



Biotech Daily

Thursday October 1, 2020

Daily news on ASX-listed biotechnology companies

- * SEPTEMBER BDI-40 UP 1%, ASX200 DOWN 4%, BIG CAPS UP 2.5%
- * TODAY: ASX, BIOTECH UP: IMPEDIMED UP 12%; ANTISENSE DOWN 14%
- * FEDERAL \$1.5b FOR MANUFACTURING
- * KAZIA RIGHTS OFFER FOR \$25.2m
- * MESOBLAST REQUESTS 'FDA RYONCIL FOR GVHD RESULT' TRADING HALT
- * IMPEDIMED: STUDY BACKS SOZO FOR HEART FLUID MONITOR
- * PARADIGM: 'PPS REDUCES KNEE OSTEO-ARTHRITIS PAIN 50%'
- * HYDRIX IMPLANTS^{1st} US ANGEL GUARDIAN PATIENT
- * CHINA PATENT FOR AZURE (INVICTUS) TRANSMUCOSAL TOCOTRIENOLS
- * REGENEUS: AUSTRALIAN PATENT FOR STEM CELL BIOMARKERS
- * ASX SUSPENDS SIMAVITA FOR LATE FILING
- * CRESO REQUESTS 'CAPITAL RAISING' TRADING HALT
- * RECCE'S DR GRAHAM, OLGA MELROSE INCREASE, DILUTED TO 24%
- * RECCE APPOINTS EXECUTIVE DIRECTOR MICHELE DILIZIA CSO
- * CHIMERIC APPOINTS DR BEHNAM BADIE, DR DONGRUI WANG ADVISORS

MARKET REPORT

The Australian stock market rose 0.98 percent on Thursday October 1, 2020, with the ASX200 up 57.0 points to 5,872.9 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Impedimed was the best, up 0.8 cents or 11.8 percent to 7.6 cents with 8.8 million shares traded. Resonance rose 9.1 percent; Proteomics climbed 8.65 percent; Paradigm was up 7.9 percent; Imugene improved 6.25 percent; Universal Biosensors and Uscom were up more than five percent; Actinogen, Dimerix and Orthocell climbed more than three percent; Optiscan and Starpharma rose two percent or more; Compumedics, Immutep, Nanosonics and Osprey were up one percent or more; with Avita, Cochlear, CSL, Opthea, Polynovo, Resmed and Volpara up by less than one percent.

Yesterday's 26.1 percent best, Antisense, led the falls, down two cents or 13.8 percent to 12.5 cents, with 5.7 million shares traded. Amplia lost 5.6 percent; Oncosil was down 3.85 percent; Alterity, Clinuvel, Next Science and Pro Medicus shed two percent or more; Cyclopharm, Cynata and Pharmaxis were down more than one percent; with Genetic Signatures and Neuren down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

Spring has sprung again for the Biotech Daily Top-40 Index (BDI-40), up 0.8 percent to a collective market capitalization of \$16,484 million, just 1.8 percent below the January 31 all-time high of \$16,788 million.

By comparison, the benchmark S&P ASX200 fell 4.0 percent in September to 5,816 points and 13.0 percent below September 30, 2019.

The BDI-40 was up 13.2 percent for the year to September 30, 2020.

The Nasdaq Biotechnology Index fell 0.1 percent in September but was up 36.1 percent for the year.

The collective market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) climbed 2.5 percent in September, up 24.25 percent for the year.

CSL climbed \$4,497 million or 3.5 percent to \$134,457 million with Cochlear up 5.5 percent to \$13,325 million. Resmed slipped a further 1.9 percent to \$34,346 million.

In September, 21 of the BDI-40 companies were up, 13 by more than 10 percent and three by more than 60 percent. Nineteen fell, with nine down by more than 10 percent and two down by more than 20 percent.

Cyclopharm was the best, following its US phase III Technegas lung imaging trial meeting its primary efficacy endpoint, up \$82 million or 73.9 percent to \$193 million.

