



Biotech Daily

Friday February 22, 2019

Daily news on ASX-listed biotechnology companies

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- * **MAYNE H1 REVENUE UP 13% TO \$274m, LOSS TO PROFIT OF \$1m**
- * **UNIVERSAL BIO REVENUE UP 176% TO \$70m, LOSS TO \$38m PROFIT**
- * **ELLEX H1 REVENUE UP 9% TO \$41.6m, LOSS DOWN 0.4% TO \$2.7m**
- * **MEDLAB H1 REVENUE UP 17% TO \$2.3m, LOSS UP 60% TO \$3.7m**
- * **OBJ P&G LICENCE DEAL FOR OLAY MAGNETIC INFUSER**
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MARKET REPORT

The Australian stock market was up 0.46 percent on Friday February 22, 2019, with the ASX200 up 28.1 points to 6,167.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and two were untraded. All three Big Caps were up.

Impedimed was the best, up one cent or 4.4 percent to 23.5 cents, with 11.6 million shares traded. Kazia climbed 4.35 percent; Pharmaxis was up 3.9 percent; LBT and Paradigm rose more than two percent; Genetic Signatures, Optiscan, Polynovo, Telix and Volpara were up more than one percent; with Cochlear, CSL, Mesoblast, Nanosonics and Resmed up by less than one percent.

Ellex led the falls, down three cents or 4.9 percent to 58 cents with 1.1 million shares traded. Patrys and Universal Biosensors fell more than four percent; Avita, Cynata and Uscom were down more than three percent; Prana and Prescient shed more than two percent; Medical Developments, Pro Medicus, Proteomics and Starpharma were down more than one percent; with Clinuvel and Neuren down by less than one percent.

DR BOREHAM'S CRUCIBLE: CELLMID

By TIM BOREHAM

ASX code: CDY

Share price: 26 cents

Market cap: \$21.9 million

Shares on issue: 84,108,592

Chief executive officer: Maria Halasz

Board: Dr David King (chairman), Maria Halasz, Dennis Eck, Bruce Gordon, Dr Edward Walton, Dr Martin Cross

Financials (December half): revenue \$3.6 million (up 12%), net loss \$3.5 million (previously \$1.09 million deficit)

(December quarter): receipts \$1.1 million, cash outflows \$2.8 million, cash \$5.4 million, estimated March quarter outflows \$2.0 million.

Identifiable major shareholders: Dennis Eck 6.5%, Washington H Soul Pattinson 2.5%, Jasgo Family 2.4%, Gregory Glenn Worth 2.1%, Moore Family 1.7%, Cell Signals 1.5%.

As a life sciences company purveying hair loss prevention tonics and also running pre-clinical programs with its portfolio of midkines, Cellmid is frequently asked of investors: "Who are you?"

Apologies to The Who there.

"We are an unusual business with a consumer health and biotech component," says Cellmid CEO Maria Halasz, who concedes that investors might have got a tad confused along the journey.

But Cellmid's board has the answer to please both camps: within two years the company plans to demerge its clinical program, probably as a private entity funded by venture (or similar) capital.

"In the last two to three years we have been growing the market to make the consumer division more profitable, and so there is a strong sentiment from the market that we need to split the two businesses," Ms Halasz says.

The proposal to split is central to Cellmid's blueprint, dubbed Path to Profitability 2020. But beyond this statement of intent, no firm decisions have been made on how the bifurcation will be executed.

Ms Halasz says Cellmid first needs to grow both sides into “sustainable businesses” - a quest helped by this week’s first half results showing record hair revenue.

On the hair side, Cellmid must be doing something right, because Askmen.com last year accorded Cellmid its top grooming award in the category “best natural alternative for hair loss”.

Move over Advanced Hair: “Yeah, yeah.”

About Cellmid

As is the biotech norm, Cellmid’s focus has shifted over the years.

Then known as Medical Technologies, Cellmid listed in December 2005 on the back of work on inflammatory diseases undertaken by the University of Sydney and Western Sydney University.

