

### ASX ANNOUNCEMENT

### CELLMID INVITED TO PRESENT AT BIO CONVENTION

- Cellmid will be presenting at the Breakfast @ BIO event at the invitation of Ausbiotech, Colorado BioScience Association and Independent Investment Research
- The BIO 2015 Convention is the largest annual gathering of biotechnology companies globally with around 15,000 participants

**SYDNEY, 17 June 2015: Cellmid Limited (ASX: CDY)** has been invited to present at the Breakfast @ BIO event jointly held by Ausbiotech, Colorado BioSciences Association, The Society of Physician Entrepreneurs and Independent Investment Research on 17<sup>th</sup> June 2015 at Thomas Jefferson University.

The event is part of BIO 2015, currently underway in Philadelphia, USA, the five day long international gathering of biotechnology and pharmaceutical companies where attendance is expected to reach 15,000.

The BIO 2015 convention hosts thousands of partnering meetings between biotechnology and pharmaceutical companies and Cellmid will be focusing its presentation on its diabetic nephropathy program, which is likely to be developed with a partner in the future.

Presentation slides for the event are attached below.

End Contact: Maria Halasz, CEO T +612 9221 6830 @mariahalasz



### Cellmid Limited (ASX: CDY)

Cellmid is a revenue stage Australian biotechnology company with a strong product pipeline. The Company generates revenue through its consumer health business and is also developing innovative novel therapies and diagnostic tests for a number of cancer inflammatory indications. Cellmid holds the largest and most comprehensive portfolio of intellectual property related to the novel target midkine and midkine antagonists globally. The Company's most advanced development programmes involve using its anti-midkine antibodies in addition to commercialising midkine as a biomarker for the early diagnosis and prognosis of cancer. For further information please see <u>www.cellmid.com.au</u>.

#### Midkine (MK)

Midkine is a growth factor that is highly expressed during embryonic development. Midkine modulates many important biological interactions such as cell growth, cell migration and cellular adherence. These functions are relevant to cancer, inflammation, autoimmunity, ischemia, nerve growth/repair and wound healing. Midkine is barely detectable in healthy adults and only occurs as a consequence of the pathogenesis of a number of different disorders. Midkine expression is often evident very early in disease onset, even before any apparent physical symptoms. Accordingly, midkine is an important early marker for diagnosing cancers and autoimmune diseases. Finally, midkine is only present in a disease context, and targeting midkine is not expected to harm normal healthy tissues.

#### Investment in life sciences companies

There are a number of inherent risks associated with the research, development and commercialisation of pharmaceutical products. Investment in companies specialising in these activities carry specific risks which are different to those associated with trading and manufacturing businesses. As such, these companies should be regarded as highly speculative. Cellmid recommends that investors seek professional advice before making an investment in its shares.

## Cellmid Limited



# Revenue stage biotech with a high value drug pipeline and rapidly growing consumer health business

Presentation to "Breakfast at BIO" 17<sup>th</sup> June 2015

Maria Halasz

CEO & Managing Director

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## Important notice

### **Event disclaimer**

The Breakfast at BIO event in Philadelphia on June 17 (the "Reception") is a gathering for purposes of business networking and is intended for general information only and does not constitute any type of advice, financial, business, legal or otherwise. Independent Investment Research makes no representations or warranties of any kind, express or implied, as to the content expressed in any presentations or information given, or as to the correctness, accuracy, reliability or otherwise of such presentations or information. In no event shall Independent Investment Research or any of its partners, directors, officers, employees, agents or affiliates be liable, directly or indirectly, under any theory of law (securities, contract, tort, negligence or otherwise), to you or anyone else, for any claims, losses or damages, direct, indirect, special, incidental, punitive or consequential, resulting from or occasioned by your attendance at the Reception or use of or reliance on any of the content or materials given or presented at the Reception. None of the presentations, discussions or information disseminated at the Reception should be construed as investment advice, as any recommendation of a transaction or business opportunity, or as an offer to buy or sell any security or other financial instrument. Independent Investment Research is not soliciting any action based upon it.

#### **Summary information**

This presentation contains summary information about Cellmid Limited (Cellmid) and its activities as at June 2015. The information in this presentation is of a general nature and does not purport to be complete or contain all information that a prospective investor should consider when evaluating an investment decision in Cellmid or that would be required in a prospectus or product disclosure statement prepared in accordance with the requirements of the Corporations Act 2001 (Cth) (Corporations Act). This Presentation should be read in conjunction with Cellmid's other periodic news releases or ASX disclosure documents as available from time to time.

### **Forward looking statements**

This Presentation contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks that may cause the actual results, performance or achievements of Cellmid to be materially different from the statements in this presentation. Actual results could differ materially depending on factors such as the availability of resources, regulatory environment, the results of advertising and sales activities and competition.

