sep	jan-dec
	2006	2005	2005
Equity at beginning of the period	132 846	83 939	83 939
Share issue	-	84 603	84 603
Benefit employee stock option (IFRS2)	362	-	548
Loss for the period	-46 527	-30 214	-36 244
Equity at end of the period	86 681	138 328	132 846



#### **CASH-FLOW ANALYSIS**

	Group	Paren	t
Amounts in SEK thousands	jan-sep	jan-sep	jan-dec
	2006	2005	2005
Operating activities			
Net loss after financial items	-46 527	-30 214	-36 244
Adjustment for items not effecting cash flow	22 186	6 275	9 715
Cash flow from operating activities			
before changes in working capital	-24 341	-23 939	-26 529
Cash flow from changes in working capital			
Changes in inventories	-49	-486	-652
Changes in receivables	-1 654	-1 480	-73
Changes in liabilities	1 296	841	-1 140
Cash flow from operating activities	-24 749	-25 062	-28 393
Investing activities			
Acquisition of intangible fixed assets	-838	-1 729	-2 161
Acquisition of tangible fixed assets	-929	-277	-1 141
Cash flow from investing activities	-1 767	-2 006	-3 301
Financing activities			
Share issue	-	84 603	84 603
Cash flow from financing activities	0	84 603	84 603
Cash flow for the period	-26 515	57 534	52 909
Liquid funds at beginning of period	104 186	51 277	51 277
Liquid funds at end of period	77 670	108 811	104 186

Gothenburg, November 9, 2006 Artimplant AB (publ) This interim report has not been reviewed by Artimplant's auditors

The Board of Directors



# History

**1997** - The Company acquires a Swedish patent in respect of Artelon<sup>®</sup> hydrolyzable fiber polymers for use in temporary implants. New share issue raises SEK 67.5m less costs and the Company is introduced on the Stockholm Stock Exchange. First cruciate ligament operations on human patients using implants from Artimplant carried out within the framework of a pilot study.

**1998** - The Company acquires Gothenburg Medical Center, a hospital specializing in sports-related injuries.

**1999** - Pilot studies in treatment of damaged thumb ligament and arthritis of the thumb initiated. Artimplant's first multicenter trial in ACL reconstruction begins. The Company begins cooperation with Mölnlycke Health Care AB in the field of wound care.

**2000** - Operations in first multicenter trial in ACL reconstruction concluded. Second multicenter ACL reconstruction trial begins. Directed new share issue, first and foremost in favour of overseas corporate investors, raises SEK 143m less costs. Artimplant's Artelon<sup>®</sup> patent is recognized in the USA and Europe.

**2001** - The Company's quality assurance system is granted certification by Lloyds Register Quality Assurance. Artimplant's first product, the Artelon<sup>®</sup> ACL Augmentation Device, gains CE certification, and can now be marketed in Europe.

**2002** - Strategic review. Products and materials technology are to be commercialized by the granting of licenses to leading partners with global presence and strong brand names. Licensing agreement on wound care signed with Mölnlycke Health Care AB. Tord Lendau takes over as CEO in October. The Company undertakes wide-ranging measures designed to reduce overhead and put in place a more efficient organization matched to its new strategy. Directed new share issue raises SEK 30m less costs.

**2003** - The Company implements its new strategy and reduces its overheads by more than fifty percent. Its focus is now on licensing its technology, product development and creation of a balanced product development portfolio. Artimplant reinforces its biological angle of attack by pre-clinical studies in which a porous matrix is tested as a scaffold for proteins, growth factors and stem cells. The Company signs an agreement with Atlantech for trial sales in the UK of its Artelon<sup>®</sup> ACL Augmentation Device.

Artelon<sup>®</sup> Spacer CMC-I for treating arthritis of the thumb is granted CE certification. Artelon<sup>®</sup> Surgical Suture is cleared by the FDA. New share issues in March and December raise about SEK 62m less costs. Gothenburg Medical Center is divested.

**2004** - Artelon<sup>®</sup> Spacer CMC-I receives approval from the FDA for sale on the US market. Licensing agreements signed with Avanta Orthopaedics (now owned by Small Bone Innovations) for sale of Artelon<sup>®</sup> Spacer CMC-I in the US and rest of the world. Development and licensing agreement signed with Biomet for development of a product for repairing damaged soft tissue. In December the first shipment of Artelon<sup>®</sup> Spacer CMC-I is sent to Avanta in the US. Artelon<sup>®</sup> Surgical Suture approved for sale on the European market. Products previously approved for sale on the European market are approved for additional indications. Trial sales of Artelon® ACL Augmentation Device in the UK is completed. Cooperation between Artimplant and Mölnlycke Health Care on the development and licensing of wound care products using Artelon<sup>®</sup> ends. Directed new share issue raises SEK 14m less costs.

**2005** - Artelon<sup>®</sup> Spacer CMC-I is launched at AAOS. Oversubscribed preferential rights issue raises about SEK 89m before costs for the Company. Focus on new product areas, odontology and craniomaxillofacial surgery, initiated. Two new products in odontology, Artelon<sup>®</sup> Bone Scaffold and Artelon<sup>®</sup> Membrane, approved for sale in Europe. Several sizes of Artelon<sup>®</sup> Surgical Suture approved for sale in the United States and Europe. Four new licensing and development agreements signed with Small Bone Innovations. Distribution agreement for Artelon<sup>®</sup> Surgical Suture in North America signed with Arthrocare. Artelon<sup>®</sup> implant for reinforcing rotator cuffs approved for sale in Europe. Office opened in the United States. Artelon<sup>®</sup> TMC Spacer approved for sale in Australia.