However, this related to a different technology. In August 2008, Medical Development acquired its midkine portfolio from Cell Signals Inc. In late 2009, the company changed its name to Cellmid - the ‘mid’ being a reference to the midkines, which are growth factors that modulate cell growth, cell migration and cellular adherence.

The company claims to have the world’s most extensive collection of midkine patents.

Because they are not evident in healthy adults, over-expressed midkines are a handy indicator of early disease onset before physical symptoms become apparent.

Cellmid believes its portfolio is relevant not just for cancers and inflammatory diseases, but autoimmunity issues, ischemia (heart blood vessel damage), nerve growth repair and wound healing.

Midkines are also relevant to hair repair, but Cellmid’s range of Évolis hair tonics are based on another technology called fibroblast growth factor five (FGF5). Évolis is the key brand of Advangen, acquired by Cellmid from its Japanese owners in 2013 for roughly \$3.9 million in cash and scrip.

Hair, there and everywhere

Advangen has established a sales presence in the US and Japan and more recently in China and New Zealand.

In the US, Évolis has shelf space in Neiman Marcus, Soft Surroundings and Bloomingdales (about 40 shops, in all).

Last October, Advangen launched local sales of Fillarina - as in “fill ‘er in” - the world’s first, non-injectable, transdermal filler to reduce wrinkles and increase “facial volume”.

Potential products in the lab include a dry shampoo that doesn’t clog up follicles, as well as eyebrow and eyelash growth agents.

In China last year, Cellmid inked a five-year agreement with Fukangren Bio-Pharm Tech Co, by which Fukangren distributes Évolis lotions and shampoos to more than 500 chemists, hospitals and clinics.

In Japan, the products are marketed on QVC’s home-shopping channel, which accesses 21 million households. QVC China was due to follow suit in January.

While the US recorded the highest growth rate, Japan continues to be the biggest contributor to Cellmid’s revenues.

The hair-loss market is worth \$US7 billion a year - presumably that includes a few ‘rugs’ as well - with treatments based on minoxidil, a repurposed blood pressure medication.

“The problem is, it smells bad and is sticky,” Ms Halasz says.

It’s a rude question in the cosmetics milieu, but do the Évolis lotions actually work? Look no further than Ms Halasz who has a healthy thatch, having been the first to use the products after experiencing hair loss in her 40s.

Clinical progress

Cellmid’s pre-clinical programs are focused on antibodies to treat myocarditis, heart failure, cancer, fibrosis, chronic kidney disease and associated conditions.

In a dense, but welcome, update on the clinical program last week, Cellmid highlighted the role of its midkine antibodies in heart muscle damage arising from the auto immune disease myocarditis.

There is no other cure for the chronic inflammatory heart disease, which can !!!!!be triggered by using checkpoint inhibitors as cancer treatments.

A paper prepared by Cellmid collaborators Dr Ludwig Weckbach and Prof Barbara Walzog, of Munich’s Ludwig Maximilian University, was recently reviewed by Nature Reviews Cardiology.

Ja! Ja!

The studies to date have been based on cardiac biopsies from 14 autoimmune myocarditis patients and mice induced with the disease.

Between December 2015 and September 2018, Cellmid also issued positive updates relating to other inflammatory and autoimmune ailments, including chronic kidney disease and experimental autoimmune encephalitis.

In July 2017, Cellmid proclaimed that its midkine antibodies showed “anti-metastatic and anti-tumor benefits” for melanomas.

As a result, Cellmid plans to explore whether the midkine antibodies will not only improve myocarditis induced by the cancer drugs, but also have a direct anti-cancer action by limiting the spread of primary tumors to other organs.

Cellmid says: “The common feature of these studies is that blocking midkines modifies the behavior of immune and inflammatory cells that perpetuate the destructive tissue injury and organ dysfunction associated with several chronic diseases.”

Cellmid now plans to validate its pre-clinical work further mouse-based work.

“We will come out with a single indication but we haven’t decided on that yet,” Ms Halasz says.

Finances and performance

Cellmid is making hair-raising progress with global sales of its Évolis elixirs, with December half sales growing to \$3.6 million (11.6 percent higher year on year).

