



Research Note

Cellmid Limited

Revenue stage biotech with strong pipeline



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Name:	Cellmid Limited
Country:	Australia
Price:	AUD 0.031
ISIN Code:	AU000000CDY3
Reuters Code:	CDY.AX
Market Cap (AUD m):	27.7
EV (AUD m):	22.1
Cash & cash eq. (AUD m):	5.6
Shares outstanding (m):	928
Average Daily Volume (m):	4.1
Free float:	100%
52-week Range (AUD):	0.02-0.04

AUD million (ending 30/6)	2014A	2015A	2016E
Total Income	3.549*	2.967	4.500
Net (Loss)/Profit	(1.481)	(3.337)	(1.500)
Net loss per share (cents)	(0.21)	(0.43)	(0.16)
R&D costs	2.100	2.200(E)	3.000
Cash increase/(decrease)	0.764	(0.908)	10.000
Cash and marketable sec.	2.501	5.600	15.600

*) Includes AUD 1.6 million in one-off license revenue. Consumer revenue for FY2014: AUD1.15 million , for FY2015: AUD 1.85 million.



Executive Summary

- Cellmid Limited (ASX:CDY) is an Australian biotechnology company with a revenue generating consumer health division and a strong pipeline around a novel target, midkine (MK), with applications in the treatment of cancer and inflammatory diseases.
- Cellmid has a fast growing consumer health division, which is generating increasing revenues from the Company's proprietary FGF5 inhibitor hair growth products. Via its wholly owned subsidiary, Advangen, the Company develops and sells scientifically validated treatments for various forms of hair loss (alopecia). Its branded product, évolis®, contains natural extracts that inhibit FGF5, a growth factor that regulates hair growth. Recently, a 32 patient clinical study showed strong positive results in both reduction of hair loss and increase in hair growth for the product.
- Cellmid acquired the Advangen business in 2013 and has closed its first full year of operation in 2014 with AUD 1.15 million revenue. In 2015 the Company's revenues increased by 63% to AUD 1.82 million and it is expected to generate close to AUD 4 million during the 2016 financial year from sales in Australia and Japan alone. Cellmid is expected to expand its distribution globally during the coming years, with the key target markets of US, Europe and China.
- In addition to this revenue generating business Cellmid holds the largest and most comprehensive portfolio of intellectual property related to the novel target MK and MK antagonists globally. The Company's most advanced development programs involve using its anti-MK antibodies for the treatment of cancer and inflammatory conditions in addition to commercializing MK as a biomarker for the early diagnosis and prognosis of cancer. Its first in class MK antibody drug, CAB102, was the first ever anti-MK drug subject to formal toxicology tests and showed no dose limiting toxicities in a single



dose study of rats and cynomolgus macaques. Cellmid is currently planning its 'first in men' clinical study for CAB102.

- Recently, the company was successful in raising AUD 4 million with new investors to leverage its sales growth in relation to its FGF5 inhibitor hair growth products. Earlier this year, the company entered into an R&D advance loan agreement to receive AUD 1 million to accelerate its research and development into the CAB102 program. The current cash level should be sufficient to continue the development of its MK programs as well as rolling out the marketing of its évolis® products in Australia.
- Based on NPV based valuation, we believe that Cellmid is clearly undervalued at the current share price of AUD 0.03. Using our valuation model, the Company's current total value is AUD 80 million, or AUD 0.086 per share. This is based on the current value of évolis® and the further roll out of its consumer care business in Australia, Asia and North America. This valuation represents a substantial upside from the current share price.



Company Profile

Cellmid Limited (ASX: CDY) is an Australian biotechnology company with a rapidly growing consumer health division and a strong pipeline in oncology and inflammatory diseases. Its consumer health division leads the market with an FGF5 inhibitor hair growth product range, branded évolis® in Australia. The évolis® products have significant global market potential and the Company has recently raised sufficient capital to be able to make a move to other markets.

The Company's product pipeline, which is around the novel therapeutic target MK, has therapeutic and diagnostic assets. Cellmid holds the largest and most comprehensive portfolio of intellectual property related to MK and MK antagonists globally. In the medium term this portfolio can represent significant upside.



Consumer Health Division: Product leader in hair growth

The importance of the hair growth program comes from the fact that little innovation has been evident in hair growth technologies since the early 1990's, when minoxidil was launched. There is a dearth of clinically validated products in this category, and Cellmid's FGF5 inhibitors are the first topical treatments with hair specific mechanism of action since. Even more significantly, the products address female, as well as male, hair loss. Women suffering from hair loss have had limited options given the side effect profile of minoxidil based products (amongst other things, they are associated with facial hair growth).

