

11 March 2013

**ASX CODE: CDY**
**Speculative Buy**
**Capital Structure**

Sector	Healthcare
Share Price (A\$)	0.05
Target Price	0.072
Fully Paid Ordinary Shares (m)	545.1
Options (ex 3-10c, 4/13-8/17 (m))	38.3
Options (ex 3.4c, 24/10/16 (m))	297.5
Market Capitalisation (undil) (A\$m)	27.3
Share Price Year H-L (A\$)	0.01-0.05
Approx Cash (A\$m)	1.7

**Directors**

David King	Non-Exec Chairman
Maria Halasz	Managing Director
Graeme Kaufman	Non-Exec Director
Martin Rogers	Non-Exec Director

**Major Shareholders**

Cell Signals Inc	5.3%
Seistend Pty Ltd	4.1%
Hera Investments	3.9%
Worth S/F A/C	3.5%
Tuite Super 1 A/C	3.4%

**Analyst**

Anton Uvarov, PhD +61 8 9488 0800

**Share Price Performance**


# Cellmid Limited

**Increasing Price Target To A\$0.072 As Royalty Revenues Are Knocking On The Door And Hair Loss Business Is Stronger Than Expected**

**Summary** - Cellmid started year 2013 on a positive note with major updates on their hair loss and therapeutic programs. We are not surprised to see strong share price action as company performed extremely well: a) posting first sales for the hair loss product that exceeded our expectations, b) providing major update on the first therapeutic indication showing strong preclinical data, c) obtaining a new option to license agreement for its proprietary anti-midkine diagnostic antibodies for validation on Fujikura's latex platform, providing a strong validation of midkine's future potential in the diagnostic space.

We update our Price Target to A\$0.072 primarily based on the fact that the company is now only a few months away from receiving a milestone payment and initial royalty revenues from the commercial launch of Lung Dx (by Quest Diagnostics) and Cxbladder (by Pacific Edge Biodiagnostics). We also update our view on commercial opportunity of evolix® hair loss product as first sales numbers exceeded our original estimates.

**Update on Lung Dx (partnership with Quest Diagnostics)** - We value Lung Dx at A\$0.03 (+ A\$0.009 from previous valuation) as test moves closer to commercialization. While we are still awaiting the annual update from Quest on the readiness of the Lung DX test to hit the market (update should be available by the end of March), we remain confident and expecting the launch at the end of FY2013. Quest recently announced the sale of its HemoCue and OralDNA businesses (both Point-of-Care tests) and realigned their business strategy focusing on esoteric growth (refers to tests performed at reference laboratories that use rigorous testing and that exceed what most hospitals and basic labs can do, i.e. Lung DX) through disease focus and laboratory information services. We view Lung DX as a perfect fit with their new strategy and expect Quest to launch the test in few months.

**Update on Cxbladder (partnership with Pacific Edge Biodiagnostics, PEB)** - We value Cxbladder at A\$0.015 (+ A\$0.009 from previous valuation) as test moves closer to commercialization and we increase our estimate of the royalty rates from 1.5% to 2%. According to most recent update from PEB's management the company is on track to get CLIA certification by the end of March with commercial launch to follow shortly after.

**Hair Loss Business Surprises on the Upside** - We are increasing sales estimates for evolix® on the back of a strong launch and currently value Advangen business at A\$0.027 (+ A\$0.015). Company recently announced that since the commencement of cash receipts of its evolix® hair growth products in September 2012 the Company has receipts of \$286K (with \$187K in the last quarter). This relates to orders for approximately 400 stores, and implies a rate of 12 bottles per store per quarter which is well above our previous estimate of 6 bottles per store per year (note that we estimated 1100 stores in FY2013). Our new estimate assumes 24 bottles per store per year and 700 stores. We estimate A\$672K in receipts in FY2013.

**Strong Investment Thesis Going Forward: Multiple Catalysts and Upside Opportunities**

**- A Rare Find** - The stock will remain on the radar of many investors due to strong newsflow. These could include commercial launch of Lung Dx and Cxbladder, sales numbers from hair loss business, potential update on the therapeutic programs, and any additional commercial and licensing deals. In addition, we view diabetic nephropathy program and future partnerships in molecular diagnostics as an upside to our current target price, with strong IP around midkine at the core of the business. Preclinical data collected to date identify MK as a key molecule in diabetic nephropathy and suggest that MK accelerates the intracellular signaling network evoked by hyperglycemia in diabetic nephropathy. We believe anti-midkine antibodies could offer superior clinical profile over the key current therapies that we evaluated (see inside note for our detailed analysis on that opportunity).

- The diabetic nephropathy program could move into clinical stage in FY2014 potentially adding A\$0.056/share
- Future molecular diagnostic partnership could add A\$0.02 per share per test.

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## First Midkine Clinical Program Will Put Company on a New Level – Significant Upside from Diabetic Nephropathy

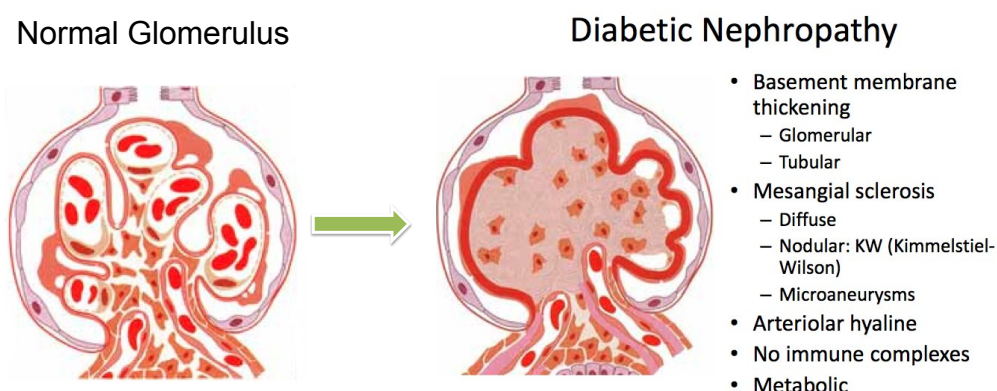
### High Unmet Need for Agents That Can Slow Progression to End-Stage Renal Disease – What is The Market Opportunity for Midkine?

The prevalence of diabetes mellitus worldwide is projected to reach an estimated 366 million by 2030. Current reports estimate the number of adults in the U.S. with diagnosed diabetes is 25 million or 8.3% (Source: American diabetic association, 2012). In Europe the estimated prevalence of diabetes is 6% - 7%. Data from the AusDiab study suggest that 7.2% of adult Australians (more than 900,000 people) have type 2 diabetes. Approximately one third of adults with diabetes will develop nephropathy over 20 years. Our medical literature review showed that 10 years after a diagnosis of diabetes, the prevalence of micro- and macro-albuminuria could vary 24.9% - 31% and 5.3% - 12%, respectively.

The development of diabetic nephropathy is characterized by glomerular hyperfiltration, hypertrophy of glomerular and tubuloe epithelial components, and thickening of glomerular basement membranes, followed by an expansion of extracellular matrix (ECM) in mesangial areas and an increased albumin excretion rate. These structural changes are illustrated in Figure 1.

These changes are only one aspect of a complex series of metabolic and biochemical alterations caused by disturbed glucose homeostasis. Hyperglycemia is a necessary prerequisite but genetic susceptibility is also crucial for the development of diabetic nephropathy.

