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## NEW PRODUCT! MK ELISA



Cellmid has launched its recently validated midkine blood test, the MK ELISA. The test detects midkine at very low and very high blood concentrations making it ideal for a diagnostic test. It is currently being sold to researchers and will be used in Cellmid's in-house cancer diagnostic programs.

## Dear Shareholder,

Our **half yearly report**, released at the same time as this newsletter, has detailed financial information on Cellmid. In summary, it is worthwhile to note that the Company has been well funded and as a result has been able to increase funding for product development. Our cancer diagnostic, antibody and protein therapeutic programs have all made significant progress and reached critical development milestones since 30 June 2010.

In addition to our product development efforts during the period we have raised the global profile of midkine as a significant diagnostic and therapeutic target during the inaugural **midkine conference**. More than 50 participants from 11 countries spent two days discussing the clinical opportunities for this exciting target. Some of the researchers stayed for a Sydney Harbour Cruise following the conference; a photo of the memorably rainy event is on page 4 of this newsletter.

One of our key achievements for the period has been the launching of our proprietary, **fully validated midkine ELISA**, which is expected to be the definitive test for midkine to be used for the early diagnosis, prognosis and treatment monitoring of cancer. Cancer markers have to date not delivered their promise and we feel that midkine may change this. You can read our opinion piece on how we expect midkine to contribute to the early diagnosis and better management of various cancer types.

Establishing Advangen International Pty

Ltd has opened up the opportunity to commercialise our midkine intellectual property in the hair loss (alopecia) treatment field. We have started to build the business by acquiring exclusive Australasian rights to a range of scientifically validated hair loss products (**Advangen hair loss product range**). Product revenues are expected to contribute significantly to the business over time. More on this on page 2.

We are entering a very exciting period of our heart attack (AMI) treatment trials having completed three stages of a six stage preclinical validation program. Final results are expected to become available during calendar 3Q2011. An update on this program is on page 2.

The Company is financially sound with funding in place for the diagnostic and therapeutic product development programs. Key milestones for 2011 include the completion of our AMI trials, GMP manufacturing of midkine, humanisation of our lead antibody, completion of pre-clinical studies for our hair growth product and an ongoing out-licensing program of our cancer diagnostic portfolio.

Yours Sincerely,

Maria Halasz  
CEO and Managing Director

## Therapeutic Programmes

### CAMI103

#### Midkine for the treatment of heart attack (AMI)

The six stage preclinical program to validate midkine for the treatment of AMI has progressed to stage 4, the examination of co-morbidities such as diabetes and hyper-lipidemia. This is an important step as in real life people who suffer a heart attack often have diabetes and high cholesterol. In the past drugs that seemed to work well in animals sometimes failed in the clinic because these factors were not taken into account. Our collaboration partners, Pharmahungary, are experts in co-morbidity studies and we expect robust data as a result of their thorough approach to cardiac drug development. Stage 5 of the program will assess midkine for AMI in large animals, pigs, with similar physiology to humans. Concurrently, GMP quality midkine production will commence in 2Q2011 in preparation for clinical trials.



Professor Peter Ferdinandy  
CEO of Pharmahungary

### CAB101

#### Humanisation program to develop a clinical antibody drug candidate

Cellmid originally had over 100 monoclonal antibody candidates with various binding ability to midkine. These have been assessed for performance and those that had the strongest binding ability to midkine have been further tested in cell migration assays. The final stage of this selection process has now been completed and the lead antibody candidate will be humanised, optimised and de-immunised by Cellmid's collaboration partner. If successful, the program will yield Cellmid's first midkine inhibitor that may enter clinical trials as autoimmune and inflammatory disease treatment.

## Advangen International Pty Ltd

Advangen has a substantial global commercial opportunity as only two products have ever been approved by the FDA for the treatment and prevention of hair loss. An effective, safe and scientifically validated treatment that addresses different types of hair loss is expected to be an attractive alternative to more invasive therapies. Cellmid has established Advangen, its dedicated, wholly owned subsidiary, to exploit this opportunity.

Advangen has filed a patent application for the treatment of alopecia using midkine and developed a strategy for building a successful alopecia business. In the meantime, we have acquired exclusive Australasian distribution rights to a range of scientifically validated hair growth products. It is expected that Advangen may be able to generate substantial revenues more expeditiously with a ready for market product range.

These first products are now available for purchase on the Advangen website ([www.advangen.com.au](http://www.advangen.com.au)), where information on clinical trials and efficacy can also be found. These products work by extending the growth phase of the hair cycle resulting in a thicker, fuller head of hair. A number of marketing initiatives are planned for calendar 2011 to maximise the products' potential while regulatory approval will be sought for extending the therapeutic claims in Australia.