The Company's branded products are based on plant extracts that inhibit FGF5, a growth factor that regulates hair growth. FGF5 is well recognized as the ultimate regulator of hair cycle and hair length in humans. Expressed by macrophage-like cells surrounding the hair follicle, it acts by triggering the dermal papilla to transition from growing (anagen) to resting (telogen) phase. Overexpression of FGF5 induces hair follicles to undergo premature entry into catagen (transitional) phase and fall out.

Recent clinical trial yielded strong positive results

In April 2015 Cellmid announced strong positive results in all measured areas of its independently conducted, randomized, blinded and placebo controlled human clinical study of its évolis ONE product. The 32 patient study was conducted with the FGF5 inhibitor formulation évolis® ONE, a fully optimised, GMP manufactured and market ready product. Using Gravimetric Analysis, évolis® ONE showed a statistically significant 80.2% reduction in hair loss over 112 days (16 weeks) with twice daily use. Hair differentiation (or anagen/telogen ratio, a measure of growing versus resting hair follicles) improved with an increase of 44.2% in growing follicles during the same period, as analysed by the Van Scott "hair pluck" method. Hair release and recovery (overall improvement in hair quality and volume) was quantified by PhotoGrammetrix measurements and has shown an improvement by a statistically significant 143.3%. The trial was



conducted by AMA Laboratories in New York, a leading independent CRO specialising in dermatological product testing. The efficacy study followed a 51 subject Repeat Insult Patch Test (RIPT) to assess safety by evaluating skin irritation and sensitisation. The safety study, also conducted by AMA Laboratories, resulted in a “zero adverse event” report.

Three-pillar Australian sales and distribution strategy beginning to show results

Following successful beta testing of its lotions in pharmacies Cellmid launched its full range of products, which includes six SKUs (stock keeping unit) in May 2015. The range includes lotions and shampoos, as well as “Active Packs” for men and women. The Company has also begun to expand its distribution and plans to stock up to 2,000 Australian pharmacies by the end of 2016 as the first pillar of its market strategy. With a dedicated sales team to medical practitioners and pharmacies the Company has been increasing visibility through promotion to health care professionals, which serves as the second pillar. Finally, Cellmid commenced a major advertising campaign on 30 August 2015, which includes television, digital and online influencer programs to consumers as the third pillar of its comprehensive market expansion strategy in Australia.

Replicating the Australian model internationally

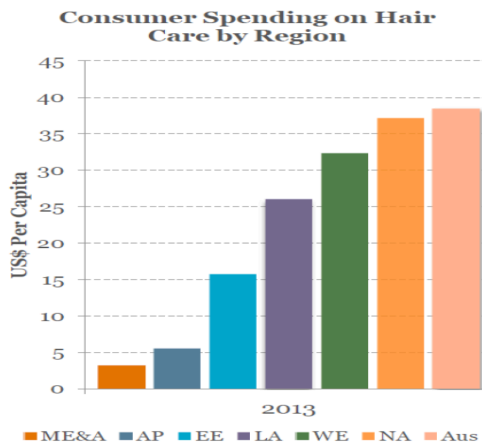
With an Australian retail distribution model based initially on pharmacies the Company is well placed to replicate this strategy in the United States, where the hair care market reached USD 11.6 billion in sales in 2014. Évolis® branded hair growth products are positioned at the premium end of this category and the products are stand-alone as clinically validated cosmetics. In addition to the 20,000+ US pharmacies as potential retailers for its évolis® branded products, Cellmid’s proprietary active ingredients are suitable for out-licensing to other brand owners either as active ingredients or fully formulated products. Further to its active engagement with the US market the Company is currently reviewing the European market to assess the feasibility of replicating its Australian pharmacy distribution model there.



Since the acquisition by Cellmid in 2013 Advangen Japan has built a strong multichannel distribution business, and commenced sales in other parts of Asia. Recently, Cellmid has signed a private label supply agreement with a leading hair care brand in Taiwan, Maywufa, and have early discussions with potential partners in Thailand, South Korea, China, Hong Kong and Indonesia.

In Japan the company uses the duty free shopping channel, which is an interesting opportunity particularly for the tourist market from other Asian countries where Japanese products represent a premium quality. With the number of tourists increasing closer to the Tokyo Olympics in 2020, Cellmid has plans to capitalize on this channel in the medium to long term. In Japan, the most significant contributor to the recent increase in sales has been QVC, the largest television shopping channel operator locally.

With a market leading product range, innovative positioning and solid distribution and marketing plan Cellmid is well placed to experience significant sales growth in its consumer health division.





MK – a promising new target for cancer and inflammation

Cellmid is leader in MK intellectual property with a patent portfolio that currently includes 82 patents in 21 patent families, covering the use of MK and anti-MK agents for therapeutic purposes in a number of diseases, as well as the use of MK as a diagnostic marker in cancer and other disorders. The IP position together with a library of more than 120 anti-MK antibodies makes the company the clear leader in MK antagonists globally and a potentially attractive partner for a large pharma or biotech company.