### Not an offer of securities

This presentation is not a prospectus, product disclosure statement or other offering document under Australian law (and will not be lodged with ASIC) or any other law. This presentation does not constitute an offer, invitation, solicitation or recommendation with respect to the purchase or sale of any CDIs nor does it constitute financial product or investment advice nor take into account your investment objectives, taxation situation, financial situation or needs. An investor must not act on the basis of any matter contained in this presentation but must make its own assessment of Cellmid and conduct its own investigations and analysis. Before making an investment in Cellmid, a prospective investor should consider whether such an investment is appropriate to their particular investment objectives and financial situation and seek appropriate advice, including legal, taxation and financial advice appropriate to their jurisdiction and circumstances.



## Cellmid (CDY:ASX)

- Cellmid is a publically listed biotechnology company
- Cellmid has a promising drug pipeline and is the leader in midkine based targeted therapies for cancer, kidney and cardiovascular conditions
- Cellmid licensed its cancer marker, midkine, to three companies to date, one of which has resulted in the commercial launch of a bladder cancer test in 2013
- Cellmid owns a consumer health business with market leading products in hair loss treatments.

#### **KEY STATISTICS**

•	Share price	2.5 cents
•	Market cap	\$20M
•	Shares on issue	795M
•	Options	290M
•	Cash (31 March 2015)	\$1.7M
•	Capital raising (15 May)	\$1M
•	Тор 20:	35%
•	Average daily volume	1.1M





## Board and management



### Dr David King | Chairman

An experienced independent chairman with expertise in high growth companies, Dr King has a track record in building business ventures and developing them into attractive take-over targets.



### Darren Jones | Head of Product Development

Darren brings more than 14 years of technical product development expertise in all aspects of drug development, intellectual property management and strategic business planning.



### Maria Halasz | CEO and Managing Director

With over 22 years in the life sciences sector Maria started in corporate finance before joining Cellmid seven years ago as CEO. Maria led the acquisition of the company's current portfolio of midkine and FGF5 inhibitor assets.



### Graeme Kaufman | Non-Executive Director

Graeme has over 46 years experience in biotechnology spanning technical, commercial and financial areas. Graeme previously held senior positions at CSL, and became independent director of a number of companies.



**Martin Rogers | Non-Executive Director** A successful start-up investor and company director. Mr Rogers has a depth of experience in incubating companies and publicly listed organisations.



### Emeritus Professor Takashi Muramatsu | Scientific Advisor

Professor Muramatsu is the co-discoverer of midkine and advisor to Cellmid. He has authored more than 200 peer-reviewed publications on midkine during the past 25 years and continues to actively contribute to the field.



### Professor Kenji Kadomatsu | Scientific Advisor

Professor Kadomatsu is the co-discoverer of midkine and advisor to Cellmid. He has authored over 150 peer reviewed publications on the function and properties of midkine and actively contributes to ongoing research in the field.



## Cellmid businesses



Leader in midkine intellectual property with late preclinical therapeutics and on market diagnostics

Broad Australian market launch underway targeting 2,000 pharmacies and \$5M\* in sales in FY2016



## Midkine (MK)

### Midkine (MK; NEGF-2)



Highly basic 13kD (121aa) protein 2 functional domains + flexible hinge

- Midkine: A growth factor prominent in embryogenesis but barely detectable in <u>healthy</u> adults
- In adults, increased midkine expression occurs in the onset of inflammatory diseases and cancer and in preservation/ repair of injured tissue
- In cancer, midkine expression is strongly prognostic of poor patient outcomes
- Important biological activities include
  - Promoting inflammatory cell infiltration
  - Pro-angiogenesis (blood vessel growth)
  - Inhibiting apoptosis (cell death)
  - Facilitating cell migration (metastasis)
  - Promoting cell growth and differentiation

Midkine is an important and novel target to treat cancer, inflammatory kidney disease and ischemic heart conditions



## Strong target validation

#### Discovered in 1988, subject of over 700<sup>\*</sup> publications 55N 0007-1188 (print) 55N 1476-5381 (print) Midkine is one of the most extensively validated disease targets Oncogene 2014: British Journal of Pharmacology publishes midkine special edition Cell Death & British Journal Pharmacology 2012: Springer book dedicated to midkine **Differ**entiation 2010-2014: Three midkine symposia, well attended by global research Heart leaders from 15 countries WILEY THE OURNAL OF IMMUNOLOGY NTERNATIONAL (SN) Official journal of the International Society of Nephrology Mine Ergüven - Takashi Muran Avhan Bilir Editors The FASEB Journal The American Journal of 2012 PATHOLOGY Midkine: From Clinical Embryogenesis blood Cancer Cancer to Pathogenesis Research Research and Therapy THE JOURNAL Springer



