

Biotech Daily

Monday February 3, 2020

Daily news on ASX-listed biotechnology companies

- * BDI-40: YTD UP 125%, BIG CAPS 62%, ASX 20%, NBI 4% - JANUARY BDI-40 UP 13%, BIG CAPS 12% - ALL RECORDS BROKEN * TODAY: ASX, BIOTECH DOWN: OPTISCAN UP 13%; IMPEDIMED DOWN 12% * ADHERIUM COMPLETES \$5.4m RAISING * PAINCHEK RECEIVES \$798k FEDERAL R&D TAX INCENTIVE * INVION TO SUPPLY SKIN CARE PRODUCT TO CHINA'S PAVAY * MESOBLAST COMPLETES US FDA GVHD APPLICATION * TGA REVIEWS CLINUVEL SCENESSE FOR EPP * PYC ADDS 6 RETINAL DRUG DELIVERY PROGRAMS * CRONOS TAKES 51% OF CANNADOC HEALTH * INVICTUS EURO PATENT FOR TOCOTRIENOLS DELIVERY * ZELIRA REQUESTS CAPITAL RAISING TRADING HALT * ELIXINOL RECEIPTS DOWN 8% TO \$33m, ASSET SALES * G MEDICAL RECEIPTS UP 106% TO \$8.1m * CANN H1 RECEIPTS \$1.6m: LESS THAN 2 QUARTERS CASH * OPYL H1 RECEIPTS DOWN 3% TO \$464k; LESS THAN 2 QUARTERS CASH * NEUROTECH H1 RECEIPTS DOWN 58%; LESS THAN 2 QUARTERS CASH * RESPIRI HAS LESS THAN TWO QUARTERS CASH * MEDIGARD HAS LESS THAN ONE QUARTER CASH * PHILLIP THEMATIC TAKES 6.7% OF ADHERIUM * JAMES MIDDLEWEEK INCREASES. DILUTED BELOW 5% IN ADHERIUM * CORRECTION: CRYSTAL AMBER HAS 73% OF GI DYNAMICS * HERAMED APPOINTS ALEXANDER RADKE US EXECUTIVE * RESPIRI APPOINTS LUDEKENS, VAN HOOF, DR SHIRAZI EXECUTIVES
- * NEUROSCIENTIFIC APPOINTS ABBY MACNISH AS CO-CO SEC

MARKET REPORT

The Australian stock market fell 1.34 percent on Monday February 3, 2020, with the ASX200 down 93.9 points to 6,923.3 points. Ten of the Biotech Daily Top 40 stocks were up, 26 fell, and four traded unchanged. All three Big Caps fell.

Optiscan was the best, up 0.4 cents or 12.9 percent to 3.5 cents, with 103,755 shares traded. Medical Developments climbed 8.1 percent; Orthocell, Pro Medicus and Uscom improved four percent or more; Avita and Genetic Signatures were up more than three percent; Universal Biosensors rose 2.8 percent; with Polynovo up 1.1 percent.

Impedimed led the falls, down 1.5 cents or 11.5 percent to 11.5 cents, with 1.4 million shares traded. Oncosil lost 10.3 percent; Osprey retreated eight percent; Cyclopharm and Ellex were down more than six percent; Next Science, Patrys and Proteomics were down more than five percent; Antisense, Clinuvel, Compumedics, Paradigm and Resmed fell more than four percent; Immutep, Imugene, Kazia, LBT, Neuren and Prescient were down three percent or more; Resonance and Starpharma shed more than two percent; Amplia, Cynata, Mesoblast, Nanosonics and Volpara were down more than one percent; with CSL, Cochlear and Opthea down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Australian Biotech started the year by breaking all previous records, again.

The Biotech Daily Top-40 Index (BDI-40) climbed a further 13.1 percent in January, to a record collective market capitalization of \$16,788 million (unadjusted, raw data), with the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) up 12.4 percent to a collective market capitalization of \$190,721 million.

The sector's best companies are worth more than \$200 billion. A further 100 companies have market capitalizations ranging from \$2 million to \$750 million.

