

Biotech Daily

Monday September 2, 2019

Daily news on ASX-listed biotechnology companies

- * AUGUST BDI-40 UP 13%, BIG CAPS UP 3%, ASX200 DOWN 3%
 - OPTHEA UP 341%, POLYNOVO 31%; OSPREY DOWN 32%, CLINUVEL 21%
- * TODAY: ASX, BIOTECH DOWN: OPTHEA UP 19%; CYCLOPHARM DOWN 8%
- * COMPUMEDICS RECORD REVENUE \$41.5m. PROFIT UP 43.2% TO \$4m
- * IQ3 REVENUE DOWN 5% TO \$6.5m, LOSS from \$1k TO \$1m
- * PHARMAUST REVENUE UP 32.5% TO \$4.4m, LOSS DOWN 36% TO \$1.6m
- * G MEDICAL H1 REVENUE UP 191% TO \$4.3m, LOSS DOWN 20% TO \$10m
- * CARDIEX REVENUE DOWN 2.5% TO \$3.9m, LOSS UP 1% TO \$3m
- * IMMURON REVENUE UP 30% TO \$2.4m, LOSS UP 54% TO \$4.6m
- * THC H1 REVENUE UP 67% TO \$2.1m, LOSS UP 80% TO \$5.8m
- * STEMCELL REVENUE UP 437% TO \$1.6m, LOSS DOWN 37% TO \$2.1m
- * US FDA CLEARS OVENTUS O2VENT OPTIMA
- * ANTISENSE, REGULATORS MEET ON ATL1102 FOR DMD
- * AMPLIA RECEIVES 1kg AMP945 FOR TRIAL
- * MEMPHASYS RECEIVES \$1.1m FEDERAL R&D TAX INCENTIVE
- * NEUROSCIENTIFIC EXPECTS \$2m OFF-SHORE R&DTI OVER 3 YEARS
- * DIRECTOR ANDREW KROGER TAKES 38% OF CRYOSITE
- * ALLAN GRAY REDUCES TO 15% OF IMPEDIMED
- * MEDIBIO: CLARIFICATION
- * ADMEDUS REQUESTS 7th FUNDING SUSPENSION EXTENSION
- * GENETIC TECHNOLOGIES APPOINTS NICK BURROW DIRECTOR

MARKET REPORT

The Australian stock market fell 0.38 percent on Monday September 2, 2019, with the ASX200 down 24.8 points to 6,579.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Opthea was the best, up 65 cents or 19.4 percent to \$4.00, with 1.1 million shares traded. Neuren climbed 12.6 percent; Prescient was up 9.3 percent; Amplia improved 6.7 percent; LBT was up five percent; Polynovo, Starpharma and Volpara improved more than four percent; Alterity and Next Science were up more than three percent; Nanosonics rose 2.7 percent; with Cynata and Paradigm up by less than one percent.

Cyclopharm led the falls, down 10.5 cents or 7.75 percent to \$1.25, with 9,123 shares traded. Compumedics lost 5.6 percent; Dimerix, Ellex and Patrys fell more than four percent; Kazia and Proteomics were down more than three percent; Antisense, Avita, Oncosil, Orthocell, Pro Medicus, Telix and Universal Biosensors shed two percent or more; Cochlear and Medical Developments were down more than one percent, with Clinuvel, CSL, Genetic Signatures, Mesoblast and Resmed down less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The graphs below tell it all. The adjusted Biotech Daily Top 40 Index (BDI-40) is at a record high, and since the Global Financial Crisis all-time low, is just shy of a "10-bagger", up from \$2,087 million at December 31, 2008, to an adjusted \$18,413 million on Friday.

The unadjusted BDI-40 was up 13.1 percent in August, to a collective market capitalization of \$14,288 million, the AX200 retreated 3.1 percent to 6,604 points, while the Nasdaq Biotechnology Index (NBI) fell a further 2.6 percent.

In August, the collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) was up 3.2 percent to a record \$148,614 million, despite Cochlear slipping 3.1 percent to \$12,325 million. Resmed was up 8.6 percent to \$29,579 million and CSL was up 2.6 percent to \$106,710 million.

While 24 of the BDI-40 stocks fell, with just 11 up and five unchanged, the falls were mostly in the much smaller Second 20. The Top 20 boasts four companies worth more than \$1 billion each (see last page), including Pro Medicus at \$3.8 billion, along with Avita, Mesoblast and Opthea most of the way to \$1 billion each.