### IP position

Cellmid owns the most comprehensive global patent portfolio around midkine (MK), a novel therapeutic and diagnostic target

- Over 80 patents worldwide including:
  - Anti-MK agents (antibodies and siRNAs) to treat cancers, inflammatory diseases and autoimmunity
  - Composition of matter/method of treatment (MK antibodies)
  - MK as a biomarker to detect cancer
  - MK to treat heart and brain ischemia
  - Production of anti-MK mAbs using Mdk-/- mice
  - Production of recombinant MK



## Therapeutic pipeline

Platform	Disease	Program	R&D	Pre-clinical	Phase I	Phase II	Phase III	On market	Anticipated milestone
Anti-midkine Antibodies	Solid tumours	CAB102							Clinical development
	Kidney injury and disease	CAB101							Preclinical Collaboration
Midkine Protein	Cardiac Ischemia	СМК103							IND-enabling studies



## Diabetic nephropathy

- Diabetic nephropathy affects:
  - >40% of type 2 diabetes patients
  - ~40% of end-stage renal disease patients

- Diabetic nephropathy is caused by:
  - Monocyte infiltration into kidneys
  - Abnormal renal blood vessels (endothelial dysfunction)
  - Both are midkine driven mechanism of actions









## MK in diabetic nephropathy

### MK expression high in diabetic nephropathy patient biopsies

- Low levels of constitutive MK expression in healthy adult kidney (by proximal renal tubular epithelium)
- Kidney expression increased during acute kidney injury and chronic kidney disease
- Diabetic nephropathy: high MK expression in glomeruli, tubules and interstitially
- Nodular lesions occur in Mdk+/+ mice only
- Kidney function (uPr, BUN) preserved in Mdk-/-



MK expression in diabetic nephropathy patient biopsy. Arrows show interstitial MK expression. MK expression was high for 8/8 diabetic nephropathy patients (versus low/no MK expression in 19/19 minor glomerular abnormality patients).



**MK is a key molecule in the pathogenesis of diabetic nephropathy.** Nephropathy was induced using Streptozotocin in Mdk<sup>+/+</sup> and Mdk<sup>-/-</sup> mice and glomerular damage was monitored for 6 months. Diabetic nodular lesions developed in Mdk<sup>+/+</sup> mice (A-D) but not in Mdk<sup>-/-</sup> mice (E-H).

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## Adriamycin-induced model of diabetic nephropathy

### Preclinical study: Adriamycin (AN) induced kidney injury in mice

- Aggressive assault to kidney
- Renal damage induced resembles that seen in human diabetic nephropathy
- Cellmid's lead murine anti-MK mAb IP14 (now humanised; HuIP14) assessed



- N = 8 mice per group
  - Group 1: Healthy control
  - Group 2: Adriamycin induced, no treatment control
  - Group 3: Adriamycin induced, murine anti-MK mAb (25mg/kg)



## Adriamycin model results

Anti-MK antibody (IP14) treatment:

- Reduced AN-induced death and morbidity
- Protected glomerulus and tubules from damage
- Prevented renal protein deposition













## Adriamycin model results

Anti-MK antibody (IP14) treatment:

- Maintained renal function
- Curtailed inflammatory cell infiltration
- Reduced fibrosis and associated injury

The effect of IP14 on reducing renal injury is the strongest we have ever seen in the AN model from more than 20 interventions tested, including other monoclonals, small molecules, RNAi, and adoptive transfer experiments using anti-inflammatory macrophages and DCs

**Dr Yiping Wang** The Centre of Transplantation and Renal Research Westmead Millennium Institute The University of Sydney







## Humanised antibody development program

### HuIP14: humanised IP14 anti-MK antibody candidate arising from assessment of >100 anti-MK mAbs

Late pre-clinical development stage

- Research cell bank complete
- Formulation optimised, storage and stability assessed
- Single dose 14 day toxicity and pK in rats and cynomolgus macaques complete:
  - 3 doses (10, 50 and 100mg/kg)
  - No dose limiting toxicities
  - No abnormal clinical pathology
- Healthy human adult tissue cross-reactivity studies underway

### HulP14 is GMP-ready



### MK-ELISA

- Companion biomarker test
  - Patient selection
  - Prognosis
  - Treatment monitoring
  - Disease recurrence
- GMP manufactured and CE marked
- Convenient kit format
- In use by numerous groups globally (USA, UK, Japan, China, Netherlands, Germany, Spain, Australia, Turkey)





## Thank you

## **Cellmid Limited**

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