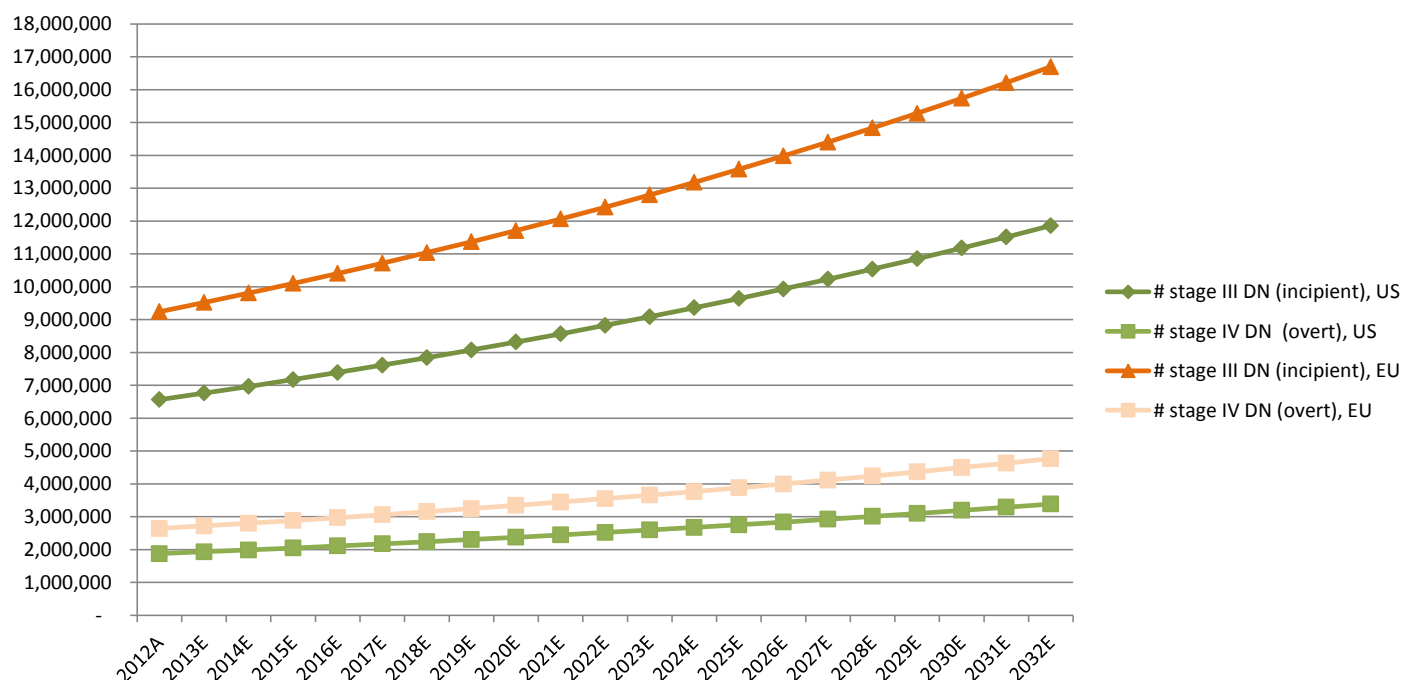
**Figure 1.** Diabetic Nephropathy Pathology.  
Source: American Diabetes Association, 2012



Five clinical stages characterize the progression of diabetic nephropathy. These stages are classified on the basis of the values of the glomerular filtration rate (GFR), urinary albumin excretion (UAE or protein content in the urea), and systemic blood pressure. The discrete structural lesions in the renal parenchyma and vasculature generally become more severe with advancing clinical stages, but the diagnosis of diabetic nephropathy is often made on clinical grounds without the need for renal biopsy except in atypical presentations. We estimate that midkine will primarily be used in stages 3 (incipient) and 4 (overt) (Figure 2).

**Figure 2.** Clinical Classification of Diabetic Nephropathy.  
Source: Chen et.al., 2013

	Designation	Characteristics	GFR (minimum)	Albumin Excretion	Blood Pressure	Chronology
Stage 1	Hyperfunction and hypertrophy	Glomerular hyperfiltration	Increased in type 1 and type 2	May Be Increased	Type 1 normal Type 2 normal hypertension	Present at time of diagnosis
Stage 2	Silent stage	Thickened BM Expanded mesangium	Normal	Type 1 normal Type 2 may be <30-300 mg/d	Type 1 normal Type 2 normal hypertension	First 5 years
Stage 3	Incipient stage	Microalbuminuria	GFR begins to fall	30-300 mg/d	Type 1 increased Type 2 normal hypertension	6-15 years
Stage 4	Overt diabetic nephropathy	Macroalbuminuria	GFR below N	>380 mg/d	Hypertension	15-25 years
Stage 5	Uremic	ESRD	0-10	Decreasing	Hypertension	25-30 years



**Figure 3.** Diabetic Nephropathy  
MK-Ab Target Population Estimate.  
Source: RM Research

We model 6.5M people with stage 3 and 1.9M people with stage 4 diabetic nephropathy in US in 2012. We model 9.2M people with stage 3 and 2.6M people with stage 4 diabetic nephropathy in EU in 2012. These estimates include both diagnosed and undiagnosed patients. Our forecast of the prevalence of these conditions for Y2012—Y2032 is shown in Figure 3.

There is high unmet need for therapies that directly target the underlying etiology and pathophysiology responsible for the progression of diabetic nephropathy and to prevent progression to end-stage renal disease (ESRD). Once a patient reaches ESRD, their only treatment options are dialysis and kidney transplant; both of which are associated with high costs and mortality rates. ESRD is estimated to account for more than 6% (\$23 billion) of total annual Medicare spending in US.

According to US Renal Data System the healthcare costs associated with the consequences of diabetic neuropathy are:

- Annual costs of dialysis (\$68,586);
- Renal transplantation (\$102,638 and \$17,400 during first and subsequent years, respectively);
- Graft failure (\$79,900).

In addition, the diabetic patient with proteinuria has a two- to four fold increased risk of morbidity and mortality from cardio-vascular diseases. Even with chronic dialysis, the cardiac death rate of diabetic patients is ~50% higher than non-diabetic patients.

#### Current Therapies in Use

The onset of microalbuminuria (stage 3) and progression from microalbuminuria to macroalbuminuria (stage 4) can be attenuated with intensive diabetes and hypertension management to control blood glucose and blood pressure levels. Specifically, renin-angiotensin system blockade in adults with diabetes is associated with decreased cardiovascular and end-stage renal disease (ESRD) morbidity. Angiotensin converting enzymes inhibitors (ACEi) and angiotensin receptor blockers (ARBs) are the recommended first line of therapy for patients with proteinuria because they have been shown to be effective in preventing the progression of diabetic nephropathy independent of their effect on blood pressure. In addition, intensive treatment of hyperglycaemia also reduces risk of microvascular complications, including renal disease. The list of drugs that are currently being used for the management of diabetic nephropathy is provided in figure 4.

Drug	Supplier	Class of Drug	Annual Cost
Valsartan	Novartis's Diovan	angiotensin II receptor antagonist	\$800 - \$1000 / year
Irbesartan	Sanofi-Aventis/Bristol-Myers Squibb's Avapro	angiotensin II receptor antagonist	\$550 - \$600 / year
Telmisartan	Boehringer Ingelheim's Micardis	angiotensin II receptor antagonist	\$550 - \$650 / year
Ramipril	King Pharmaceuticals' Altace	angiotensin-converting enzyme (ACE) inhibitor	\$350 - \$400 / year
Aliskiren	Novartis's Tekturna/Rasilez	Direct renin inhibitor	\$900 - \$1000 / year

**Figure 4.** Currently Used Therapies For Diabetic Nephropathy and Relative Therapy Pricing.  
Source: RM Research

Nevertheless, many patients continue to demonstrate progressive kidney damage despite these therapies. We believe there is high unmet need for therapies that directly target the underlying etiology and pathophysiology responsible for the progression of diabetic nephropathy and to prevent progression to end-stage renal disease (ESRD). Once a patient reaches ESRD, their only treatment options are dialysis and kidney transplant; both of which are associated with high costs and mortality rates. In US, ESRD is estimated to account for more than 6% (\$23 billion) of total annual Medicare spending.

To date there was limited success with the new targeted therapies in development. Until recently, Bardoxolone (an inducer of Nrf2 pathway, Abbot) was the most prominent agent in development for diabetic nephropathy with a blockbuster potential. However the Phase III trial of Bardoxolone (BEACON trial) was terminated due to an excessive number of serious adverse effects, including death, among those taking bardoxolone in the study. The result was very surprising, as the drug showed promise earlier in Phase II (BEAM) easing the symptoms of kidney disease and been able to reverse it through anti-inflammatory mechanisms. Termination of the Phase III Bardoxolone study removed \$9B US in market value from Abbot upon the announcement.

There are few other targeted therapies that are currently being studied (Figure 5). We view chemokine receptor antagonists as the most promising candidates in development.

Drug	Class of Drug	Sponsor	DN Indication / Stage	N patients
MT-3995	Aldosterone receptor blocker	Mitsubishi Tanabe Pharma	DN with Albuminuria	90
CCX140	Oral antagonist of chemokine receptor known, CCR2	ChemoCentryx	DN	270
Acthar	Adrenocorticotrophic hormone	Questcor Pharmaceuticals	Proteinuria in DN	40
Probucol	anti-hyperlipidemic drug	Korea Otsuka Pharmaceutical	DN	120
Baricitinib	an oral JAK1 and JAK2 inhibitor	Eli Lilly	Diabetic Kidney Disease	250
PF-00489791	Phosphodiesterase inhibitor	Pfizer	Overt Nephropathy	176
PF-04634817	Antagonist of CCR2/5	Pfizer	Overt Nephropathy	230

**Figure 5.** New Drugs in Development For Diabetic Nephropathy.  
Source: RM Research

*In summary, we view diabetic nephropathy as a blockbuster indication with limited competition. Preclinical data for midkine as a treatment of diabetic nephropathy (see details below) looks very promising and we put a high probability on midkine entering a clinical stage development as early as FY2014 providing significant upside to the current share price levels.*



### Role of Midkine in Diabetic Nephropathy - Where Midkine Fits?

Based on the most recent literature and currently ongoing early stage clinical trials in diabetic nephropathy, we believe the new paradigm in treatment strategy is imminent and midkine fits perfectly with this new wisdom.