The benchmark S&P ASX200 improved 5.0 percent in January, while the Nasdaq Biotechnology Index (NBI) fell 5.6 percent.

For the 12 months to January 31, 2020, the BDI-40 was up 125.1 percent, the three Big Caps rose 61.6 percent, the ASX200 improved 19.6 percent, with the NBI up 3.6 percent.

In January, Resmed climbed 14.4 percent to \$36,014 million, CSL was up 12.6 percent to \$140,926 million, with Cochlear up 6.0 percent to \$13,781 million.

Twenty-one BDI-40 companies were up in January, 11 by more than 10 percent and four up more than 40 percent in 31 days; while 18 fell, with eight losing more than 10 percent.

Nanosonics was up a modest \$147 million or 7.7 percent, to re-join Pro Medicus in the \$2 billion club, but Polynovo was January's best, up 49.8 percent to \$1,950 million – just outside the \$2 billion club and needing to climb 22.5 cents to \$3.025 to be included.

Paradigm was up 44.0 percent to \$831 million, followed by Mesoblast (42.9%), Next Science (42.8%), Immutep (29.7%), Amplia (25%), Opthea (15.5%), Oncosil (14.95%), Medical Developments (14.5%), Neuren (14.1%) and Genetic Signatures (12.2%).

Pharmaxis led the falls, down 28.6 percent to \$45 million and less than half its value a year ago, followed by Impedimed down 21.4 percent, Optiscan (16.7%), Compumedics (16.2%), Osprey (15.4%), Resonance (14.6%), Antisense (13.2%) and Prescient (12.5%).

Outside the Top 40, Alcidion is hovering around the \$200 million mark. Biotron has returned to favour, Mach7 and Medadvisor improved in January and for the year to January 31, with Cogstate, Palla Pharma and Zelira recovering.

On the Nasdaq, Eyepoint (formerly Psivida) climbed 26.9 percent to \$302 million Queensland's Protagonist improved 8.8 percent to \$297 million, while Israel's Redhill with Australian assets fell 8.2 percent to \$279 million.

Cannabis Corner straightened up 21.2 percent in January from the historic low of \$869 million to \$1,052 million, but still 45 percent down from the July 31 high of \$1,913 million. Cann Group bounced back 104.4 percent from \$90 million to \$184 million, Elixinol was up 35.9 percent to \$106 million – a long way from its \$587 million peak. Note the volatility.



BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2020- Adjusted

Big Caps \$m (Cochlear, CSL, Resmed) Jan 31, 2017 – Jan 31, 2020



ADHERIUM

Adherium says that its rights issue at three cents a share has raised the full amount of \$5.4 million, triggering the conversion of notes which previously raised \$2.9 million. Adherium company secretary Rob Turnbull told Biotech Daily that in August and November 2019 Adherium issued secured notes for \$2.9 million, converting should the company raise \$2.5 million.

Mr Turnbull said that following applications for \$526,000 in the rights issue the company placed all of the \$4.9 million shortfall.

Adherium fell 0.4 cents or 10 percent to 3.6 cents.

PAINCHEK

Painchek says it has received \$798,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Painchek said the rebate related to research and development expenditure for the year to June 30, 2019.

Painchek was up two cents or 14.3 percent to 16 cents with 7.1 million shares traded.

INVION

Invion says it will be paid \$250,000 to manufacture and supply active dermatological ingredients to the Shanghai-based Guilin Pavay Biotechnology.

Invion said the deal, through its subsidiary, Epitech Dermal Science, included an unspecified amount of ongoing services fees for the research, development and production specifications for the Australia-made dermatological ingredients. Invion was unchanged at 1.2 cents with 1.1 million shares traded.

MESOBLAST

Mesoblast says it has submitted the last module of its US biologics licence application for remesterncel-L for paediatric steroid-refractory acute graft versus host disease.