Opthea was the clear percentage best, on positive phase II Wet AMD trial results (BD: Aug 7, 2019), up 340.5 percent and adding \$647 million to its market capitalization, but Pro Medicus added \$654 million to the indices. Polynovo quietly rose \$330 million in August, up 31.2 percent to \$1,388 million, followed by Neuren (24.2%), Pro Medicus (20.5%), Nanosonics (up \$258m; 15.6%), Resonance (14.6%) and Immutep (14.1%).

Osprey continued to struggle, down just \$10 million but 32.3 percent to \$21 million. Clinuvel retreated \$340 million or 21.4 percent to \$1,252 million on the terrible news that its revenue was only up 22 percent to a record \$31 million, with a record net profit after tax up 37 percent to \$18 million - and it paid a dividend. That's not very biotechy, is it?

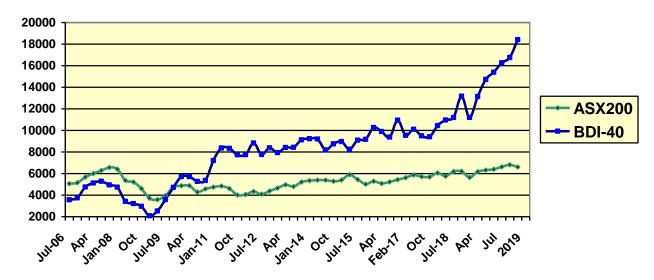
Uscom also fell on good end-of-year news, down 21.1 percent to \$15 million, followed by Pharmaxis (18%), Optiscan (16.7%), Next Science (16.4%), Starpharma (16.4%), Medical Developments (16.3%), Imugene (15.6%) and Proteomics (12.0%).

Cannabis Corner lost \$300 million or 15.7 percent to \$1,613 million, with 13 of the 18 falling, two unchanged and just three higher. Elixinol lost \$169 million or 36.9 percent.

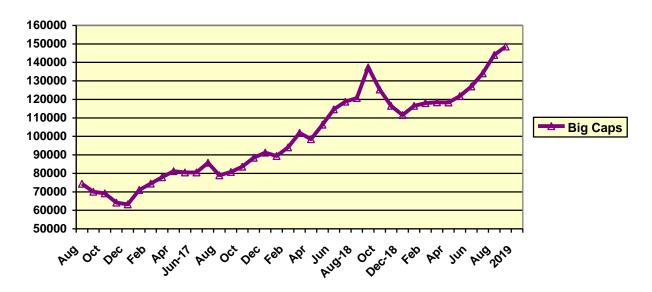
In the US, Queensland's Protagonist jumped 34.7 percent to \$508 million, Israel's Redhill with Australian assets was up 16.4 percent to \$319 million, Eyepoint (Psivida) was up 10.2 percent to \$237 million, with Vaxart (Biota) up 6.25 percent to \$17 million.

Outside the BDI-40, Painchek was up 523.3 percent from \$30 million a year ago to \$187 million, Alcidion climbed 321.2 percent for the year, Bluechiip put on 64.2 percent to \$87 million in August, Mach7 passed the \$100 million barrier and Mayne Pharma continued its slide, down 15.1 percent to \$712 million for the month and 61.7 percent for the year.

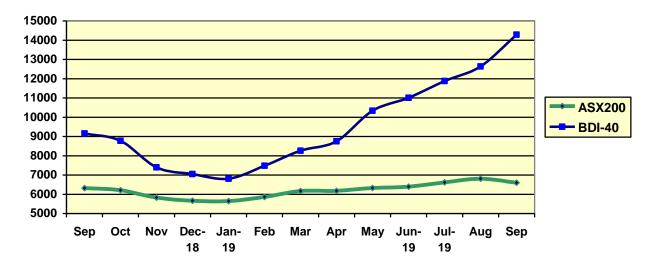
BDI-40 v ASX200 Jun 30, 2006 to Aug 31, 2019- Adjusted



Big Caps \$m (Cochlear, CSL, Resmed) Jul 31, 2016 - Jul 31, 2019



BDI-40 (\$m) v S&P ASX 200 - Aug 31, 2018 - Aug 31, 2019 (current, raw data)



COMPUMEDICS

Compumedics says that revenue for the 12 months to June 30, 2019 rose 12.2 percent to a record \$41,505,000 with net profit after tax up 43.2 percent to \$3,988,000. Compumedics said the record revenue was partly from sales of its Orion Lifespan magneto-encephalography, including its "largest system contract" with the Barrow Neurological Institute, along with sales of its sleep and brain blood flow diagnostic systems doubling in Australia and the US to more than 30 sites, with Chinese sales up 26 percent, and a 17 percent increase for its Germany-based DWL business. Compumedics said net tangible asset backing per share was up 7.4 percent to 11.6 cents, diluted earnings per share improved 43.8 percent to 2.3 cents and it had cash and cash equivalents of \$4,598,000 at June 30, 2018, compared to \$3,906,000 at June 30, 2018. Compumedics fell four cents or 5.6 percent to 68 cents.