Until recently, to identify targets for therapeutic intervention in diabetic nephropathy, most studies have been focused on biochemical understanding how abnormal levels of glucose metabolites cause diabetic nephropathy. However, less focus was on the systemic toxic mechanisms that hyperglycemia and dyslipidemia might have through inhibition of the endogenous vascular protective factors such as insulin, vascular endothelial growth factor, and platelet-derived growth factor as well as growth factors such as midkine. We believe this is about to change in the coming years with midkine fitting well with the new paradigm.

To date, pathophysiological roles of midkine have been described in acute kidney injury as well as the progression of chronic kidney diseases that are accompanied by hypertension, renal ischemia and diabetic nephropathy. Strong underlying scientific evidence include:

- MK knockout (Mdk -/-) mice less susceptible to kidney disease;
- Renal damage difficult to induce in Mdk -/- mice;
- Therapeutic intervention in animal model;
- MK antisense reduced kidney damage in I/R renal injury;
- MK expressed in biopsy with diabetic nephropathy patients (but not in controls);
- In the streptozotocin (STZ)-induced diabetic animal model, midkine induces glomerular sclerosis accompanied by infiltrated macrophages (major sign of inflammation);
- Hyperglycemia enhances MK expression in mesangial cells (cells around blood vessels in the kidneys that regulate blood flow), which promotes the accumulation of extracellular matrix (i.e. changes in glomerulus morphology).

This pre-clinical evidence suggests that midkine plays a harmful role in diabetic nephropathy.

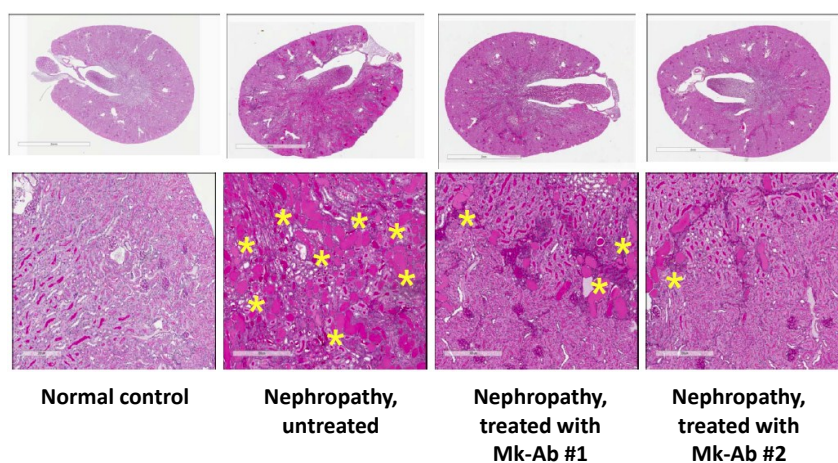
### New Pre-clinical Proof-of-Concept Study Provides Strong Data and Suggests that Anti-midkine Antibody Could Enter Clinical Program as Early as FY2014.

The study was conducted by scientists at the Centre for Transplantation and Renal Research (CTRR), based at the Westmead Millennium Institute and University of Sydney, Westmead Hospital. Two anti-midkine antibodies (MK-Ab) were tested in Adriamycin (AN)- induced mouse model of nephropathy. In this model, a single AN injection leads to kidney damage that is similar to one observed in human diabetic nephropathy.

#### Study Results:

**Figure6.** Anti-MK antibodies reduce protein cast deposits in the kidneys of mice with AN-induced nephropathy.

Source: Company Presentation, 2013



Kidney function was preserved in animals treated with Mk-Ab, showing reduced protein leakage into the urine compared to untreated controls. Protein casts in the kidney, indicating damage, were also significantly reduced in antibody treated animals (yellow stars, Figure 6).

Importantly, the MK-Ab treated animals showed healthy weight gain and reduced mortality compared to untreated controls; only 6.3% of treated animals died before the end of the study, compared to 25% of the untreated animals.

On a microscopic level, histological assessment of animal's kidneys showed that:

- Glomerular sclerosis (i.e. hardening of kidney tissue) was reduced from 48% in untreated animals to below 20% in both MK-Ab treated groups ( $p < 0.01$ );
- Interstitial volume (functional measure) was also significantly reduced, from 35% in untreated animals to 12% in both antibody groups ( $p < 0.01$ );
- MK-Ab treatment also maintained tubular cell height (resorptive function) - untreated animals had mean cell heights below  $2\mu\text{m}$ , compared to  $4\mu\text{m}$  for treated animals ( $p < 0.05$ ).

In summary, preclinical data collected to date identify MK as a key molecule in diabetic nephropathy and suggest that MK accelerates the intracellular signaling network evoked by hyperglycemia in diabetic nephropathy. We believe anti-midkine antibodies could offer superior clinical profile over the key current therapies that we evaluated.

We see tolerability and toxicity as key risks to the clinical program in diabetic nephropathy. Midkine have previously been shown to have a protective role against cardiac ischemia/reperfusion and thus application of anti-midkine antibodies could be associated with certain cardiovascular risks. However, we believe that correct and carefully developed dosing schedule as well as properly defined patient population could mitigate these risks down the road.

#### **Significant Upside from MK-Ab; The Program Could Add A\$0.056/share**

##### **Anti-Midkine Antibody Potential Sales Modeling Assumptions (*Not Included in the Current Price Target*)**

We use the following assumptions to model the market size and future revenues for anti-Midkine Antibody (MK-Ab) in diabetic nephropathy (US and EU27).

- We assume that MK-Ab will be approved for patients with Stage 3 (incipient) and Stage 4 (overt) diabetic nephropathy in patients that were previously diagnosed with type II diabetes;
- We model diabetic prevalence at 8.3% and 7.3% in US and EU respectively;
- We model that of all diabetic patients 28% will develop microalbuminuria (incipient stage DN) and 8% will develop macroalbuminuria (overt stage DN).
- We assume that MK-Ab will be predominantly used in sick stage 4 diabetic nephropathy patients that are close to progressing towards End Stage Renal Disease (ESRD) - up to 95% of stage 4 patients in US and up to 80% of stage 4 patients in EU (*see our model for our estimates of eligible patient population*);
- We use moderate estimates to assume eligibility among stage 3 patients with diabetic nephropathy, modelling 28% eligibility in this group.
- We use conservative market penetration rates despite high medical need in this medical indication. For US we estimate 0.1% - 5% for Y2023-Y2032 respectively. For EU we estimate 0.1% - 3% for Y2023-Y2032 respectively (Figure 7).
- We price Mk-Ab above currently available ACE inhibitors and angiotensin receptor antagonists as MK-Ab represents a different drug class and we expect better efficacy profile of the drug. We estimate US price at \$4.5K and EU price at €3.2K in Y2023 which is more in line with Amylin's (now part of Bristol-Myers Squibb) Bydureon that was approved by FDA for type II diabetes in January 2012 (wholesale price about \$4.2K a year).
- We believe that MK-Ab could get FDA and EMA approval by the YE2023 and will be commercially available mid 2023.

Using above mentioned assumptions we estimate that MK-Ab sales could reach \$24.4M US in Y2023 (not a full year) growing to \$1.7B US in Y2032 in the United States. In Europe we model sales of €9.8M in Y2023 (not a full year) growing to €842M in Y2032.

While we expect the program to be partnered prior to commencement of Phase III, we do not account for it in our model and valuation analysis as we are not in a position to predict the future economics of the potential transaction. Instead, we provide a stage-by-stage NPV analysis of MK-Ab program outlining the value of the program as it moves from one phase of clinical development to another (Figure 8).

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#### anti-Midkine-DN Revenue Model

