



## ASX/MEDIA RELEASE

### ASDM - POSITIONED FOR GROWTH

**Sydney, 26<sup>th</sup> August 2009** - Leading Sydney medical device design, manufacturing and marketing company, Advanced Surgical Design and Manufacture Limited (ASDM) (ASX: AMT), announced its 2009 Full Year Financial Results.

During the financial year ended 30 June 2009, the company achieved a number of significant milestones including:

- Continued trials of the efficacy of the PAD;
- Lodging a Class IIa registration application for the PAD, with approval recently granted;
- Continued investment in developing new markets with the appointment of a distributor in the United States and supporting UK growth;
- Receiving milestone payments for the successful progress of our “Ultra-Polishing Technology” licensed with a US based global orthopaedic group;
- Maintaining a positive operating cash flow position, notwithstanding continued reinvestment in product development, , and
- Cash balance increase at 30 June 2009 to \$852k from \$451k at 31 December 2008.

Product sales revenue for the year ended 30 June 2009 was \$6.2m, a 9.2% decrease from the 2008 financial year (“FY08”). Core sales was in-line with FY08 with year on year variance predominantly relates to a once-off stocking order for the UK in June 2008.

	<b>Full Year Jun-08</b>	<b>1st Half Dec-08</b>	<b>2nd Half Jun-09</b>	<b>Full Year Jun-09</b>
<b>Revenues</b>				
Sale of goods	6,815	2,689	3,499	6,188
Other revenue	280	135	86	221
Total revenue from ordinary activities	7,094	2,824	3,585	6,409
Other income	-	-	3	3
<b>Expenses</b>				
Cost of sales and purchases of consumables	(2,931)	(1,589)	(1,670)	(3,259)
Corporate and administration expenses	(2,152)	(1,183)	(1,318)	(2,501)
R&D and Quality control expenses	(957)	(649)	(414)	(1,063)
Sales and marketing expenses	(765)	(757)	(369)	(1,126)
Finance costs	(106)	(51)	(49)	(100)
<b>(Loss)/profit before income tax</b>	<b>183</b>	<b>(1,405)</b>	<b>(232)</b>	<b>(1,637)</b>
Income tax benefit/(expense)	(3)	450	163	613
<b>(Loss)/profit for the year</b>	<b>180</b>	<b>(955)</b>	<b>(69)</b>	<b>(1,024)</b>
<b>Cash balance</b>	<b>1,524</b>	<b>451</b>	<b>852</b>	<b>852</b>

Corporate and administration costs have increased in line with expectation as a result of being a publicly listed company. During the year we have continued with our strategy of consolidation of operations and R&D and have constructed a significant platform from which to execute our goals effectively and efficiently.

ASDM growth strategy, to invest earnings into promising areas of biotechnology and investment in new markets, as foreshadowed in our Prospectus of 2007, remains on track. As a result the earnings before interest, tax and depreciation and amortisation (“EBITDA”) was a loss of \$0.7m compared to a profit of \$0.9m in FY08.

Net loss after tax was \$1.0m, compared to a net loss of \$1.1m at December 2008 and a profit of \$0.2m in FY08. This result is after the expensing of all research and development related expenses.

Earnings per share for FY09 was a loss of 2.90 cents per share, a decrease from 0.54 cents for FY08.

## **Orthopaedic Products**

One core sector of our business, orthopaedic implant manufacturing and sales, has a significant time lag between the incurring of sales and marketing expenses and the consequent revenue growth. Our surgeon customers are conservative, and are always cautious in evaluating new products and suppliers. This has resulted in increased sales and marketing costs during the financial year ended 30 June 2009 that are not fully reflected in revenues.

During the financial year we completed 20 instrument sets for use by new surgeons and are now embarking on an additional 30 instrument sets to further strengthen our position and underpin our growth both domestically and internationally. The development of these sets, which positions ASDM for growth in all markets, has resulted in a negative margin impact from non recoverable manufacturing costs, due to manufacturing tooling and methods refinement, and start up efficiency issues being resolved effectively. As a consequence the quality and the design of these instruments are now world class. We expect to see further positive outcomes from this strategy over the next 12 months.

Our marketing initiatives are gaining new surgeon acceptance of our products and we are now seeing growth into markets which we previously had no or limited presence. This includes Victoria, United Kingdom and United States. Pricing across most product lines has remained strong.

## **Peripheral Access Device “PAD”**

During the year we have intentionally increased our R&D spend by 11%, with significant focus being the continued development of the Peripheral Access Device “PAD”. ASDM has exclusive worldwide manufacturing rights for this product and is working extensively with the developer, Dr Rodney Lane, to pursue clinical trials and TGA certification of the device.

As a result of this effort, we gained successful TGA Class IIa approval for this device in early August 2009. The Class IIa approval allows the device to be sold for vascular access purposes in Australia and Europe, with recognition in many other parts of the world as a result.

The PAD under its Class IIa approval provides surgeons with intermittent and repeatable vascular access. This is a major development, providing a new tool for the vascular surgeon and other branches of the medical profession that opens up an entirely new range of therapies requiring this regular access.

For example, chemotherapy treatments can now be delivered to isolated areas of the body day after day. Currently, isolated organ and isolated limb perfusion is restricted to “one off” doses. With the PAD inserted into the patient for up to a month a longer course of chemotherapy can be delivered with likely survival improvements.

It is possible that the “isolated” nature of the chemotherapy regime will allow the use of a broader range of chemotherapy treatments previously precluded due to whole body toxicity effects. Much as arthroscopy opened up the knee joint to new and innovative therapies, the ability to intermittently access the arterial system of patients opens the doors for an array of new intervention methods, not just for cancer.

Our other work with the PAD in developing the Hyperperfusion treatment for limbs threatened with amputation, say from diabetes or smoking, continues apace. We are pursuing the multi-centre multi-surgeon clinical trials that will provide Class III TGA approval.

The market potential for the PAD is very large, both for the Hyperfusion treatment and as a device permitting intermittent and repeated vascular access.

## **Outlook**

We continue to reinvest our available free cash in promising areas of new product and market development. ASDM is well placed to continue developing new and innovative products with the assistance of Australia’s leading surgeons.

During the current year we have continued to follow our strategy and have built a significant platform to enable us to achieve our goals effectively and efficiently. The year ahead brings with it challenges and opportunities that we are now well positioned to capitalise upon.

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## **About ASDM**

ASDM designs and manufactures medical devices. Its principal product is the Active Knee, a prosthetic implant of which more than 5,000 have been implanted. This product is supported by a range of Orthopaedic accessories and surgical tools and other Orthopaedic products.

Since 1994 ASDM has provided a highly effective integrated service to surgeons building on its strengths in design and engineering. Core capabilities that underpin this service are integrated design and engineering, regulatory/compliance competency, manufacturing, distribution and customer service.

The company has built an extensive patent and product development portfolio through collaborative research relationships with universities, companies and surgeon inventors that extends beyond orthopaedics. These collaborations are yielding promising projects in several specialities with strong prospects for commercialisation over the next few years.

For more information, please visit [www.asdm.com.au](http://www.asdm.com.au)