IQ3 CORP

IQ3 says that revenue for the 12 months to June 30, 2019 was down 4.7 percent to \$6,160,849, with net loss after tax up 103,339.7 percent from \$1,062 to \$1,098,530. IQ3 said that revenue came its life science corporate finance and advisory services. The company said that net tangible assets per share fell 64.2 percent to 0.57 cents, with diluted loss per share down from 0.0. cents to 1.06 cents and cash and cash equivalents of \$252,995 at June 30, 2019 compared to \$512,927 at June 30, 2018. IQ3 was untraded at 28.5 cents.

PHARMAUST

Pharmaust said that revenue for the year to June 30, 2019 was up 32.5 percent to \$4,365,000, with net loss after tax down 35.9 percent to \$1,617,000.

Pharmaust director Sam Wright told Biotech Daily that the revenue primarily came from its Epichem synthetic and medicinal chemistry subsidiary, which increased its revenue by 74 percent to \$3.8 million for the year to June 30, 2019.

The company said that net tangible assets per share was down 24.6 percent to 1.53 cents, diluted loss per share was down 57.0 percent to 0.74 cents and it had cash and equivalents of \$2,090,625 at June 30, 2019 compared to \$1,875,431 at June 30, 2019. Pharmaust rose three cents or 28.6 percent to 13.5 cents, with 3.9 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says revenue for the six months to June 30, 2019 was up 190.5 percent to \$US2,908,000 (\$A4,321,940) with net loss after tax down 19.6 percent to \$US6,839,000 (\$A10,164,287).

G Medical said that revenue came mostly from sales of its Telerhythmics LLC cardiac diagnostic monitoring service.

G Medical said that basic loss per share fell 24.0 percent to 1.9 US cents and net tangible assets per share fell from 0.002 US cents at June 30, 2018 to negative 0.018 US cents at June 30, 2019.

The company said it had cash and cash equivalents of \$US352,000 at June 30, 2019 compared to \$US3,204,000 at June 30, 2018.

G Medical fell 1.7 cents or 16.2 percent to 8.8 cents, with 1.8 million shares traded.

CARDIEX

Cardiex says revenue for the 12 months to June 30, 2019 fell 2.47 percent to \$3,907,093, with net loss after tax up 0.6 percent to \$2,979,278.

Cardiex said the revenue came from sales of its Xcel for the management of hypertension and related cardiovascular disorders, with revenue in the Americas up by four percent and decreased revenue in Europe and the Asia Pacific region.

The company said that net tangible assets per share was up 11.1 percent to 1.0 cent, with diluted loss per share fell 50 percent to 0.5 cents compared to 1.0 cent at June 30, 2018. Cardiex said it had cash and equivalents of \$4,980,826 at June 30, 2019 compared to \$2,736,517 at June 30, 2018.

Cardiex fell 0.2 cents or 7.4 percent to 2.5 cents, with one million shares traded.

IMMURON

Immuron says revenue for the year to June 30, 2019 was up 29.5 percent to \$2,387,426 with net loss after tax up 53.9 percent to \$4,632,743.

Immuron said that sales of its over-the-counter gastrointestinal and digestive health supplement Travelan had increased in all territories, with record revenues in Australia of \$1.22 million and the US of \$1.02 million.

The company said that diluted loss per share increased 42.2 percent to 3.2 cents and net tangible assets per share fell 23.9 percent to 4.5 cents

Immuron said it had cash and cash equivalents of \$5,119,887 at June 30, 2019 compared to \$4,727,430 at June 30, 2018.

Immuron fell half a cent or 4.55 percent to 10.5 cents.

THC GLOBAL GROUP (FORMERLY THE HYDROPONICS COMPANY)

THC says that revenue for the six months to June 30, 2019 was up 67.4 percent to \$2,136,894, with net loss after tax up 80.4 percent to \$5,765,724.

THC said its main source of revenue was its Canadian subsidiary, Crystal Mountain Products, a hydroponics retailer and distributor of equipment, material and nutrients to marijuana growers and producers.

The company said that net tangible assets per share fell 10.5 percent to 19.0 cents, with diluted loss per share up 70.1 percent to 4.44 cents and cash and cash equivalents of \$5,689,612 at June 30, 2019 compared to \$8,609,460 at June 30, 2018.

THC was up half a cent or 1.1 percent to 44.5 cents.