		2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
<b>Diabetic Nephropathy - United States</b>													
<b>Patient breakdown</b>		2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Total # of pts with diabetes	3.0%	33,995,685	35,015,556	36,066,022	37,148,003	38,262,443	39,410,317	40,592,626	41,810,405	43,064,717	44,356,658	45,687,358	47,057,979
Diabetes Mellitus type II	90.0%	30,596,117	31,514,000	32,459,420	33,433,203	34,436,199	35,469,285	36,533,363	37,629,364	38,758,245	39,920,993	41,118,622	42,352,181
# stage III DN (incipient), US	28%	8,566,913	8,823,920	9,088,638	9,361,297	9,642,136	9,931,400	10,229,342	10,536,222	10,852,309	11,177,878	11,513,214	11,858,611
# of patients eligible	33%	2,827,081	2,911,894	2,999,250	3,089,228	3,181,905	3,277,362	3,375,683	3,476,953	3,581,262	3,688,700	3,799,361	3,913,342
# stage IV DN (overt), US	8%	2,447,689	2,521,120	2,596,754	2,674,656	2,754,896	2,837,543	2,922,669	3,010,349	3,100,660	3,193,679	3,289,490	3,388,174
# of patients eligible	95%	2,325,305	2,395,064	2,466,916	2,540,923	2,617,151	2,695,666	2,776,536	2,859,832	2,945,627	3,033,995	3,125,015	3,218,766
Total # of eligible patients		5,152,386	5,306,958	5,466,166	5,630,151	5,799,056	5,973,028	6,152,218	6,336,785	6,526,889	6,722,695	6,924,376	7,132,107
% penetration	0.0%	0	0	0.1%	0.5%	2.0%	3.0%	4.0%	5.0%	5.0%	5.0%	5.0%	5.0%
# patients treated		0	0	5,466	28,151	115,981	179,191	246,089	316,839	326,344	336,135	346,219	356,605
anti-Midkine-DN price, annual	1%	\$4,375	\$4,418	\$4,463	\$4,507	\$4,552	\$4,598	\$4,644	\$4,690	\$4,737	\$4,785	\$4,832	\$4,881
US Sales of anti-Midkine-DN		\$0	\$0	\$24,393,715	\$126,883,909	\$527,989,324	\$823,900,941	\$1,142,805,532	\$1,486,075,743	\$1,545,964,596	\$1,608,266,969	\$1,673,080,128	\$1,740,505,257
<b>Diabetic Nephropathy - EU27</b>													
<b>Patient breakdown</b>		2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Total # of pts with diabetes	3.0%	47,862,342	49,298,213	50,777,159	52,300,474	53,869,488	55,485,573	57,150,140	58,864,644	60,630,583	62,449,501	64,322,986	66,252,675
Diabetes Mellitus type II	90.0%	43,076,108	44,368,391	45,699,443	47,070,426	48,482,539	49,937,015	51,435,126	52,978,180	54,567,525	56,204,551	57,890,687	59,627,408
# stage III DN (incipient), EU	28%	12,061,310	12,423,150	12,795,844	13,179,719	13,575,111	13,982,364	14,401,835	14,833,890	15,278,907	15,737,274	16,209,392	16,695,674
# of patients eligible	25%	3,015,328	3,105,787	3,198,961	3,294,930	3,393,778	3,495,591	3,600,459	3,708,473	3,819,727	3,934,319	4,052,348	4,173,919
# stage IV DN (overt), EU	8%	3,446,089	3,549,471	3,655,955	3,765,634	3,878,603	3,994,961	4,114,810	4,238,254	4,365,402	4,496,364	4,631,255	4,770,193
# of patients eligible	80%	2,756,871	2,839,577	2,924,764	3,012,507	3,102,883	3,195,969	3,291,848	3,390,603	3,492,322	3,597,091	3,705,004	3,816,154
Total # of eligible patients		5,772,198	5,945,364	6,123,725	6,307,437	6,496,660	6,691,560	6,892,307	7,099,076	7,312,048	7,531,410	7,757,352	7,990,073
% penetration	0.0%	0	0	0.1%	0.5%	1.0%	2.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
# patients treated		0	0	3,062	31,537	64,967	133,831	206,769	212,972	219,361	225,942	232,721	239,702
anti-Midkine-DN price, annual	1%	€ 3,150	€ 3,181	€ 3,213	€ 3,245	€ 3,278	€ 3,310	€ 3,344	€ 3,377	€ 3,411	€ 3,445	€ 3,479	€ 3,514
EU27 Sales of anti-Midkine-DN		€ 0	€ 0	€ 9,838,147	€ 102,346,244	€ 212,941,595	€ 443,046,282	€ 691,351,571	€ 719,213,039	€ 748,197,324	€ 778,349,677	€ 809,717,169	€ 842,348,770

**Figure 7. MK-Ab Revenue Model**  
Y2021 - Y2032.

Source: RM Research

Using our revenue model, industry average cost assumptions and probability adjusted 10-year DCF method (15% discounting) we valued the MK-Ab program throughout different stages of clinical development during the next 10 years. While the program is still at the pre-clinical stage, we believe this method reflects the long term potential of Cellmid for investors. Using this methodology we estimate the value of the MK-Ab program at A\$30.6M in 2014 and growing to A\$1.5B in Y2032.

We assigned probabilities based on the clinical approval success rates and phase transition probabilities outlined in a recent study from Tufts Center for the Study of Drug Development (Tufts University, Boston, Massachusetts).

Year	1H2014	2014 - 2015	2015	2016	2017	2018	2019	2020	2021	2022	2023
Clinical Stage	Phase I start	Phase I-II	Phase II	Phase III	Phase III	Phase III	Phase III	Phase III	NDA, Reg Review	Approved	Approved
Probability	8%	15%	20%	30%	60%	60%	60%	60%	90%	90%	100%
Potential NPV, A\$M	\$30.6	\$66.0	\$101.3	\$174.7	\$401.8	\$462.0	\$531.3	\$611.0	\$1,054.1	\$1,212.2	\$1,548.9

**Figure 8. Probability Adjusted 10-Year NPV Analysis of MK-Ab in Diabetic Nephropathy.**

Source: RM Research

We also provide a sensitivity analysis of program's net present value (NPV) relative to different discount rates and probabilities of approval. We believe this could further assist investors to value the MK-Ab program based on their own risk perception.

		Probability of Approval						
		1%	3%	5%	7%	8%	9%	10%
Discount Rate	10%	\$7.5	\$22.4	\$37.4	\$52.3	\$59.8	\$67.3	\$74.8
	15%	\$3.8	\$11.5	\$19.1	\$26.8	\$30.6	\$34.5	\$38.3
	20%	\$2.0	\$6.1	\$10.2	\$14.2	\$16.3	\$18.3	\$20.3
	25%	\$1.1	\$3.3	\$5.6	\$7.8	\$8.9	\$10.0	\$11.1
	30%	\$0.6	\$1.9	\$3.1	\$4.4	\$5.0	\$5.7	\$6.3
	35%	\$0.4	\$1.1	\$1.8	\$2.6	\$2.9	\$3.3	\$3.7
	40%	\$0.2	\$0.7	\$1.1	\$1.5	\$1.7	\$2.0	\$2.2

**Figure 9. What Does MK-Ab Could Worth - Applying Different Discount Factors And Probability of Approval.**  
Source: RM Research



## Part II. Molecular Diagnostics – Valued at A\$0.045/share (+ A\$0.018 as Both Tests Move closer to Commercialization)

### Midkine is a Part of Highly Expected Lung Cancer Diagnostic Test

With the exception of the prostate specific antigen (PSA) test for prostate cancer, screening technology for early detection of other major cancers has not been within reach of the Diagnostics sector until recently. For lung cancer a non-invasive IVD-based test that would allow detection with high accuracy and at an early stage, would be very attractive, considering the many issues with current, mainly *in vivo*-based (invasive) procedures (i.e. lung biopsy).

In 2009 Cellmid licensed midkine as a biomarker for the early diagnosis, prognosis and disease monitoring of lung cancer to be used in Celera's proprietary biomarker panel. The terms of the license are not publically disclosed but involve upfront and milestone payments and royalties on product sales. Celera Corporation is now a part of Quest Diagnostics (NYSE: DGX). The test is scheduled to hit the market in 2H2013 as a Laboratory Developed Tests (LTD) that will be regulated under Clinical Laboratories Improvement Amendment and thus do not require FDA approval. Under the license agreement Cellmid will receive milestone payments in addition to single digit royalties. We estimate 2% royalty to Cellmid from future sales of the test.

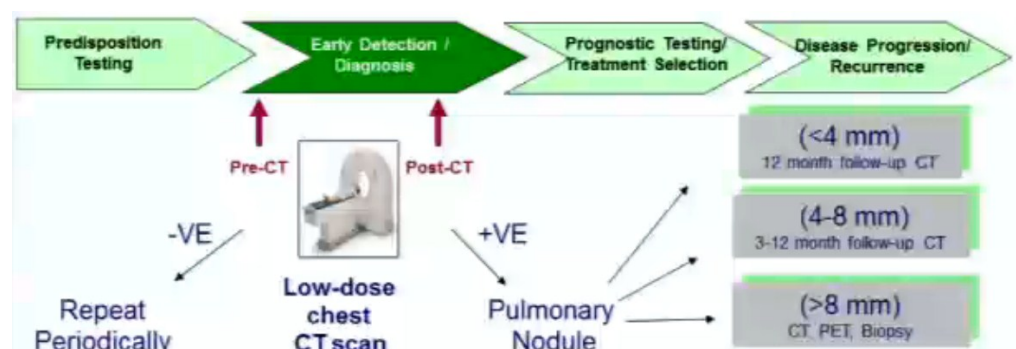
The test showed 85% sensitivity and 83% specificity in clinical settings, and compared well with CT (computer tomography) scanning. CT is the current gold standard screening method and has a much lower specificity (see definition). According to Celera the specificity rate for CT is about 75%.

Considering the associated risks of CT scans and morbidity associated with invasive follow-up diagnostics, it is expected that Celera's test will be at least an adjunct screening method and will assist in further clarifying the diagnosis in patients who have tested positive during their CT screening (Figure 8, Post-CT). This patient population is estimated to be 1.7 million. In addition the test could be used in pre-CT serving as a filter to identify high risk individuals whose malignant state could be checked through test. That would provide an upside to our sales estimates.