Mesoblast said the application to the US Food and Drug Administration for remestemcel-L, or Ryoncil (formerly known as Prochymal when it was acquired from Osiris in 2013), covering quality control and manufacturing (BD: Oct 11, 2013).

The company said it had requested priority review under the product candidate's existing fast track designation.

Mesoblast said that, if approved, Ryoncil was expected to launch in the US in 2020. Mesoblast chief executive Prof Silviu Itescu said the completed application was "a major corporate milestone for Mesoblast".

Mesoblast fell four cents or 1.3 percent to \$2.96 with 2.9 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the Australian Therapeutics Goods Association will take about 150 days to review its application for Scenesse for erythropoietic protoporphyria (EPP).

Last October, Clinuvel said that the US Food and Drug Administration had approved Scenesse for EPP (BD: Oct 9, 2019).

In 2014, Clinuvel said that the European Commission had ratified the European Medicines Agency recommendation for market approval of Scenesse for EPP.

Clinuvel fell \$1.15 or 4.15 percent to \$26.55 with 185,585 shares traded.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says it has added six new programs developed with Perth's Lions Eye Institute to its retinal drug development pipeline.

PYC said the programs were developed by its majority-owned joint venture with Lions Eye, Vision Pharma Pty Ltd, with "a subset expected to reach the [investigational new drug application]-enabling stage-gate by [the] end of 2020".

The company said the expansion showed the benefit of combining the Lions Eye understanding of retinal diseases with its ability to design and deliver RNA therapeutics". PYC said the target indications were confidential while it finalized the intellectual property protection for the programs and it was exploring other areas where it could "leverage its growing capability in precision medicines".

The company said that an animal model of Duchenne muscular dystrophy had been used to evaluate the ability to deliver an antisense oligonucleotide to a muscle cell using one of its cell penetrating peptides, the processing of tissue samples was pending and the results were expected by July 2020.

PYC was unchanged at 5.8 cents with 1.6 million shares traded.

CRONOS AUSTRALIA

Cronos says it has paid \$300,000 to acquire 51 percent of Melbourne's Cannadoc medical clinic business for medical marijuana, effective from January 1, 2020.

Cronos said it would pay Cannadoc founders Dr David Feng and Kevin Brabazon \$300,000 in cash and they "may also be entitled to receive two further earn out payments on the first and second anniversaries of completion".

The company said that the payments would equal 51 percent of five times the future earnings before interest, taxation, depreciation and amortization (Ebitda) of Cannadoc, with \$300,000 to be deducted from the first earn out payment.

Cronos said that the founders were issued 500,000 performance rights each vesting on September 1, 2023, pending conditions.

The company said Cannadoc was "a growing medical practice" having been established about one year ago and it would work with the founders to expand the business, which included engaging additional medical practitioners and opening further clinics.

Cronos said it would provide a secured loan facility of up to \$1 million to Cannadoc for working capital and to expand the business.

Cronos fell two cents or 10 percent to 18 cents.

INVICTUS BIOPHARMA

Invictus says the European Patent Office has issued granted a patent for the transmucosal delivery of tocotrienols.

Invictus said the patent, titled 'Transmucosal Delivery of Tocotrienol' would provide commercial rights until November 13, 2033.

The company said the patent covered the transmucosal delivery of tocotrienols for promoting the treatment or prevention of post-exercise muscle soreness, delayed onset muscle soreness, and improving exercise endurance and performance.

Invictus said the patent claims were also directed at reducing inflammation, cardiac fibrosis and treatment of cancer.

Invictus executive chairman Dr Glenn Tong said the EU patent grant was "another positive step forward" for the company.

Invictus is a public unlisted company.

ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Zelira has requested a trading halt "pending an announcement by the company in relation to a capital raising".

Trading will resume on February 5, 2020 or on an earlier announcement. Zelira last traded at 6.5 cents.

ELIXINOL GLOBAL

Elixinol says receipts from customers for the year December 31, 2019 were down 8.1 percent to \$33,102,000 compared to the previous corresponding period.

Elixinol said that customer receipt for the three months to December 31 fell 40.8 percent to \$6,705,000.