In the month of December, Cellmid made a \$278,000 profit, the first month of profitability.

As a guide to the revenue trajectory, Cellmid posted \$5.65 million of consumer health revenue in the 2017-'18 year, up 25.5 percent. The company also lost \$3.73 million in that year.

The ‘official’ December quarter numbers show receipts of \$1.1 million, down 24 per cent. The company attributes this decline to the timing of QVC Japan’s promotional ‘million day event’ which saw strong sales. This revenue was due in January and should lead to a “robust” March quarter.

As of December 31, Cellmid has receivables of \$1.5 million and a cash balance of \$5.4 million (down from \$9.2 million in the previous quarter).

During the quarter the company repaid a \$2.0 million loan facility from specialist fund Platinum Road, which was just as well given the attached 12 percent interest.

In June 2018, the company raised \$9 million in a placement.

On a bum note, Cellmid last year lost a legal stoush against its former ad agent Ikon Communications.

The matter ended up in the New South Wales Supreme Court after Ikon sued for unpaid bills. In a counter claim, Advangen alleged non-performance from the admen.

Ultimately it was a case of Ikon one, Cellmid nil, as His Honor Justice Michael Ball sided with the ponytails and awarded the agency \$939,000, plus interest.

Accounting for a 20:1 share consolidation in early 2018, Cellmid shares have traded in a 10-year range of 86 cents (October 2013) and 20 cents (March 2009). Over the last 12 months they've traded between 57 cents (May 2018) and 25 cents (December 2018).

Dr Boreham's diagnosis:

The demerger decision means Cellmid should emerge as a more definitive consumer health company, with no risk of the profits being diverted to speculative drug programs.

For investors that prefer the clinical side, it's not clear at this stage if they will be allowed any ongoing exposure to that part of the business.

Cellmid's drugs and consumer health focus draws loose parallels with the flagging Phosphagenics, which flogged cosmetics while also developing its transdermal drug delivery technology. Of course, Phosphagenics had a well-aired problem called Esra, but investors never really knew whether the company was Arthur or Martha.

Luckily - and with apologies to Julie Andrews - Cellmid doesn't have a Problem Like Maria to solve, although the company is mitigating "founder risk" with some recent sales and marketing hires.

It's hard to know how much of Cellmid's \$20 million-ish market cap can be attributed to the hair loss side, but given the early stage of the clinical stuff we would guess it's the lion's share.

Cellmid's register includes no fewer than 10 institutions including Washington H Soul Pattinson, backer of chemist-shop owner Australian Pharmaceutical Industries.

Cellmid also has an enthusiastic supporter in Dennis Eck, who ran that little retailer called Coles between 1997 and 2001. Eck joined the Cellmid register in December 2017, became a director in March 2018 and late last year lifted his stake to 6 per cent via a \$9m share placement.

An 'eck of a commitment, one could say.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Given he has a full thatch; his follicular challenges are limited to helmet hair and bad hair days.

PHARMAXIS

Pharmaxis says it has dosed the first of 56 subjects in a phase I trial of an anti-fibrotic lysyl oxidase (LOX) inhibitor compound for pancreatic cancer.

Pharmaxis said the double-blind, placebo-controlled study would have two stages, a single ascending dose stage in 40 healthy subjects in five groups, and a multiple ascending dose stage in 16 healthy subjects in two groups, with each group taking a different dose or placebo for seven days, with results expected in June 2019.

The company said it would use an oral once-a-day drug to inhibit all lysyl oxidase family members, LOX and LOXL1, LOXL2, LOXL3 and LOXL4.

The company said it cleared pre-clinical safety and toxicity studies in 2018 and showed “significant reductions in in-vivo models of kidney fibrosis, lung fibrosis, myelofibrosis and pancreatic cancer”.

Pharmaxis said the drug would be suitable to treat severe fibrosis, as well as cancer with prominent stroma or fibrotic metastatic niches, but would initially be developed for pancreatic cancer.