In order to commercialize the lung cancer panel the assay is currently being transferred to a multiplex format. With Quest Diagnostics' extensive distribution capabilities it is expected to be launched as a Lab Developed Test (LDT).

**Figure 10.** Where Does Lung Dx Fits In Current Lung Cancer Diagnostics. Pre-CT or Post-CT settings?

Source: AACR, 2011



### Market Size (US only) and Our Revenue Model for Celera's Test

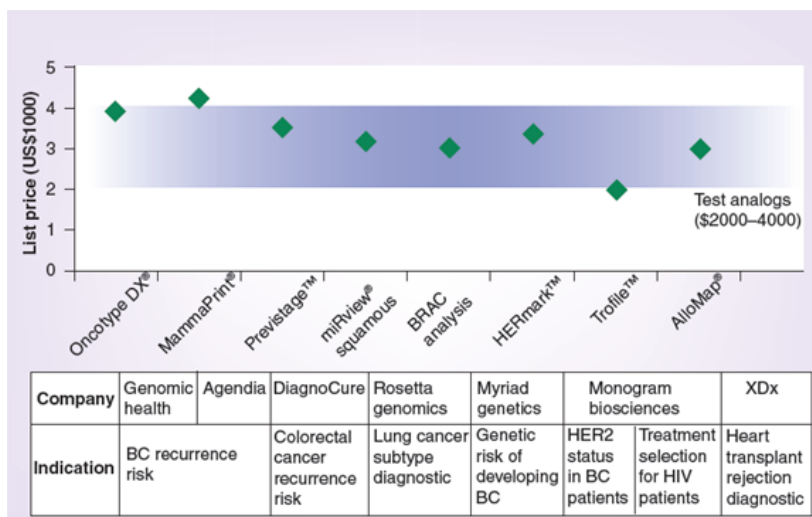
The high risk group (for developing lung cancer) consists of current and past cigarette smokers. Currently cigarette smokers make up 24% of adults in the US (or 47.5 million people) and past smokers comprise another 24.1 million adults. This group is greater than twenty times more likely to develop lung cancer than non-smokers. However according to medical literature, there are currently about only 7 million people in the US who would meet the eligibility criteria for the National Lung Screening Trial (NLST) and thus would be eligible for regular CT screening.

The rate of positive screening tests in NSLT was determined at 24.2% with low-dose CT. We thus estimate that there is about 1.75 million people who could test positive upon CT imaging (in clinical settings there could be up to 96% of false-positives after first scan). We use this number as a target population for Celera's lung cancer diagnostic product.

We currently do not have information on the pricing of Celera's lung cancer test and thus using a conservative estimate of \$1200 per test given the \$1000 - \$4000 range for LDT test in the US with some high complexity tests fetching in excess of \$4000 per test.

**Figure 11.** Illustrative US Pricing Of Leading Molecular Diagnostic Tests.

Source: FSG, 2011



	FY2013E	FY2014E	FY2015E	FY2016E	FY2017E	FY2018E	FY2019E	FY2020E	FY2021E	FY2022E
<b>Lung Cancer Dx</b>										
Patients Eligible for CT	7,000,000	7,070,000	7,140,700	7,212,107	7,284,228	7,357,070	7,430,641	7,504,947	7,579,997	7,655,797
Patients CT positive	1,750,000	1,767,500	1,785,175	1,803,027	1,821,057	1,839,268	1,857,660	1,876,237	1,894,999	1,913,949
Total annual US test market	1,750,000	1,767,500	1,785,175	1,803,027	1,821,057	1,839,268	1,857,660	1,876,237	1,894,999	1,913,949
Potential Market Penetration	0.2%	1%	3%	5%	6%	7%	7%	7%	7%	7%
Number of Tests Performed	3,500	17,675	53,555	90,151	109,263	128,749	130,036	131,337	132,650	133,976
Price per test	\$ 1,200	\$ 1,248	\$ 1,298	\$ 1,350	\$ 1,404	\$ 1,460	\$ 1,518	\$ 1,579	\$ 1,642	\$ 1,708
Revenue to Quest Diagnostics	\$ 4,200,000	\$ 22,058,400	\$ 69,510,430	\$ 121,689,593	\$ 153,387,298	\$ 187,971,021	\$ 197,444,760	\$ 207,395,976	\$ 217,848,733	\$ 228,828,310
<b>Royalties to CDY</b>	<b>\$ 84,000</b>	<b>\$ 441,168</b>	<b>\$ 1,390,209</b>	<b>\$ 2,433,792</b>	<b>\$ 3,067,746</b>	<b>\$ 3,759,420</b>	<b>\$ 3,948,895</b>	<b>\$ 4,147,920</b>	<b>\$ 4,356,975</b>	<b>\$ 4,576,566</b>
PV@10%	\$84,000	\$410,733	\$1,176,638	\$1,872,637	\$2,145,837	\$2,390,593	\$2,282,799	\$2,179,865	\$2,081,573	\$1,987,713

**Figure 12.** How Big Is The Market Opportunity For Celera's Lung Dx?

Source: RM Research

**We Value Lung Dx at A\$0.03 (+ A\$0.009 from previous valuation) as Test Moves Closer to commercialization**

Using conservative market penetration rates of 0.2% - 7% in Year1 – Year10, we estimate revenues from the test of \$4.2M - \$229M in Year1 – Year 10 respectively. Using a royalty rate of 2% (Midkine is only 1 out of 6 biomarkers in the test) we forecast \$84K - \$4.6M in royalties to Cellmid in Year1 – Year 10 respectively. Higher penetration and royalty rates, as well as price per test will provide an upside to our current estimates and CDY valuation. We increase the valuation on Lung DX by reducing discounting periods (-1) and lowering the discounting rate according to our valuation grid (Figure X) as Lung Dx moves closer to the commercialization stage.

Stage of Development	Discount Rate
Cost of Capital / Royalty Streams	10%
Marketed Product	15%
Regulatory Review	20%
Phase III	25%
Phase II	30%
Phase I	40%

### Summary on Quest's Lung DX

While we are still awaiting the annual update from Quest on the readiness of Lung DX test to hit the market (expected by the end of March), we remain confident that the launch of the test is imminent and expect it at the end of FY2013. Quest recently announced the sale of its HemoCue and OralDNA businesses (both Point-of-Care tests) and realigned their business strategy focusing on esoteric growth (refers to tests performed at reference laboratories that use rigorous testing and that exceed what most hospitals and basic labs can do, i.e. Lung DX) through disease focus and laboratory information services.

*We view Lung DX as a perfect fit with their new strategy and expect Quest to launch the test in few months. Quest has demonstrated a strong capacity in commercializing of their assets successfully launching two tests during last 8 months (for enhanced thyroid cancer and cervical cancer detection).*

Our worse cost scenario assumes launch in FY2014 removing \$84K from top-line (not incremental to our Price Target).

### Midkine is a Part of Cxbladder – a Bladder Cancer Test That is Scheduled for Commercial Launch in 2H2013

*According to PEB's management the company is on track to get CLIA certification by the end of March with commercial launch to follow*



In 2010 Cellmid have entered into a non-exclusive license agreement with Pacific Edge Biotechnology Limited (PEB) for the use of Cellmid's midkine technology in PEB's bladder cancer test. Cellmid is eligible to receive milestone payments in addition to royalties on product sales. We estimate a 2% royalty rate (vs our previous estimate of 1.5%).

The test provides general practitioners and urologists with a quick, cost effective and accurate measure of the presence of a bladder cancer, and provides urologists with the opportunity to reduce their reliance on the need for invasive tests such as cystoscopy. A non-invasive nature of Cxbladder should be more compelling for the patient and will likely lead to overall higher compliance to the monitoring regimen comparing to cystoscopy alone.

### Clinical Evidence Suggests Cxbladder Will Have Market Leading Performance

The Cxbladder clinical study met its primary clinical end point of identifying bladder cancer significantly more accurately than other commercially available tests benchmarked in the trial. Cxbladder demonstrated 82% sensitivity at 85% specificity. Impressively, Cxbladder showed 100% sensitivity in detecting late stage bladder cancer (all stages other than Ta).

In our view, Cxbladder has sufficient performance to challenge urine cytology as the routine adjunct to cystoscopy. In addition, based on its ability to distinguish between high and low risk tumors Cxbladder could potentially be used to prioritize primary care patients for urgent cystoscopic evaluation.

### Current Diagnostic Options for Bladder Cancer

Cytology is the most common test used by general practitioners to triage patients with haematuria. If cytology indicates the possibility of cancer, the patient is referred to a urologist for cystoscopy (invasive and expensive) to confirm the diagnosis. Cytoscopy cost is in the region of \$600 - \$1000.

Cxbladder is designed to potentially replace cytology and to also be used as an adjunct to cystoscopy.

### Market Size (US only) and Our Revenue Model for Cxbladder

The US is the largest market opportunity for the *Cxbladder* and PEB is building a laboratory for the provision of the *Cxbladder* test to urologists and physicians across the US. The laboratory will be regulated under the Clinical Laboratories Improvement Amendment Act (CLIA) which will enable PEB to offer *Cxbladder* as a Laboratory Developed Test meaning it would not require FDA approval.