The company said it had cash and cash equivalents of \$20,373,000 at December 31 and expected to spend \$13,231,000 for the three months to March 31, 2020.

Elixinol chief executive officer Stratos Karousos said that the company's revenue for the six months to December 31, 2019 was "disappointing".

"We have taken steps to reduce our cash burn to account for the delayed development of the hemp derived [cannabidiol] market, in particular in the US, Europe and [the] UK," Mr Karousos said.

In a separate announcement, the company said it would sell its subsidiary Hemp Foods Australia to China's Shanghai Shunho New Materials Technology Co, through its subsidiary Yunnan Biological Pharmaceutical Co for \$500,000 by April 2020.

Elixinol said the sale was conditional on a three-year licencing agreement which would appoint Shunho as manufacturer and distributer of Elixinol branded hemp-based cannabidiol (CBD) products in China, Hong Kong, Taiwan and Macau.

The company said it expected the sale to have a "non-cash impairment charge" of about \$12.5 million but would "improve future operating cash flow of the group and allow the Company to focus its capital and resources solely on its hemp derived CBD products business".

Elixinol said it would sell land and assets owned under its subsidiary Nunyara Pharma, which would "give rise to a non-cash impairment charge of \$4.8 million".

Elixinol fell 14 cents or 18.2 percent to 63 cents with 3.9 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says customer receipts for the year to December 31, 2019 were up 105.6 percent to \$US5,422,000 (\$A8,102,000) compared to the previous corresponding period. G Medical said it had receipts from customers for the three months to December 31, 2019 were up 4.2 percent to \$1,404,000.

The company said that the majority of customer receipts were from sales of its "remote independent diagnostics testing facility services".

G Medical said it had cash and cash equivalents at December 31, 2019 of \$US93,000 and a cash facility of \$US25,052,000.

G Medical fell 1.5 cents or 13.0 percent to 10 cents with 1.1 million shares traded.

CANN GROUP

Cann says it has receipts from customers of \$1,660,000 for the six months to December 31, 2019, compared to \$3,000 in the previous corresponding period.

Cann said that customer receipts for the 12 months to June 30, 2019 were \$1,466,000. The company said it had cash and cash equivalents of \$8,093,000 at December 31 and expected to spend \$6,430,000 for the three months to March 31, 2020.

Cann said it would implement cost cutting measures, including a 25 percent reduction of staff.

Cann fell nine cents or seven percent to \$1.20 with 2.9 million shares traded.

OPYL (FORMERLY SHAREROOT)

Opyl says receipts from customers for the six months to December 31, 2019 were down 3.1 percent to \$464,000 compared to the previous corresponding period.

Opyl said receipts from customers for the three months to December 31, 2019 increased 45.85 percent to \$264,000.

The company said it had cash and cash equivalents of \$464,000 at December 31 and expected to spend \$726,749 for the three months to March 31, 2020.

Opyl fell two cents or 13.3 percent to 13 cents.

NEUROTECH INTERNATIONAL

Neurotech says receipts from customers for the six months to December 31, 2019 were down 58.0 percent to \$58,000 compared to the previous corresponding period. Neurotech said that customer receipts for the three months to December 31 were down 10 percent to \$36,000.

The company said it had cash and cash equivalents of \$186,000 at December 31, 2019 with a \$96,000 loan facility, and an expected cash burn for the three months to March 31 of \$239,000.

Neurotech was unchanged at 0.9 cents.

<u>RESPIRI</u>

Respiri says it has cash and cash equivalents of \$1,091,000 at December 31, 2019 and expects to spend \$1,211,000 for the three months to March 31, 2020. Respiri fell 0.7 cents or 8.2 percent to 7.8 cents.

MEDIGARD

Medigard says it had cash and cash equivalents of \$3,000 at December 31, 2019 and expects to spend \$41,000,000 for the three months to March 31, 2020. Medigard was suspended at two cents.

ADHERIUM

Singapore's Phillip Thematic Fund says it has become a substantial shareholder in Adherium with 33,333,333 shares or 6.71 percent of the company.