From a lower base, Optiscan was up 63.3 percent to \$49 million, followed by Antisense (61.4%), Immutep (28.4%), Amplia (26.7%), Patrys (23.5%), Prescient (18.9%), Resonance (17.7%), Clinuvel (17.3%), Cynata (16.3%), Oncosil (13.7%), Opthea (11.1%) and Compumedics (10.1%).

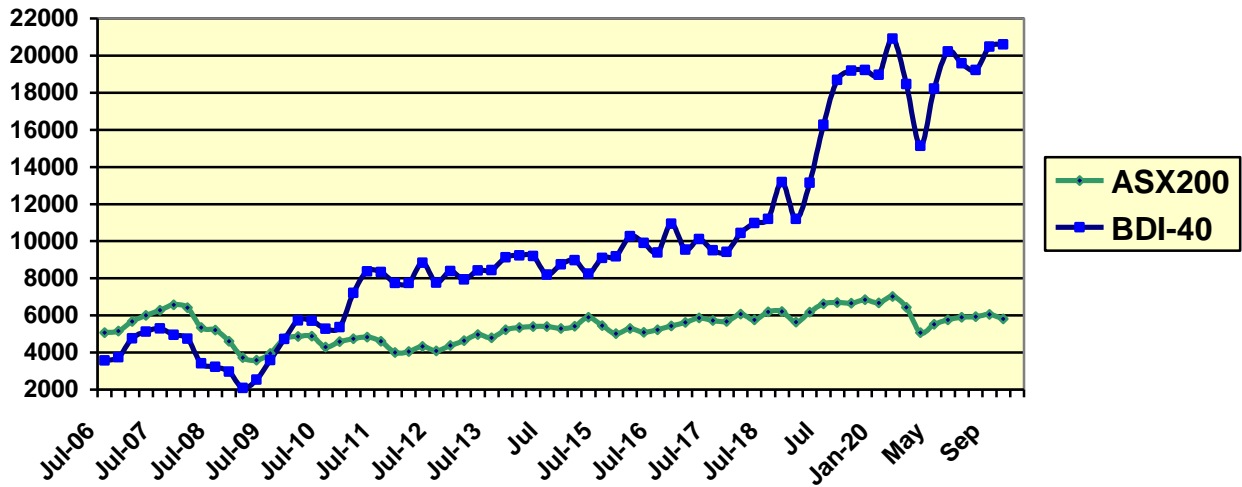
Dimerix led the falls, following DMX-200 for diabetic kidney disease not meeting its phase II primary endpoint, down \$86 million or 58.9 percent to \$60 million.

Genetic Signatures continuing to ease from its July high, down 24.9 percent to \$244 million, followed by Imugene (14.5%), Proteomics (14.3%), Neuren (13.0%), Kazia (12.5%), Medical Developments (11.1%), Universal Biosensors (10.9%) and Pharmaxis (10.5%).

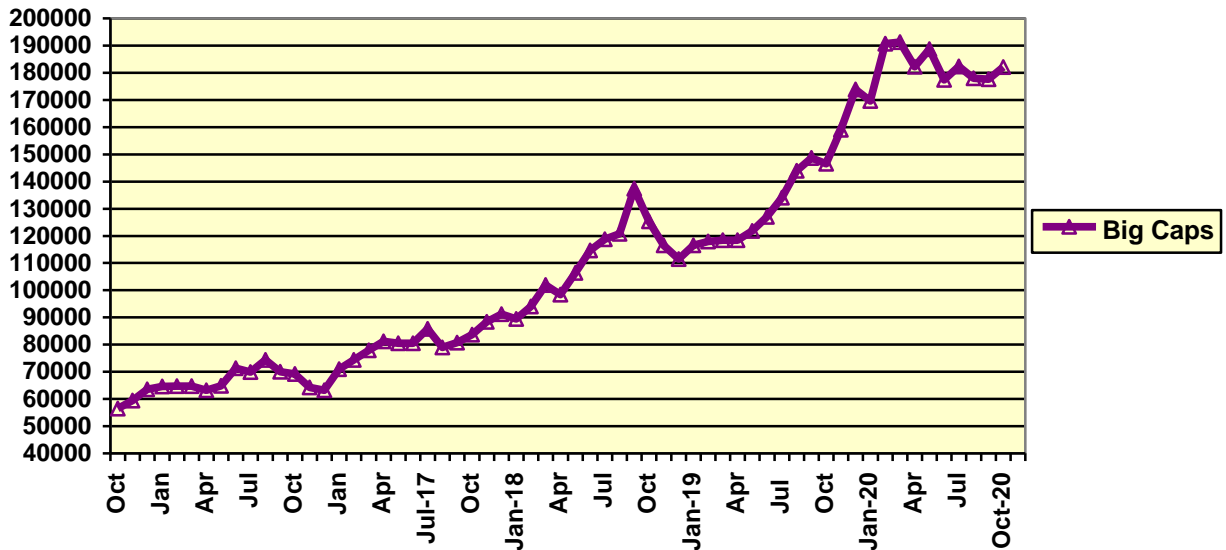
Cannabis Corner was up 10.5 percent in August to \$1,266 million, but down 33.9 percent for the year to September 30.