STEMCELL UNITED

Stemcell says that revenue for the 12 months to June 30, 2019 was up 437.2 percent to \$1,561,429, with net loss after tax down 36.9 percent to \$2,116,280.

Stemcell said the revenue mainly came from its Resina business, which extracted Resina from Daemonorops draco blume or 'Dragon's Blood' for traditional Chinese medicine (BD: Dec 5, 2018).

Last year, the company said it had a \$US10 million (\$A13.5 million) five-year deal to supply "Dragon's Blood" to China's Zhejiang Forest Rainbow Medical (BD: Jul 13, 2018). Today, Stemcell said that net tangible assets per share increased 52.2 percent to 0.35 cents, with diluted loss per share down 49.4 percent to 0.39 cents, compared to 0.77 cents at June 30, 2018.

The company said it had cash and cash equivalents of \$1,901,250 at June 30, 2019 compared to \$1,086,365 at June 30, 2018.

Stemcell was up 0.1 cents or 7.1 percent to 1.5 cents, with 1.2 million shares traded.

OVENTUS MEDICAL

Oventus says it has US Food and Drug Administration clearance for its O2Vent Optima oral device for obstructive sleep apnoea.

Oventus said the O2Vent Optima was a custom-made, 3D-printed nylon oral device with a lower jaw, or mandible, advancement and provided a separate airway for "stability to the upper airway" for obstructive sleep apnoea patients.

The company said the Optima formed part of its sleep treatment platform and its laboratory inside a laboratory, or 'lab in lab' business model, and would be distributed as part of a contract with Virtuos, Carestream Dental, Lyon Dental and an unnamed American sleep medicine group (BD: Jul 15, 16, 2019).

In June, Oventus chief executive officer Dr Chris Hart told Biotech Daily that the laboratory inside a laboratory "uses a scanner to measure the patient's mouth size for a custom-fit for the O2Vent" for sleep apnoea (BD: Jun 24, 2019).

Today, Dr Hart said that with the FDA clearance, the company could launch its "material agreements within US sleep channels and [work] with our customers across their various treatment sites to deliver Optima devices to patients".

Oventus was up seven cents or 14.6 percent to 55 cents, with 2.9 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it expects to meet regulators in October and November to discuss the design and conduct of the next trial of ATL1102 for Duchenne muscular dystrophy. Antisense said that it had advice from regulatory consultants that, based on the existing pre-clinical and clinical data generated for ATL1102, the company could seek approval for a phase IIb trial in Europe, in parallel with the current phase II study at Melbourne's Royal Children's Hospital (BD: Jul 16, 2018, Jul 24, 2019).

The company said that the focus of the scientific advice meetings would be on the phase IIb trial design, dose escalation plans, applicability of the study end-points and the study duration, and following the scientific advice it would seek advice from the European Medicines Agency on the study design and path for product registration for ATL1102 for in Duchenne muscular dystrophy (DMD).

Antisense fell 0.1 cents or two percent to 4.9 cents.

AMPLIA THERAPEUTICS (FORMERLY INNATE IMMUNOTHERAPEUTICS)

Amplia says its contract manufacturing organization has released the final quality certificate for a 1.0 kg batch of clinical grade AMP945, completing scale-up.

Amplia said the clinical good manufacturing practice (cGMP) program for its anti-FAK kinase inhibitor AMP945 mean that the production process was "robust and scalable" and had the necessary purity profile to be suitable for human use.

Amplia chief executive officer Dr John Lambert said that "as for many small molecule drugs, the manufacturing process for AMP945 is a multi-step process and each step must be carefully performed before the materials can be released for use in clinical trials". "Securing this cGMP certificate allows the release of enough clinical grade AMP945 to meet our needs for the coming year, including completion of our first clinical study," Dr Lambert said.

Amplia said that pre-clinical safety studies were scheduled to finish by April 2020 with the phase I trial planned to begin by July 2020.

Amplia was up 0.6 cents or 6.7 percent to 9.5 cents.

MEMPHASYS

Memphasys says it has received \$1,103,264 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Memphasys said that the funds related to expenditure for the year to June 30, 2019. The company said that the funds would be used to further develop its Felix sperm separation device for in-vitro fertilization, and for working capital. Memphasys was unchanged at five cents with 1.1 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says the Federal Government has approved a potential overseas Research and Development Tax Incentive finding of about \$2 million over three years. Neuroscientific said that under the Industry Research and Development Act 1986, the certificates provided by the Department of Industry and Science applied to the pre-clinical safety and toxicity profile studies of its novel peptide Emtin B that are currently being conducted outside Australia.