Pacific Edge estimates that the annual potential US market for bladder cancer tests is approximately 1.8M tests. PEB uses the following assumptions to estimate the market:

- In the United States 1,000,000 patients per year present to their GP with haematuria;
- 68,800 patients are diagnosed each year with bladder cancer<sup>1</sup>;
- NCCN Clinical Practice Guidelines in Oncology specify that patients receive 12 monitoring cystoscopies in the five year monitoring period – 4 in the year of diagnosis and 2 in each following year.

All in all, PEB estimates 1,825,000 assays to be required per year. PEB's new facility in Hershey, Pennsylvania would have a capacity of producing 260K tests per annum. These represents 14% of the overall market.

PEB expects smooth reimbursement process in US. A third party market survey of Medical and Benefits Review Committees for Health Insurers in the US that covered a wide spectrum of private plans showed a very high level of acceptance and concordance with the payers systems.

According to PEB, total supported price for *Cxbladder* using composite CPT coding for CMS patients is expected to be approximately US\$786 per test. Reimbursement by insurers in the US generally occurs at 70% to 80% of the composite CPT code, meaning it will be in the range of US\$550 - US\$630 per test.

	FY2013E	FY2014E	FY2015E	FY2016E	FY2017E	FY2018E	FY2019E	FY2020E	FY2021E	FY2022E
<b>Cxbladder</b>										
Total annual US assay market, prevalence	1,825,600	1,862,112	1,899,354	1,937,341	1,976,088	2,015,610	2,055,922	2,097,041	2,138,981	2,181,761
Potential market penetration	0.2%	1%	3%	5%	6%	7%	7%	7%	7%	7%
Number of test carried out	3651	18621	56981	96867	118565	141093	143915	146793	149729	152723
Price per test	\$ 550.00	\$ 572.00	\$ 594.88	\$ 618.68	\$ 643.42	\$ 669.16	\$ 695.93	\$ 723.76	\$ 752.71	\$ 782.82
Revenue to Pacific Edge	\$ 2,008,160	\$ 10,651,281	\$ 33,896,636	\$ 59,929,252	\$ 76,287,540	\$ 94,413,460	\$ 100,153,798	\$ 106,243,149	\$ 112,702,732	\$ 119,555,058
<b>Royalties to CDY</b>	<b>\$ 40,163</b>	<b>\$ 213,026</b>	<b>\$ 677,933</b>	<b>\$ 1,198,585</b>	<b>\$ 1,525,751</b>	<b>\$ 1,888,269</b>	<b>\$ 2,003,076</b>	<b>\$ 2,124,863</b>	<b>\$ 2,254,055</b>	<b>\$ 2,391,101</b>
PV@10%	\$40,163	\$198,329	\$573,785	\$922,229	\$1,067,237	\$1,200,739	\$1,157,949	\$1,116,684	\$1,076,889	\$1,038,513

**Figure 13. How Big Is The Market Opportunity For PEB's Cxbladder?**  
Source: RM Research

**We Value Cxbladder at A\$0.015 (+ A\$0.009 from previous valuation) as test moves closer to commercialization**

Using conservative market penetration rates of 0.2% - 7% in Year1 – Year10 and using PEB's market size model we estimate revenues of \$2M - \$120M in Year1 – Year 10 respectively.

Using a royalty rate of 2% we forecast \$40K - \$2.4M in royalties to Cellmid in Year1 – Year 10 respectively. We use a price of \$550 per test which is on the lower side of the range provided by PEB. Higher penetration and royalty rates will provide an upside to our current estimates and CDY valuation.

### Future Molecular Diagnostic Partnership Could Add A\$0.02 or More Per Share Per Test

According to PwC, M&A and partnership deal values in the diagnostic space jumped to exceptional levels during the last two years. Interestingly, partners were not only existing players in the diagnostics sector, but also private equity, life sciences research groups, clinical laboratories, and medical technology players. New entrants also included pharmaceutical companies in search of companion diagnostic products. According to EvaluatePharma consulting group, *in-vitro* diagnostics will be the industry's top segment by 2018, pulling in sales of \$54.5B and outstripping old standbys like cardiac devices and imaging technologies.

The surge and diversity of these deals encourages our belief in the growth prospects of Cellmid's highly validated diagnostic pipeline and more future out licensing deals. We believe Cellmid will be eligible for similar economics in each new deal, adding A\$0.02 per current share price per deal or more. That could include both *in-vitro* diagnostics and companion diagnostics applications.

In line with that, Cellmid has recently signed an important option agreement with listed Japanese company Fujikura Kasei Co Ltd (Fujikura), a major supplier of latex particles used in medical diagnostics.

Under the terms of the option to license agreement Cellmid will supply its proprietary anti-midkine diagnostic antibodies for validation on Fujikura's latex platform. Cellmid will receive an initial fee and a further payment should Fujikura elect to exercise its license option. Cellmid will also receive royalties on any future midkine diagnostic products sold by Fujikura.

While it is premature to attribute any value to this new deal, we view an agreement as a further validation of midkine's opportunity in the diagnostics space and upside to our current company valuation.

## **Updating Our View on the Hair Loss Business As Sales Exceed Our Expectations - We Value Advangen at A\$0.027 (+ A\$0.015 from previous valuation) on Higher Sales**

Advangen International Pty Ltd is a controlled entity of Cellmid Limited. Advangen owns exclusive international manufacturing, marketing and distribution rights for a range of scientifically validated products that prevent hair loss with the exception of China, Japan, South Korea, Malaysia, Singapore and Taiwan. These products contain FGF-5 inhibitor. FGF-5 was shown to shorten hair growth cycle in numerous animal studies and its inhibition provides therapeutic benefits. According to management the Company has a comprehensive licensing and distribution plan and is actively pursuing opportunities outside of Australia.

Cellmid received a TGA listing for the évolis® hair growth tonics in February 2012. TGA certification provides a validation of the clinical performance and safety of the product by the regulatory body of Australia. We view TGA listing as a great marketing tool as it supports évolis®' therapeutic claims. Advangen's hair loss prevention products will not require a prescription and will be sold as over the counter medicines in pharmacies. Recommended retail price for évolis® is \$89 for each 50 ml bottle. The évolis® shampoo is expected to be available for sale in February 2013; however it will not be listed with the TGA.

Advangen's évolis® product range was launched in June 2012, and 700 outlets agreed to stock the products by the end of September. The list of pharmacies includes some of the largest pharmacy chains such as Priceline, Terry White and National Pharmacies. Frostbland Pty Ltd is appointed as an exclusive distributor for the pharmacy and drug store market in Australia and New Zealand. During the reporting period orders have been received for approximately 400 stores, while the remaining stores are likely to come online during the course of calendar 2013. We expect distribution to reach 1300 – 1400 pharmacies in the next couple years.

In addition, company recently commenced direct sales to hair salons in New South Wales. Advangen is aiming to target approx. 200 salons in Sydney for the start. There are more than 20000 hair salons in Australia.

The range has four products at this stage all containing active ingredients inhibiting FGF-5. The products could be used together or separately, as well as with other treatment available on the market. These products are not listed with the TGA and currently being manufactured in Japan.

The product range includes:

- Jo-Ju Shampoo, unisex shampoo suitable for all hair types;
- Jo-Ju Lotion, scalp treatment for women;
- Léxis lotion, scalp treatment for men;
- Jo-Ju Conditioner, conditioning treatment for men and women.