On the Nasdaq, Redhill (with Australian assets) was up 34.9 percent to \$533 million on the continuation of its trial of opaganib, or Yeliva, for Covid-19, while Queensland's Protagonist eased 10.2 percent to \$1,004 million, and Eyepoint (Psivida) was unchanged at \$91 million.

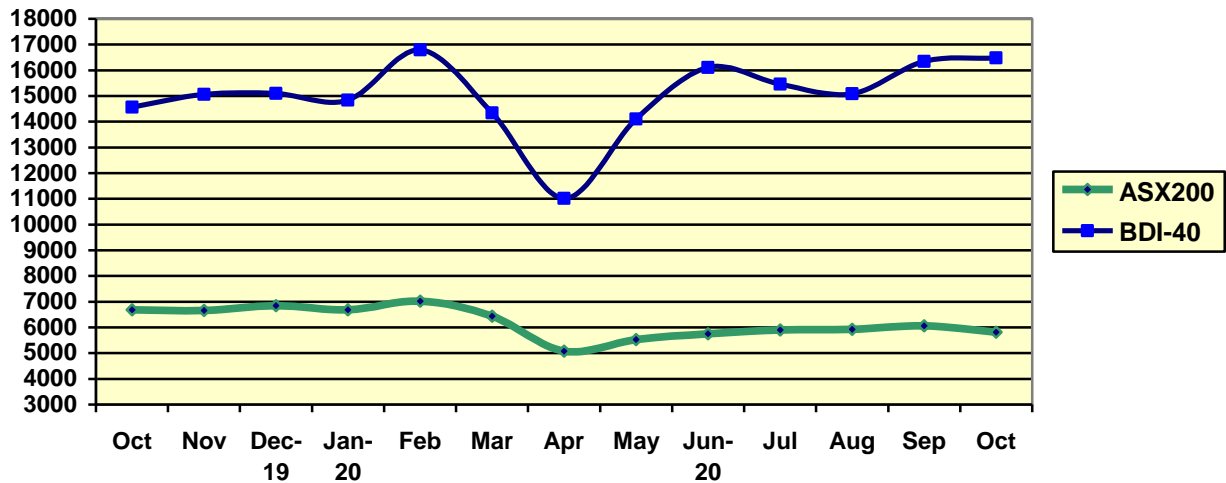
BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2020- Adjusted



5-Year Big Caps \$m (Cochlear, CSL, Resmed) Sep 30, 2015 – Sep 30, 2020



BDI-40 (\$m) v S&P ASX 200 – Sep 30, 2019 – Sep 30, 2020 (current, raw data)



FEDERAL GOVERNMENT

The Federal Government says biotechnology is one of six industries to benefit from up-to \$1.5 billion for manufacturing priorities under the Modern Manufacturing Strategy.

The Federal Government said the \$1.5 billion included \$1.3 billion for the modern manufacturing initiative, \$107.2 for the supply chain resilience initiative and \$52.8 million for the second round of the manufacturing modernization fund.