Phillip Thematic said that on January 30, 3019 it bought the shares for \$1,000,000 or three cents a share.

Adherium raised \$5.4 million in a rights issue at three cents a share (see above).

ADHERIUM

James Middleweek says he has increased his holding in Adherium from 8,997,000 shares (5.39%) to 15,925,445 shares, but has been diluted below five percent.

The Perth-based Mr Middleweek said that between July 19, 2019 and January 29, 2020 he bought, sold, transferred and converted shares at prices ranging from 2.3 cents a share to four cents a share.

<u>GI DYNAMICS</u>

Crystal Amber Fund has corrected its recent substantial shareholding in GI Dynamics and says it holds 1,337,639,375 shares or 73.10 percent of the company. Last week, Crystal Amber Fund said it has increased its holding in GI Dynamics from 1,305,918,587 shares (72.62%) to 1,567,504,005 shares (76.10%).

GI Dynamics was untraded at 1.3 cents.

<u>HERAMED</u>

Heramed says it has appointed the New York-based Alexander Radke as general manager of US operations.

Heramed said Mr Radke was previously a senior vice president at Signal Analytics, and an executive at Northwell Health.

Heramed fell one cent or 6.1 percent to 15.5 cents with 1.4 million shares traded.

<u>RESPIRI</u>

Respiri says it has appointed chief research officer Dr Samaneh Sarrah Shirazi, Philippe Ludekens, and technology strategy advisor Marc van Hoof as executives.

Respiri said Dr Shirazi had been the company's chief research officer for three years and had 10 years' experience in biomedical signal processing, with specialist skills in breath sound analysis and held a Doctor of Philosophy from Canada's University of Manitoba. Respiri said Mr Ludekens was appointed general manager of commercial operations. The company said Mr Ludekens had more than 25 years of experience in life sciences, and was previously a senior director at Gilead Sciences.

Respiri said Mr van Hoof had worked for the company on a consultancy basis and had previously "started the first internet data centre in Australia".

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Abby Macnish as co-company secretary. Neuroscientific was unchanged at 17 cents.

Biotech Daily Top 40 with Market Capitalization At January 31, 2020

Company \$Am	Feb-19	Jan-20	Feb-20
Cochlear	11,163	12,996	13,781
CSL	88,201	125,160	140,926
Resmed	18,624	31,485	36,014
BDI-20		- ,	
Avita	252	1,366	1,355
Clinuvel	1,033	1,406	1,330
Compumedics	60	142	119
Cyclopharm	82	92	94
Cynata	144	107	112
Ellex	86	111	122
Genetic Signatures	84	147	165
Immutep	98	101	131
Medical Developments	247	574	657
Mesoblast	586	1,116	1,595
Nanosonics	1,002	1,908	2,055
Neuren	131	248	283
Opthea	191	802	926
Paradigm	168	577	831
Pharmaxis	103	63	45
Polynovo	450	1,302	1,950
Pro Medicus	1,255	2,323	2,483
Starpharma	399	451	434
Telix	157	393	375
Volpara	194	399	394
Second 20			
Actinogen	60	40	39
Alterity (Prana)	23	17	18
Amplia (Innate)	6	4	5
Antisense	17	38	33
Dimerix	14	24	25
Impedimed	85	84	66
Imugene	65	138	143
Kazia	29	43	46
LBT Innovations	16	38	37
Next Science	179	339	484
Oncosil	114	107	123
Optiscan	20	18	15
Orthocell	12	90	88
Osprey	54	13	11
Patrys	24	21	20
Prescient	15	24	21
Proteomics	28	25	25
Resonance	29	96	82
Universal Biosensors	41	34	32
Uscom	17	18	19

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alterity, Amplia, Cynata, Mesoblast, Nanosonics, Neuren, Patrys, Polynovo, Telix, Volpara and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in other biotechnology companies: <u>http://www.australianethical.com.au/who-we-invest-in</u>. These holdings are liable to change.

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