## Advangen Revenue and Profit Estimates - Increasing Sales Estimates on the Back of a Strong Launch

	FY2013E	FY2014E	FY2015E	FY2016E	FY2017E	FY2018E	FY2019E	FY2020E	FY2021E	FY2022E
<b>Hair Loss</b>										
<b>Wholesale</b>										
Number of Pharmacies Stocking, ave	700	900	1100	1300	1400	1500	1600	1700	1700	1700
Evolis (for women) per pharmacy / per year	16	26	34	38	42	46	50	52	54	56
Evolis (for men) per pharmacy / per year	8	12	16	20	22	24	26	26	26	26
Evolis (both) per pharmacy / per year	24	38	50	58	64	70	76	78	80	82
Retail Price	\$80	\$80.80	\$81.61	\$82.42	\$83.25	\$84.08	\$84.92	\$85.77	\$86.63	\$87.49
Wholesale discount	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Wholesale price	\$40	\$40	\$41	\$41	\$42	\$42	\$42	\$43	\$43	\$44
Revenues to Advangen	\$672,000	\$1,381,680	\$2,244,220	\$3,107,388	\$3,729,525	\$4,414,242	\$5,163,234	\$5,686,606	\$5,890,740	\$6,098,389
COGS	\$14	\$14	\$14	\$14	\$15	\$15	\$15	\$15	\$15	\$15
Gross Margin	\$26	\$26	\$27	\$27	\$27	\$27	\$28	\$28	\$28	\$28
Profits to CDY	\$436,800	\$898,092	\$1,458,743	\$2,019,802	\$2,424,191	\$2,869,257	\$3,356,102	\$3,696,294	\$3,828,981	\$3,963,953
<b>Direct Sales to Hair Salons</b>										
Number of Hair Salons Buying, ave	200	350	450	550	650	750	850	900	950	1000
Jo-Ju and Lexilis sole per salon / per year	4	7	10	12	16	18	18	18	18	18
Average Sale Price	\$70	\$70.70	\$71.41	\$72.12	\$72.84	\$73.57	\$74.31	\$75.05	\$75.80	\$76.56
Revenues	\$56,000	\$173,215	\$321,332	\$475,999	\$757,560	\$993,204	\$1,136,888	\$1,215,801	\$1,296,179	\$1,378,043
COGS	\$31.50	\$31.82	\$32.13	\$32.45	\$32.78	\$33.11	\$33.44	\$33.77	\$34.11	\$34.45
Gross Margin	\$40	\$41	\$41	\$42	\$43	\$44	\$44	\$45	\$46	\$47
Profits to CDY	\$32,000	\$99,715	\$186,332	\$277,999	\$445,560	\$588,204	\$677,888	\$729,801	\$783,179	\$838,043
<b>Direct Internet Sales</b>										
Evolis bottles shipped per year	50	150	300	600	960	1296	1620	1863	1956	2054
Annual growth		300%	200%	100%	60%	35%	25%	15%	5%	5%
Average Sale Price	\$90	\$90.90	\$91.81	\$92.73	\$93.65	\$94.59	\$95.54	\$96.49	\$97.46	\$98.43
Revenues	\$4,500	\$13,635	\$27,543	\$55,636	\$89,908	\$122,590	\$154,770	\$179,765	\$190,641	\$202,174
COGS	\$31.50	\$31.82	\$32.13	\$32.45	\$32.78	\$33.11	\$33.44	\$33.77	\$34.11	\$34.45
Gross Margin	\$58.50	\$59.09	\$59.68	\$60.27	\$60.88	\$61.48	\$62.10	\$62.72	\$63.35	\$63.98
Profits to CDY	\$2,925	\$8,863	\$17,903	\$36,164	\$58,440	\$79,683	\$100,600	\$116,847	\$123,916	\$131,413
Total Revenues, Advangen	\$732,500	\$1,568,530	\$2,593,094	\$3,639,023	\$4,576,993	\$5,530,037	\$6,454,892	\$7,082,172	\$7,377,561	\$7,678,607
<b>Total Profits to CDY (from Advangen)</b>	<b>\$471,725</b>	<b>\$1,006,670</b>	<b>\$1,662,977</b>	<b>\$2,333,965</b>	<b>\$2,928,191</b>	<b>\$3,537,145</b>	<b>\$4,134,590</b>	<b>\$4,542,943</b>	<b>\$4,736,077</b>	<b>\$4,933,410</b>
PV@15%	\$471,725	\$906,491	\$1,302,162	\$1,589,188	\$1,733,734	\$1,821,118	\$1,851,058	\$1,768,589	\$1,603,284	\$1,452,249
Number of people using per year	5,883	12,267	19,933	27,533	33,653	39,932	46,173	50,221	51,685	53,151
Potential number of customers, eligible	1,270,497	1,270,497	1,270,497	1,270,497	1,270,497	1,270,497	1,270,497	1,270,497	1,270,497	1,270,497
% of addressable customer populaion using	0.463%	0.966%	1.569%	2.167%	2.649%	3.143%	3.634%	3.953%	4.068%	4.184%

**Figure 14.** Market Size And Revenue Estimates For Advangen's Hair Loss Prevention Products, FY 2013 - FY2022.

Source: RM Research

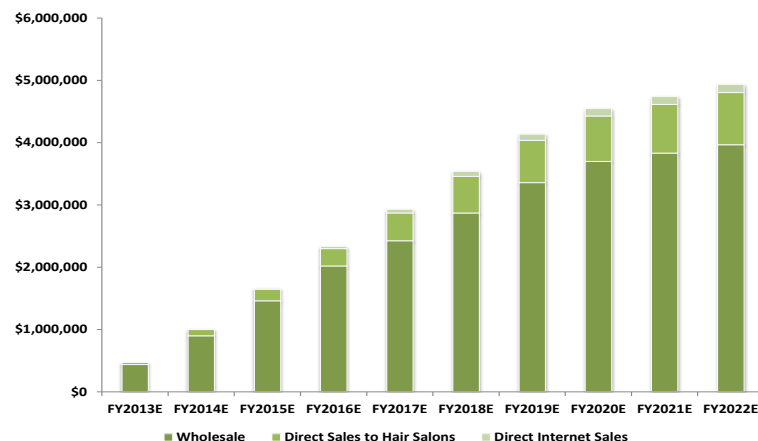
Currently we only estimate sales from the Australian operations. While US and Europe represent larger opportunities, we do not include sales from these regions into our model until we get more clarity from the company on the path forward and more information on regulatory requirements.

Company recently announced that since the commencement of cash receipts of its évolis® hair growth products in September 2012 the Company has receipts of \$286 (with \$187K in the last quarter). This relates to orders for approximately 400 stores, and implies a rate of 12 bottles per store per quarter which is well above our previous estimate of 6 bottles per store per year (note that we estimated 1100 stores in FY2013). Our new estimate assumes 24 bottles per store per year and 700 stores. We estimate A\$672K in receipts in FY2013.

Our assumptions include wholesale price of \$40 to pharmacy chains and gross margin of 65%. For direct sales we estimate ASP of \$70 and \$90 for sales to salons and internet sales respectively and COGS of \$31.50. Our model results in conservative market penetration ranging from 0.5% in Year1 to 4.2% in Year10 into addressable customer population.

**Figure 15.** Profit Estimates From Sale Of Advangen's Hair Loss Prevention Products, FY2013 - FY2022.

Source: RM Research



## Intellectual Property

We view Cellmid's almost exclusive midkine patent portfolio as a core asset to the company's present and future business. Strong IP rights on midkine as a biomarker or therapeutic agent are crucial for future partnerships. Midkine's current patent portfolio includes 20 patent families and 77 patents of which 51 granted (see list below)

- 1 Patent Family Entitled: Method for treating retinal diseases (1 patent granted Exp 2015)
- 2 Patent Family Entitled: Composition comprising midkine or pleiotrophin protein and method of increasing hematopoietic cells (2 patents granted Exp 2017/2018)
- 3 Patent Family Entitled: Drugs containing as the active ingredient midkine or inhibitors thereof (9 patents granted Exp 2018/2020)
- 4 Patent Family Entitled: Preventives or remedies for ischemic disease (7 patents granted Exp 2018)
- 5 Patent Family Entitled: Mass secretion/expression system of true MK family protein (1 patent granted Exp 2019)
- 6 Patent Family Entitled: Preventives/remedies for arteriosclerosis and post-PTCA reangiostenosis (11 patents granted Exp 2019)
- 7 Patent Family Entitled: Early cancer tumor marker (11 patents granted Exp 2020)
- 8 Patent Family Entitled: Monoclonal antibody against human MK (1 patent granted Exp 2020)
- 9 Patent Family Entitled: New method for preparing antisense oligonucleotide (1 patent granted Exp 2022)
- 10 Patent Family Entitled: Method for diagnosing rheumatism (1 patent granted Exp 2022)
- 11 Patent Family Entitled: Preventive for adhesion following abdominal surgery (2 patents granted Exp 2024)
- 12 Patent Family Entitled: Arthritis-associated gene and use thereof in examining arthritis (1 patent granted Exp 2024)
- 13 Patent Family Entitled: Method for treatment or prevention of disease associated with functional disorder of regulatory T cell (1 patent granted Exp 2026)
- 14 Patent Family Entitled: Antibody recognizing C-domain of midkine (under examination Exp 2027)
- 15 Patent Family Entitled: Composition for treating or preventing myocardial disorder or heart failure (1 patent granted Exp 2025)
- 16 Patent Family Entitled: Nitric oxide synthase activator (under examination Exp 2027)
- 17 Patent Family Entitled: Pharmaceutical composition for vascular occlusive disease (under examination Exp 2026)
- 18 Patent Family Entitled: Therapeutic agent for occlusive peripheral vascular disease, and use thereof (Filed Exp 2027)
- 19 Patent Family Entitled: Method of treatment or prevention of hair loss or for the enhancement of hair growth (awaiting filing Exp 2031)
- 20 Patent Family Entitled (PCT application): Undisclosed (Filed Exp 2032)

## Risk Analysis

We believe there are several risks to Cellmid's share price and our price target. Our price target is largely built of future royalty streams from lung and bladder cancer diagnostic products (A\$0.027). Our valuation relies on timely market entry (we expect 2H2013), commercial success of these tests, and their reimbursement levels in US. In addition, Advangen is commercializing hair loss prevention products that contribute A\$0.012/sh in our price target. As a result there are upside and downside risks associated with that product line.