Biotech Daily asked the office of the Minister for Industry, Science and Technology, Karen Andrews, whether the government would remove or delay the proposed caps and cuts to the Research and Development Tax Incentive program.

A spokesman for Ms Andrews said that the Federal Treasurer, Joshua Frydenberg, would "have more to say about these issues next week".

The Federal Government said the Modern Manufacturing Strategy was a key component in the 'Jobmaker plan' and aimed to position Australia as a modern manufacturing leader, generate income for the nation and jobs for Australians as part of the economic recovery following the Covid-19 pandemic.

The Government said that the initiative would work in partnership with businesses, and provide grants on a co-investment basis, focusing on large projects that support business-to-business and business-to-research collaboration, the translation of ideas into commercial outcomes, and connecting manufacturing with local and international supply chains and markets.

The Federal Government said the initiative would be delivered over four years with expressions of interest and yearly funding rounds opening in the first half of 2021.

The Government said the \$107.2 million supply chain resilience initiative would work with industries to identify critical products and map capabilities and vulnerabilities for normal times and periods of surge, with an early focus on medicines and medical equipment, followed by food, chemicals and plastics.

The Federal Government said the supply chain resilience initiative would be available from July 1, 2021 for businesses to establish or scale a capability that addresses a supply chain vulnerability resulting in strengthening the supply chain.

The Government said the \$52.8 million round two of the manufacturing modernization fund would open by the end of 2020 and fast-track capital investment in technology upgrades and enable up to 150 additional local businesses to invest in projects and apply for co-funding grants of between \$100,000 and \$1 million, with applicants expected to match Government funding on a three-to-one funding basis.

The Federal Government it would facilitate industry-led teams of experts to co-design road maps against each of the National Manufacturing Priorities, which would be delivered in the first half of 2021 with set goals for the next two, five and 10 years, identify the roadblocks to growth and priorities for action and investment.

KAZIA THERAPEUTICS

Kazia says it hopes to raise up to \$25,232,898 in a one-for-three rights offer at 80 cents a share a 16.7 percent discount to its last traded price of 96 cents.

Kazia said it "intended ... to enter into an underwriting agreement".

The company said that the offer of up to 31,541,123 would include an institutional component starting today and a retail offer for shareholders at the record date of October 5, opening on October 8 and closing on October 20, 2020.

The company said the funds would be used for its trial of paxalisib, or GDC-0084, for glioblastoma GBM Agile trial and for working capital.

Kazia was in a trading halt and last traded at 96 cents.

MESOBLAST

Mesoblast has requested a trading halt pending an announcement on its US biologics licence application for Ryoncil in children with acute graft versus host disease.

In August, the FDA Oncologic Drugs Advisory Committee voted nine to one in favor that the available data supported the efficacy of remestemcel-L, or Ryoncil, for steroid-refractory acute graft-versus-host disease (BD: Aug 14, 2020).

Trading will resume on October 5, 2020 or an earlier announcement.

Mesoblast last traded at \$5.08.

IMPEDIMED

Impedimed says a study of body fluid in heart failure supports its Sozo for bioimpedance spectroscopy for monitoring heart failure patients.

Impedimed said that a poster presentation at the on-line Heart Failure Society of America meeting September 30 to October 6, 2020 showed that Sozo's heart failure diagnostic (HF-Dex) measured extracellular fluid as a percentage of total body water and an assessment greater than 51 percent "a marker for heart failure hospital readmission".

An Impedimed spokesman told Biotech Daily the data was based on 172 patients in three groups, including: 92 patients with compensated heart failure, not readmitted to hospital; 11 with decompensated heart failure, or readmitted to hospital; and 69 control subjects. Impedimed said the findings showed a statistically significant ($p < 0.05$) difference in median HF-Dex for patients readmitted for heart failure (52.1%) compared to patients not readmitted for heart failure (49.0%) and healthy subjects (44.8%).

The poster's authors, doctors at the San Diego, California-based Scripps Health said that "physical exams, weights and echo measures are used to assess hydration of heart failure patients, often inadequately ... but [the] Sozo with HF-Dex has the potential to identify high-risk discharges and bend the readmission curve down"

Impedimed said patients with class II or III heart failure had the Sozo bioimpedance spectroscopy measurements in an ambulatory care setting or at home.