## Cancer markers

### Global challenge - Cellmid's opportunity

Cancer cells often produce substances that are not normally found in the healthy body or they are not normally expressed in high concentrations. These substances are called **cancer biomarkers**. The presence of a cancer biomarker in either blood, body fluid or tissue samples can alert doctors to the presence of cancer in a patient. The first cancer biomarker was described 160 years ago and thousands more have been discovered since then. However, only a handful of these are routinely used to discover, diagnose and manage cancer. Worse still, even fewer of these cancer biomarkers make a significant difference to patient outcomes and survival. The obvious question is why? And why do we believe that midkine (MK), another cancer marker, could change the way clinical utility of cancer markers

#### Most cancer biomarkers fail to make a difference

The great majority of known cancer biomarkers only **appear in later stages** of the disease when the cancer is too advanced for intervention to slow or stop the disease course. Testing patients for these cancer biomarkers has limited clinical utility, since the result of any test does not alter the treatment decisions of the doctor and it does not change the fate of the patient. Many biomarkers are **difficult to sample**, as they often require a biopsy of the cancer tissue. Biopsies are expensive, can be painful, may carry additional health risks and require initial detection of the lesion. In some instances biopsies may interfere with the cancer lesion, potentially accelerating its spread. To be useful, cancer biomarkers need to be detected from readily available patient samples, such as blood or urine. Cancer biomarkers **may become redundant**, as other cancer biomarkers may indicate disease at a similar or better stages. Finally, many cancer biomarkers can be **difficult to measure** using complex and/or expensive methods. This can make widespread testing expensive or unfeasible.

#### Why midkine is different?

MK is not limited by any of the drawbacks described above. In cancer, **MK levels are elevated early**, sometimes even before the patients have any disease symptoms. Furthermore, the MK produced by cancer is **readily detectable** in the blood even if the malignancy is a solid tumor located in an organ. Cellmid's MK ELISA has been specifically validated for measuring serum MK levels. Cellmid's MK test also uses the **most widely accepted assay format** in use today in path labs globally- ELISA (Enzyme-Linked Immuno-Sorbent Assay). This format is robust, proven and highly cost-effective. Finally, **MK adds value** to other cancer biomarkers currently used in diagnosis. When testing for MK together with established markers the rate of cancer detection often increases markedly.

#### MK is the ideal marker for preventative health and screening

In some countries trends towards preventative health are changing the way cancer is managed. In Japan widespread screening for various diseases has resulted in one of the lowest health care costs per capita of any OECD country. In Australia, cancer screening has been limited to specific populations and diseases. Pap smear testing of sexually active women for cervical cancer is one example of this. As we face escalating health care costs the potential savings from screening will inevitably push expansion of such testing. MK appears very early in a large number of cancers, and as such would be ideal for such population screening. Cellmid's ELISA is a well established format to conduct cost-effective, high throughput screening of large number of subjects.

#### MK for treatment management– an opportunity to improve patient care

Cancer therapy and patient survival continue to improve as new treatments emerge. Monitoring treatment efficacy and recurrence of cancer are becoming increasingly important for treatment success. MK is an ideal marker for monitoring treatment efficacy as levels rapidly drop following successful therapy. Levels increase again if and when the disease recurs, making MK an easy to monitor, convenient and cost-effective marker for detecting recurrent cancer. For more information on how midkine could be a useful tool for cancer diagnosis and treatment monitoring please visit our website [www.cellmid.com.au](http://www.cellmid.com.au).





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Cellmid Limited (ASX:CDY) is a biotechnology company listed on the Australian Stock Exchange. The Company is the owner of the most comprehensive intellectual property portfolio around midkine globally. Midkine is a significant novel therapeutic and diagnostic target. It is a native protein expressed during early cancer formation as well as at the onset of a number of inflammatory diseases. Cellmid is committed to the commercialisation of its portfolio of therapeutic, diagnostic and cosmeceutical products.

## Excellence in Midkine Research Conference

Cellmid held the first ever global meeting of key opinion leaders on midkine between 4th and 6<sup>th</sup> November. The conference attracted leading researchers and clinicians from eleven countries representing a number of therapeutic and diagnostic fields. Several collaborations between Cellmid and the researchers have commenced since the conference.



Sydney Harbour Cruise on Saturday, 6th November 2010, following the conference.

**Front row** (from left): Professor Kenji Kadomatsu, Darren Jones, Professor Hiroaki Ooboshi, Mrs Ooboshi, Dr Zhong Jing  
**Middle row**: Koichiro Koike, Dr Fujiko Watt, Mrs Erguven, Associate Professor Mina Erguven, Maria Halasz, Dr Sadatoshi Sakuma, Professor Takashi Muramatsu, Professor Bernard Maillere, Dr Yao Sheng, Professor Dai Licheng, Graeme Kaufman. **Back row**: Professor Peter Hitchcock, Professor Ayhan Bilir, Dr David King, Dr Sarah Svensson, Professor Gonzalo Herradón, Professor Peter Ferdinandy, Dr Kathrin Guenther, Professor Christoph Winkler,

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