### Downside

**Commercial Risk:** The majority of CDY's forecasted revenues come from royalties on lung cancer and bladder cancer tests paid by Quest Diagnostics and Pacific Edge. If the sales numbers for these tests materially differ from our forecast, our price target could be negatively impacted as well as the stock price. Same argument is valid for the Advangen business unit. In addition, future therapeutics and diagnostics developed by the company may require development partners and the company may be delayed or unsuccessful in seeking out such partners. The company has multiple product development programs to ensure that this risk is mitigated.

**Reimbursement Risks (on Partnered Tests):** Medicare reimbursement could decline. We do believe that Medicare reimbursement for the clinical lab fee schedule is likely to decline in the future, given recent chatter regarding co-payments and additional market basket reductions. Conversely, material inflation in the annual market basket adds upside to our forward estimates.

**Intellectual Property Risks:** The patent positions of biotechnology companies can be highly uncertain, and the company could face the risk in obtaining and defending its key product patents. Failure to protect midkine patents could negatively impact the stock price.

**Technical Risks:** associated with the development of the company's products which may cause a delay in development or failure to complete development programs. To mitigate this risk, the company has a diverse portfolio of assets at various stages of development and with multiple revenue opportunities.

**Competition Risks:** therapeutics or diagnostics competing with the company's products may be developed by others reducing the potential market. The company can do little to prevent competition. However, it operates in the pharmaceutical development sector where competitive products are often successfully marketed together.

### Upside

**Figure 16-17.**Sensitivity Analysis - Per Share Value For Lung Dx and Cxbladder vs Price Per Test and Royalty Rate.

Source: RM Research

**Better-Than-Expected Sales:** If molecular diagnostics or hair loss prevention products sales are better than we forecast, it could positively impact the share price.

**Higher than estimated royalty rate from Quest Diagnostics and price per Lung Dx test (see sensitivity analysis below).**

		Royalty Rate (From Quest Diagnostics)						
Price Per Test		1%	1%	2%	3%	4%	5%	6%
	\$ 1,000.00	\$0.006	\$0.013	\$0.025	\$0.038	\$0.051	\$0.063	\$0.076
	\$ 1,200.00	\$0.008	\$0.015	\$0.030	\$0.046	\$0.061	\$0.076	\$0.091
	\$ 1,500.00	\$0.010	\$0.019	\$0.038	\$0.057	\$0.076	\$0.095	\$0.114
	\$ 2,000.00	\$0.013	\$0.025	\$0.051	\$0.076	\$0.102	\$0.127	\$0.152
	\$ 2,500.00	\$0.016	\$0.032	\$0.063	\$0.095	\$0.127	\$0.159	\$0.190
	\$ 3,000.00	\$0.019	\$0.038	\$0.076	\$0.114	\$0.152	\$0.190	\$0.229
	\$ 3,500.00	\$0.022	\$0.044	\$0.089	\$0.133	\$0.178	\$0.222	\$0.267

**Higher than estimated royalty rate from Pacific Edge Biodiagnostics and price per Cxbladder test (see sensitivity analysis below).**

		Royalty Rate (From Pacific Edge Biodiagnostics)						
Price Per Test		1%	1%	2%	3%	4%	5%	6%
	\$ 500.00	\$0.003	\$0.007	\$0.014	\$0.021	\$0.028	\$0.035	\$0.042
	\$ 550.00	\$0.004	\$0.008	\$0.015	\$0.023	\$0.031	\$0.038	\$0.046
	\$ 600.00	\$0.004	\$0.008	\$0.017	\$0.025	\$0.034	\$0.042	\$0.050
	\$ 700.00	\$0.005	\$0.010	\$0.020	\$0.029	\$0.039	\$0.049	\$0.059
	\$ 800.00	\$0.006	\$0.011	\$0.022	\$0.034	\$0.045	\$0.056	\$0.067
	\$ 900.00	\$0.006	\$0.013	\$0.025	\$0.038	\$0.050	\$0.063	\$0.076
	\$ 1,000.00	\$0.007	\$0.014	\$0.028	\$0.042	\$0.056	\$0.070	\$0.084

## Directors and Management

### **Dr David King, Chairman**

Dr David King brings a depth of corporate governance, capital markets and listed company board experience to Cellmid. He has previously held positions as Executive Director, Chief Executive Officer and Managing Director in a number of private and listed companies. An expert in high growth companies Dr King has a track record in starting business ventures and developing them into attractive investment and/or take-over targets. His experience in successful start-up businesses has been instrumental in CDY's recent acquisition of the Midkine intellectual property portfolio.

Dr King is a Fellow of the Australian Institute of Company Directors, a Fellow of the Australian Institute of Geoscientists and the Australian Institute of Mining & Metallurgy (Chartered Professional, Management) and holds degrees in physics and geophysics and a PhD in Seismology from the Australian National University.

### **Maria Halasz, Managing Director and CEO**

Maria Halasz has been involved with biotechnology companies for 19 years; initially working in executive positions in biotechnology firms, then managing investment funds and later holding senior positions in corporate finance specialising in life sciences.

Prior to joining Cellmid Ms Halasz had been an adviser to an independent sector based research firm in life sciences and managed Direct Capital Group Pty Ltd, a specialist biotechnology fund. She has also been a venture partner at the Emerging Technology Fund of venture capital firm Allen & Buckeridge.

Since taking over as Chief Executive and Managing Director of Cellmid Ms Halasz has led the restructure of the business, the acquisition of the Midkine intellectual property portfolio and the recapitalisation of the company.

Ms Halasz is a Member of the Australian Institute of Company Directors and holds a science degree in Microbiology and an MBA

### **Graeme Kaufman, Non-Executive Director**

Graeme brings over 45 years' experience in biotechnology spanning technical, commercial and financial areas. Having worked for 34 years at CSL Limited, Australia's largest biopharmaceutical company, he held senior positions including Production Director, General Manager Finance and General Manager Biosciences. Graeme holds BSc & MBA with Melbourne University

### **Martin Rogers, Non-Executive Director**

Mr Rogers has a strong science background, which includes degrees in science and chemical engineering and is currently a member of the management committee of the National Breast Cancer Foundation. Mr Rogers also has strong expertise in the corporate sector, with a focus on the incubation and development of new business ideas. He has previously been involved in the origination of a number of new business concepts and the establishment of internal ventures and external partnerships, including finance concept origination in the corporate banking sector for institutions such as Macquarie Bank.

### **Darren Jones, Head of Product Development**

Darren Jones has worked in the Australian biotechnology industry for over 10 years, with particular responsibilities for developing promising therapeutic antibody candidates from discovery, screening, preclinical testing and humanising through to clinical trials. In addition to his considerable technical expertise in all aspects of the development of antibody therapeutics, he has extensive expertise in intellectual property management and strategic business planning. Prior to working in the biotechnology sector Mr Jones worked as a research scientist at the University of Technology and at St Vincent's Hospital, Sydney in the fields of immunology, cancer and HIV. Darren has a BSc from the University of Sydney and a MSc degree from the University of Technology, Sydney.

**Nicholas Falzon, Company Secretary and Financial Controller**

Nicholas Falzon has been working with Cellmid for over four years and was appointed as Financial Controller and Company Secretary on the 6th October 2010. As a partner at Lawler Partners, Nicholas works with a number of listed and unlisted companies advising them on all aspects of their financial management. His special area is R & D Tax Concessions and he has been successful in applying for substantial tax offsets for Cellmid in the past.

**Andrew Bald, Company Secretary**

Andrew Bald has 25 years of experience in banking and corporate finance, having advised private and ASX listed companies in a number of industries. Prior to his role as a corporate advisor, he was an investment banker managing balance sheet and trading risks as well as advising on a number of significant project financing transactions.

**Emma Chen - VP Business Development**

With more than 12 years' experience in the hair growth industry Emma Chen has recently been appointed as VP-Business Development by Advangen International Pty Ltd to broaden the Australian distribution network and increase sales for our évolis® and Advangen products in pharmacies and in the hair salon/beauty market.

Prior to Cellmid, Emma served as a Chief Executive Officer at Ashley & Martin from 1998 until 2008. Throughout her tenure Emma built Ashley & Martin into one the most recognised and trusted brands in the hair growth industry and established a highly profitable, premium medical clinic network in the process. Prior to this, Emma was involved in launching the first generic minoxidil brand, Hair A-Gain, in Australia in 1997 (by South Pacific Pharmaceuticals).



## ***Registered Offices***

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<b>Speculative Buy</b>	We forecast strong earnings growth or value creation that may achieve a return well above that of the broader market. These companies also carry a higher than normal level of risk.
<b>Hold</b>	A sound well managed company that may achieve market performance or less, perhaps due to an overvalued share price, broader sector issues, or internal challenges.
<b>Sell</b>	Risk is high and upside low or very difficult to determine. We expect a strong underperformance relative to the market and see better opportunities elsewhere.

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