



## **ADVANCED SURGICAL DESIGN & MANUFACTURE LIMITED**

### **2009 Annual General Meeting**

#### **Chief Executive Officer's Report**

Ladies and Gentlemen: In the two years since the listing of ASDM on the ASX we have grown our business, both geographically and in terms of product development in a significantly challenging economic environment. This past year we maintained a positive operating cash flow and continued with the growth of our market share and developing new products.

In the first part of the past year utilising our accumulated cash reserves we invested heavily on the PAD device and developing our UK operations base. As a result we succeeded in bringing our UK operations fully on line and received Class IIa CE Mark certification for the PAD's use in perfusion settings such as chemotherapy.

In the second half of the year we returned to a positive cash flow overall, which has continued into this financial year. We continued to grow our market share in orthopaedics and invest in the PAD, by using some of the profits generated from our orthopaedic business. Key achievements in this area are the opening up of US sales, growth in the UK and more recently into continental Europe. Facilitating this growth, ASDM has manufactured 25 more of the upgraded instrument sets and stock utilising cash surpluses generated by growing sales. Significantly, ASDM has been granted Class III certification for its Active Knee System, a requirement for European sales and a major achievement.

The PAD project continues to grow and to engage the complex regulatory environment and ethical approval regulations in Australia, the UK and the Continent. As had been announced earlier this year, ASDM received Class IIA CE Mark Certification for the PAD. This was based on the excellent technical file our design team assembled, in addition to the clinical experience with the device to date. Class IIa relates to the use of the device in situations where "hyperperfusion", or high pressure pumping, is not being used. While the PAD was designed for high pressure pumping to save gangrenous legs, its ability to access the arterial system repeatedly opens up a number of new treatment options for other patient groups.

One of the more exciting potential treatments is repeated isolated organ perfusion for chemotherapy. In this application, the PAD is used as a conduit into the arterial system for a number of balloon catheters. These catheters can then be used to isolate the blood supply of an organ, say the liver, and direct chemotherapy drugs to that organ alone, sparing the rest of the body exposure to the toxic chemicals. Uniquely, the PAD allows this treatment to be carried out repeatedly, potentially allowing higher cure rates due to higher concentrations of chemotherapy drug directed at the cancers, quite apart from the improved patient health during the course of chemotherapeutic treatment.

While we now have the regulatory approval for the use of the PAD in this setting, in Australia, Europe and other parts of the world which recognise the CE Mark, this is nevertheless a new style of treatment and clinical trials are being organised to assemble the sort of evidence the medical profession requires to adopt such a new therapy wholesale.

In the meantime, the establishment of a multi-centre clinical trial for the hyperperfusion continues. By attaching a pump to the patient and driving the blood through it at higher than normal pressures and flows, the use of the PAD then becomes a Class III Device use and the regulatory and clinical requirements are much higher. Our design team has done a magnificent job navigating the complex regulatory and ethics committee approval processes and this skill set further adds to ASDM's capabilities in the field of new product development.

ASDM has a long history of bringing surgical innovations to life as commercialised medical devices. As the regulatory environment becomes more stringent ASDM's capabilities have grown to meet this challenge and to continue to deliver significant growth potential into the future. The Management and Staff of ASDM wish to thank the Board for its guidance and support over the past year as well as our shareholders for their trust and support.

Greg Roger  
Chief Executive Officer  
26 November, 2009