The company said the finding covered overseas activities in the financial years 2018-'19, 2019-'20 and 2020-'21 and were eligible for the Australian R&D Tax Incentive Program. Neuroscientific chairman, Brian Leedman said the finding would provide "a significant cash rebate in the current and following financial years, supporting our plans for a first in human study in the coming months".

Neuroscientific fell 1.5 cents or 6.1 percent to 23 cents.

IMPEDIMED

Allan Gray Australia says it has decreased its substantial holding in Impedimed from 80,737,989 shares (15.92%) to 75,110,704 shares (14.81%).

The Sydney-based Allan Gray said it sold 5,627,285 shares between August 1 and August 28, 2019, for \$784,482 or an average of 13.94 cents a share.

Impedimed was unchanged at 13.5 cents.

CRYOSITE

Cryosite director Andrew Kroger says he has increased his substantial shareholding from 17,315,291 shares (36.95%) to 17,815,291 shares (38.02%).

Mr Kroger said the shares were bought off-market on August 30, 2019 at 5.7 cents a share.

Mr Kroger said that the shares were held directly and through Austen Bay Pty Ltd acting for the Andrew Kroger superannuation fund, SHR Pty Ltd and Process Wastewater Technologies Pty Ltd.

Cryosite was untraded at 5.7 cents.

MEDIBIO

The London-based Marble Bar Asset Management says its initial substantial shareholder notice for the Chelodina Fund was incorrect.

On Friday, Marble Bar said that Chelodina held 25,000,000 shares or 8.81 percent, but today corrected that to 2.51 percent (BD: Aug 30, 2019).

Marble Bar said the substantial shareholder notice "was submitted in error due to an incorrect data source for outstanding shares, which has since been rectified".

No sub-editors were hurt in making this clarification.

In fact, we could probably second a couple to Marble Bar, should they be required. Medibio was unchanged at 1.3 cents with 10.5 million shares traded.

ADMEDUS

Admedus has requested a seventh extension to its voluntary suspension to finalize its recapitalization plan.

In April, Admedus requested a trading halt "pending an announcement regarding the ... immunotherapies sale transaction" and later requested a voluntary suspension for the sale of Admedus Vaccines, formerly Coridon (BD: Apr 15, 17, 2019).

On April 23, the company responded to an ASX aware query, announced the termination of the Vaccine business sale and requested an extension to the suspension "to finalize the ... recapitalization plan" (BD: Apr 23, 2019).

Between May and August, Admedus requested five more extensions without providing any further information (BD: May 7, 21; Jun 4; Jul 1, Aug 5, 2019).

Today, the company said it expected the suspension to last until September 30, 2019. Admedus last traded at six cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Nick Burrows as an independent, nonexecutive director.

Genetic Technologies said Mr Burrows was formerly the chief financial officer and company secretary of Tassal Group for 21 years, and was currently a director of Clean Seas Seafood, Taswater and Metro Tasmania Pty Ltd.

The company said that Mr Burrows was a former national president of the Governance Institute of Australia.

Genetic Technologies was unchanged at 0.6 cents with 1.4 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT AUGUST 31, 2019

Company \$Am	Sep-18	Aug-19	Sep-19
Cochlear	12,448	12,718	12,325
CSL	102,835	104,050	106,710
Resmed	22,087	27,236	29,579
BDI-20			
Avita	130	814	852
Clinuvel	706	1,592	1,252
Compumedics	90	128	128
Cyclopharm	64	96	93
Cynata	129	183	163
Ellex	111	90	85
Genetic Signatures	52	109	109
Immutep	109	71	81
Medical Developments	256	375	314
Mesoblast	792	736	733
Nanosonics	1,054	1,653	1,911
Neuren	136	153	190
Opthea	126	190	837
Paradigm	116	284	308
Pharmaxis	115	89	73
Polynovo	372	1,058	1,388
Pro Medicus	1,053	3,186	3,840
Starpharma	482	489	409
Telix	174	351	345
Volpara	153	349	318
Second 20		4.0	_
Actinogen	62	10	9
Alterity (Prana)	25	22	23
Amplia (Innate)	15	6	5
Antisense	8	21	21
Dimerix	16	16	16
Impedimed	182	74	68
Imugene	86	90	76
Kazia	22	25	24
LBT Innovations	22	27	24
Next Science	168	323	280
Oncosil	137	42	45
Optiscan	26	24	20
Orthocell	24	67	63
Osprey	70	31	21
Patrys	46	25	25
Prescient	20	19	17
Proteomics	19	25	22
Resonance	9	41	47
Universal Biosensors	42	43	38
Uscom	22	19	15

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

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: editor@biotechdaily.com.au; www.biotechdaily.com.au; www.biotechdaily.co