Recently, the company signed a collaboration agreement with well-known Complutense University in Madrid. Together with key opinion leader in chemotherapy resistant in glioblastoma, Professor Guillermo Velasco, Cellmid will initiate a brain cancer study using its anti-MK antibodies to assess the efficacy of CAB102 in a number of animal studies. CAB102, Cellmid's lead drug candidate, has been the subject of Cellmid's recent single dose toxicity study in rats and cynomolgus monkeys, where even in high doses of 100mg/kg showed no adverse effects. Prior to commencing clinical studies Cellmid will have to complete GMP manufacture of CAB102 and multi-dose toxicity studies in the same two species.

MK: Innovative therapeutic and diagnostic target in cancer

MK is a multifunctional growth factor that is highly expressed during embryonic development. It is barely detectable in healthy adults but it is highly expressed in cancer, inflammation and auto immune diseases. MK is a growth factor with several important biological functions. It contributes to cell growth and differentiation, enhances the survival and migration of target cells. MK expression peaks around mid-gestation, and plays an important role in neurogenesis. However, MK is downregulated by the time of birth and MK expression in adult tissue is generally weak or undetectable.



In adults MK can only be detected as part of pathogenesis of certain conditions, such as cancer, inflammatory or autoimmune diseases. MK expression is upregulated following injury and it contributes to tissue repair and fibrosis by the recruitment of neutrophils and macrophages to the site of injury. MK has been implicated in the etiology of various conditions, including cancer, acute and chronic renal diseases, restenosis, rheumatoid arthritis, adhesion after surgery and multiple sclerosis. MK is expressed in most solid tumors and is associated with malignancy and poor prognosis. Thus, MK inhibitors may be considered a viable therapeutic option to for the treatment of cancer.

Increased serum MK concentrations have been reported in patients with various tumors. Cellmid owns patents for the use of MK in the early diagnosis, prognosis or disease management of any cancer. This forms the basis for Cellmid's diagnostic licensing strategy, which resulted in three licenses to date.

Diagnosis at an early stage remains a key issue for modern oncology, and is crucial for successful cancer therapy. Development of sensitive, specific, and noninvasive tumor markers, especially in serum, is urgently needed. MK, a secreted protein, was initially identified in embryonal carcinoma cells at early stages of retinoic acid-induced differentiation. Multiple studies have reported that MK plays important roles in tumor progression, and is highly expressed in blood and urine in various malignant tumors. Cellmid signed three diagnostic licenses to date, of which one has resulted in a bladder cancer diagnostic test being launched in in 2013. Cellmid licensee, Pacific Edge Biotechnology, has developed and successfully launched CxBladder® in the US, their high performing test for the early diagnosis of reoccurring bladder cancer.

Cellmid received approximately AUD 1.0 million in licensing revenue from this transaction to date, and a royalty of AUD 68K for the first part year of sales. Pacific Edge is targeting sales of AUD 100 million in year 5, and with a 4% royalty this would represent annual revenue approaching AUD 4 million for Cellmid.



Pipeline and Product Portfolio

Cellmid’s patent portfolio lends itself for the development of at least three main therapeutic programs for the treatment of cancer, inflammation and heart failure. Cellmid is currently focused, with its first-in-class anti-MK antibody CAB102, on oncology.

Therapeutic

Platform	Disease/Target	Program	R&D	Pre-clinical	Phase I	Phase II	Phase III	Market
Anti-Midkine Antibodies	Solid tumours	CAB102	→					
	Kidney injury, Inflammatory diseases	CAB101	→					
Midkine Protein	Cardiac Ischemia	CMK103	→					

Diagnostic (Licenses)

Licensee	Platform	Disease/Target	Program	Utility	POC	Clin validation	Reg approval	Market
Pacific Edge Biotechnology	MK mRNA Multiplex (Urine)	Bladder Cancer	Cxbladder	Detection, monitoring recurrence	→			
Quest Diagnostics	MK Protein Multiplex (Blood)	Lung Cancer	LungDx	Early detection	→			
Fujikura Kasei	MK Protein (Blood)	Multiple Cancers	Cancer Screen	Pan-cancer screening	→			

With a large intellectual property portfolio Cellmid’s focus is the development of its oncology asset in-house, with out-licensing the remaining therapeutic and diagnostic assets. This strategy has resulted in a large number of licenses and collaborations to date, including the therapeutic partnership signed with Zoetis, the largest animal health company in the world. Zoetis will use the Company’s antibodies to develop drugs for major diseases of companion animals.



Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoek Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.

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