The company said that the Sozo HF-Dex heart failure index measured extracellular fluid as a percentage of total body water across the three groups.

Impedimed said that patients readmitted for acute heart failure had a median extracellular fluid as a percentage of total body water of 52.1 percent supporting the HF-Dex greater than 51 percent as a marker for readmission.

The company said that the compensated group had a median rate of 49.0 percent, and the healthy population's median was 44.8 percent.

Impedimed said that the Sozo HF-Dex heart failure index was "a novel tool for assessing fluid overload in heart failure".

The company said that data from the poster, combined with individual patient case reports showed that Sozo could differentiate between fluid and tissue-related weight changes, track response to medication changes, and be a marker for readmission when HF-Dex was higher than 51 percent.

Impedimed chief executive officer Richard Carreon said that "heart failure readmissions put a substantial cost burden on both public and private payors".

"We believe our technology can reduce costs associated with managing heart failure patients as well as improve quality of life for heart failure patients and their loved ones," Mr Carreon said. "The data from this poster presentation adds to our growing body of clinical evidence for heart failure, and we anticipate first commercial sales for heart failure in the coming months," Mr Carreon said.

Impedimed was up 0.8 cents or 11.8 percent to 7.6 cents with 8.8 million shares traded.

[PARADIGM BIOPHARMACEUTICALS](#)

Paradigm says 40 of 76 knee osteoarthritis patients receiving pentosan poly-sulphate sodium (PPS) have reported a pain reduction of more than 50 percent.

Paradigm said patients receiving injectable pentosan poly-sulphate sodium, or Zilosul, under the Australian Therapeutic Goods Administration special access scheme reported pain levels using the Western Ontario and McMaster Universities Osteoarthritis Index (Womac) questionnaire.

The company said patients in the special access scheme received 2mg/kg of Zilosul twice a week for six weeks.

Paradigm said the average reduction in pain from baseline was 47.3 percent, with 56 patients reporting a pain reduction of at least 25 percent.

The company said the data was “clinically meaningful” given that reduction of chronic pain was been defined to be 25 to 30 percent pain reduction.

Paradigm chief executive officer Paul Rennie said that “consistent patient Womac pain reduction outcomes” under the special access scheme was pleasing as the company progressed towards regulatory submissions for its phase III study.

“We are seeing consistent clinically meaningful reduction in pain and improvement in joint function in [osteoarthritis] patients who have failed to respond to other medications,” Mr Rennie said.

Paradigm was up 21 cents or 7.9 percent to \$2.86 with 3.8 million shares traded.

[HYDRIX](#)

Hydrix says it has implanted its first US patient with its next generation Angel Medical Guardian cardiac arrest warning device.

Hydrix said it had US Food and Drug Administration approval to implant the first patient, and up to 260 other patients, with the Guardian device, as part of its Alerts continued access study, which provided patients in its previous Alerts clinical trial with access to its next generation Angel Medical device.

The company said the Guardian system tracked significant changes in the heart's electrical signals for the detection of heart attacks or acute coronary syndrome events, and alerted patients to seek medical attention.

In August, Hydrix said it was the exclusive distributor of the Angel Medical Guardian in eight Asia Pacific countries including Australia, Japan, and Singapore where four patient implants of the device were completed in August 2020 (BD: Aug 17, 2020).

The company said it was not entitled to any revenue generated from implants in the US or any other jurisdiction outside its distribution agreement.

Hydrix was up 10 cents or 37.0 percent to 37 cents with 42.7 million shares traded.

[AZURE HEALTH TECHNOLOGY \(MERGED WITH INVICTUS BIOPHARMA\)](#)

Azure says that the China National Intellectual Property Administration has issued a notification to grant a patent covering its transmucosal delivery of tocotrienols.

Azure said that the patent, titled ‘Transmucosal delivery of tocotrienol’, would protect its intellectual property until 2033.