Pharmaxis chief executive officer Gary Phillips said that “moving a new drug into the clinic for the first time is always a significant milestone and this will be the fourth time we have accomplished this during the last five years”.

“Our current plan is that a successful phase I trial outcome would be the launchpad for a quick transition into cancer patients and to that end we are already in discussion with key opinion leaders and working on potential trial designs,” Mr Phillips said.

Pharmaxis was up one cent or 3.9 percent to 26.5 cents.

CORRECTION: PRO MEDICUS

Last night’s edition reported that part of the Pro Medicus \$25,441,000 revenue for the six months to December 31, 2018 came from the recently-signed \$27 million seven-year contract with Boston’s Partners Healthcare.

In fact, revenue from Partners is expected over the coming years and the current figure related to existing contracts for its Visage 7 technology, radiology information system, picture archiving and communication system and electronic health products.

The mistake was made by the Half-Yearly Report sub-editor who has been sent to Biotech Daily’s contract optician and has been counselled to read complex reports more carefully. We apologize unreservedly for the error.

Pro Medicus fell 28 cents or 1.9 percent to \$14.37 with 156,064 shares traded.

MAYNE PHARMA

Mayne Pharma says revenue for the six months to December 31, 2018 was up 12.8 percent to \$274,371,000, taking last year’s \$173.1 million loss to a \$1,001,000 profit.

Mayne said revenue reflected a greater contribution from speciality brands, cost savings from bringing manufacturing in-house and sales of its speciality products fosfomycin trometamol, or Monulrol, silodosin, or Urorec, Fabior, Sorilux, Doryx and Suba-itraconazole and morphine sulphate.

The company said last year’s diluted loss per share of 11.9 cents turned to diluted earnings per share of 0.2 cents for the six months to December 31, 2018, with net tangible assets per share up 2.6 percent to 8.0 cents and the company had cash and cash equivalents of \$96,173,000 at December 31, 2018 compared to \$55,957,000 at December 31, 2017.

Mayne fell four cents or five percent to 76 cents with 16.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the twelve months to December 31, 2018 was up 175.7 percent to \$69,456,914, taking the previous loss to a net profit of \$37,564,356. Universal Biosensors said revenue was from a one-off lump sum payment for quarterly service fees of \$US31,503,880 (\$A44,635,704) from Johnson & Johnson's Lifescan which it received on February 18, as well as \$21,378,404 from the manufacture of test strips for Lifescan during 2018.

The company said that it received \$1,672,321 from test strips for Siemen's Xprecia Stride coagulation analyzer and \$1,770,485 from its Canadian subsidiary HRL for calibration services (BD: Feb 18, 2019).

Universal Biosensors said that diluted earnings per share was up from 0.0 cents to 21.0 cents for the twelve months to December 31, 2018, with net tangible assets per share up 314.3 percent from 7.0 cents to 29.0 cents.

The company said that it had cash and cash equivalents of \$11,797,789 at December 31, 2018 compared to \$26,259,918 at December 31, 2017.

Universal Biosensors fell one cent or 4.3 percent to 22.5 cents.

ELLEX MEDICAL LASERS

Ellex says revenue for the six months to December 31, 2018 was up 9.3 percent to \$41,630,000 with net loss after tax down 0.4 percent to \$2,699,000.

Ellex chief executive officer Tom Spurling told Biotech Daily that he expected the loss for the full year to June 30, 2019 to be an improvement on last year's loss.

Ellex said revenue was driven by sales of the Retinal Rejuvenation Therapy (2RT) laser for intermediate age-related macular degeneration and its Itrack laser for glaucoma, as well as its ultrasound diagnostics for eye diseases.

The company said that net tangible assets per share was down 8.1 percent to 34 cents, while diluted loss per share was 1.88 cents at December 31, 2018 compared to diluted loss per share of 2.16 cents for the previous period.

Ellex said that it had cash and cash equivalents of \$19,682,000 at December 31, 2018 compared to \$25,195,000 at December 31, 2017.

Ellex fell three cents or 4.9 percent to 58 cents with 1.1 million shares traded.