The company said the patent had been granted in the US, Europe, Japan, Australia, New Zealand, Singapore and South Africa, with a notice of allowance in Canada.

Azure is a public unlisted company

REGENEUS

Regeneus says IP Australia has accepted a patent application covering its biomarkers to monitor disease progression mesenchymal stem cell therapy patients.

Regeneus said the patent, titled 'Biomarkers for cell therapy' would cover the intellectual property until 2034, and the company the patent to be granted in January 2021.

The company said that osteoarthritis included the progressive loss of particular cartilage and the patent would allow the company to monitor the biomarkers to measure severity of the disease, determine further treatments and better manage the disease.

Regeneus was unchanged at 15.5 cents.

SIMAVITA

The ASX has suspended Simavita, along with six non-biotech companies, "for failure to lodge the relevant periodic report by the due date".

In a separate announcement, Simavita said it had "experienced an unexpected delay in finalizing its audited financial statements" and expected them to be finalized "shortly".

Simavita last traded at 1.9 cents.

CRESO PHARMA

Creso has requested a trading halt as it "considers, plans and executes a capital raising". Trading will resume on October 7, 2020 or on an earlier announcement.

Creso last traded at 3.9 cents.

RECCE PHARMACEUTICALS

Recce founder Dr Graham Melrose and Olga Melrose say their holding has increased and been diluted from 36,450,003 shares (25.28%) to 40,948,079 shares (23.58%).

The Perth-based Dr and Ms Melrose said that between September 28 and 30, 2020 they sold 1,576,924 shares off-market for \$2.05 million, or about \$1.30 a share, converted 6,075,000 class D performance shares and were diluted in a \$27,950,000 placement at \$1.30 a share (BD: Sep 23, 2020).

Recce was up 5.5 cents or 4.8 percent to \$1.20 with 973,283 shares traded.

RECCE PHARMACEUTICALS

Recce says it has appointed executive director Michele Dilizia as chief scientific officer, starting on \$230,000 a year, and continuing as an executive director.

Recce said Ms Dilizia was a co-inventor of the company's synthetic anti-infectives and specialized in medical microbiology and regulatory affairs.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed Dr Behnam Badie and Dr Dongrui Wang to its scientific advisory board.

Chimeric said Dr Badie was the chief of neurosurgery at the Duarte, California-based City of Hope and the head of City of Hope's brain tumor program.

The company said Dr Wang held a Doctor of Philosophy from City of Hope's Irell and Manella graduate school of biological sciences.

Chimeric is a public unlisted company.

Biotech Daily Top 40 with Market Capitalization At September 30, 2020

Company \$Am	Oct-19	Sep-20	Oct-20
Cochlear	12,032	12,631	13,325
CSL	106,061	129,960	134,457
Resmed	28,487	35,022	34,346
BDI-20			
Avita	1,105	754	741
Clinuvel	1,209	1,027	1,205
Compumedics	109	69	76
Cyclopharm	79	111	193
Cynata	165	104	121
Ellex	79	45	47
Genetic Signatures	108	325	244
Immutep	89	95	122
Medical Developments	331	389	346
Mesoblast	1,067	3,106	3,044
Nanosonics	1,895	1,822	1,748
Neuren	202	146	127
Opthea	838	703	781
Paradigm	555	641	623
Pharmaxis	75	38	34
Polynovo	1,415	1,461	1,514
Pro Medicus	2,893	2,697	2,861
Starpharma	427	564	598
Telix	398	419	422
Volpara	358	346	327
Second 20			
Actinogen	10	29	30
Alterity (Prana)	25	58	54
Amplia (Innate)	4	15	19
Antisense	33	44	71
Dimerix	15	146	60
Impedimed	91	71	70
Imugene	76	241	206
Kazia	35	104	91
LBT Innovations	25	36	37
Next Science	530	240	236
Oncosil	41	95	108
Optiscan	22	30	49
Orthocell	62	82	74
Osprey	20	42	39
Patrys	23	17	21
Prescient	21	37	44
Proteomics	26	56	48
Resonance	53	62	73
Universal Biosensors	35	55	49
Uscom	17	26	27

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

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