MEDLAB CLINICAL

Medlab says revenue for the six months to December 31, 2018 was up 17.0 percent to \$2,306,934 with net loss after tax up 59.9 percent to \$3,773,811.

Medlab said that including the \$772,708 Federal Research and Development Tax Incentive, the revenue for the half year to December 31, 2018 was up 26.3 percent to \$3,079,012.

The company said that revenue came from its NRGBiotic, vitamins, minerals and supplements business as well as from sales of its cannabis products through the Australian Therapeutic Goods Administration special access scheme.

Medlab said that diluted loss per share was up 41.5 percent from 1.23 cents to 1.74 cents and it had cash and cash equivalents of \$16,116,190 at December 31, 2018 compared to \$789,691 at December 31, 2017.

Medlab was unchanged at 38 cents.

OBJ

OBJ says it has a new licence with Procter & Gamble for the fourth generation of its Olay magnetic infuser.

OBJ said its magnetic infuser would expand Olay's Magnemask, part of its skin care product line that used the company's magnetic microarray technology.

The company said Magnemask provided individual skin care treatments when combined with its sheet mask and jar mask formulations.

OBJ said the launch date was yet to be confirmed.

OBJ was up 0.1 cents or five percent to 2.1 cents with 2.4 million shares traded.

FACTOR THERAPEUTICS

Factor shareholders will vote to replace chair Dr Cherrell Hirst and directors Timothy Hughes and John Michailidis with Bruce Lane and David Sanders.

Earlier this month, Factor said it received a Section 249D of the Corporations Act 2001 notice from Pura Vida Energy NL and Freshero Pty Ltd. (BD: Feb 5, 2019).

The following day the dissident investors said they had increased their holding to 155,078,397 shares and in a substantial shareholder notice signed by David Grant Sanders said the investors were the Abu Dhabi-based Steven Scott Day and the Perth, Western Australia based Pura Vida, Freshero, Canadian Nickel Corp, Alitime Nominees Pty Ltd for the Honeyham Family account, David Charles Neesham and Pamela Christine Neesham, (BD: Feb 7, 2019).

Today the company said "the resolutions have not been endorsed by, and are not supported by, the directors who have considered the resolutions".

Factor said the meeting would also vote to ratify the prior issue of 125,150,345 shares at 0.2 cents each, renew the 10 percent placement capacity, approve the remuneration report and re-elect director Mr Hughes.

The meeting will be held at McCullough Robertson Lawyers, Level 11, 66 Eagle Street, Brisbane, on March 27, 2019, at 10.30am (AEST).

Factor was unchanged at 0.3 cents with 1.5 million shares traded.

REDHILL BIOPHARMA

Israel's Redhill says it has appointed director Rick Scruggs as chief operating officer responsible for leading its US commercial operations.

Redhill said Mr Scruggs would, promote four gastro-intestinal products and prepare the potential launch of Talicia, or RHB-105, for Helicobacter pylori infection.

In 2010, Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, the company said Mr Scruggs had more than 25 years' experience in the pharmaceutical industry with Oclassen Pharmaceuticals and Watson Pharmaceuticals, before he joined Salix Pharmaceuticals and was appointed a Redhill director in 2016.

On the Nasdaq, Redhill fell 42 US cents or 5.15 percent to \$US7.73 (\$A10.89) with 127,959 shares traded.

MEDIBIO

Medibio says director Andrew Maxwell has resigned “due to his family commitments and work load related to other endeavors”.

Medibio said company secretary Melanie Leydin was appointed an interim director with chief executive officer David Kaysen promoted to executive chairman, replacing interim chairman Peter Carlisle who would continue as lead independent director.

Medibio fell 0.1 cents or five percent to 1.9 cents.

NOVITA HEALTHCARE

Novita says it has appointed Stephen Denaro as its company secretary, replacing John Osbourne.

Novita said Mr Denaro had acted as company secretary and chief financial officer for a number of public companies and with accountancy firms in Australia and the UK.

Mr Denaro was appointed Admedus company secretary in November 2018 and was formerly with Alchemia and Impedimed.

Novita was untraded at 2.6 cents.