



Biotech Daily

Monday February 1, 2021

Daily news on ASX-listed biotechnology companies

- * JANUARY BDI-40 DOWN 1%, ASX200 UP 0.3%, BIG CAPS DOWN 4%, NBI UP 6%
- * TODAY: ASX UP, BIOTECH DOWN: MESOBLAST UP 6%; PATRYS DOWN 10%
- * REDHILL: 'DSMB BACKS OPAGANIB FOR COVID-19 TRIAL'
- * MICRO-X RAISES \$30.5m, SHARE PLAN FOR \$2.5m MORE
- * ALTHEA H1 RECEIPTS UP 204% TO \$4.7m
- * TBG RECEIPTS UP 119% TO \$7.3m
- * THC RECEIPTS UP 44% TO \$6.9m
- * CARDIEX SUSPENDED; H1 RECEIPTS \$2.3m
- * POLYNOVO APPOINTS MEDIVAL NOVOSORB BTM ITALY DISTRIBUTOR
- * UK APPROVES PALLA NORWAY CODEINE FACILITY
- * OSTEOPORE, TERUMO COLLABORATE ON REGENERATIVE MEDICINE
- * NYRADA, WALTER REED, UNI NSW BRAIN INJURY COLLABORATION
- * ANATARA: ANR-PF 'SUCCESS' FOR POULTRY NECROTIC ENTERITIS
- * DORSAVI REQUESTS 'SHORTFALL PLACEMENT' TRADING HALT
- * BOTANIX REQUESTS 'BTX1801 TRIAL RESULTS' TRADING HALT
- * SUDA EGM 36% OPPOSE EMPLOYEE OPTION PLAN
- * LBT TO LOSE CHAIR KATE COSTELLO, DIRECTOR CAROLINE POPPER
- * ADHERIUM LOSES DIRECTOR BRYAN MOGRIDGE
- * CHIMERIC APPOINTS CINDY ELKINS DIRECTOR
- * EMYRIA APPOINTS DR RICHARD MAGTENGAARD ADVISOR

MARKET REPORT

The Australian stock market was up 0.84 percent on Monday February 1, 2021, with the ASX200 up 55.6 points to 6,663.0 points. Nine of the Biotech Daily Top 40 stocks were up, 23 fell, seven traded unchanged and one was untraded.

Mesoblast was the best, up 14 cents or 5.9 percent to \$2.52, with 8.1 million shares traded. Neuren climbed 5.8 percent; Dimerix was up 3.45 percent; CSL and Pharmaxis rose more than two percent; Cochlear, Kazia, Polynovo, Starpharma and Universal Biosensors were up more than one percent; with Medical Developments up 0.3 percent.

Patrys led the falls, down 0.3 cents or 10.0 percent to 2.7 cents, with 22.15 million shares traded. Cyclopharm lost 7.7 percent; Resonance retreated 5.1 percent; Imugene, LBT, Osprey and Prescient fell more than four percent; Oncosil was down 3.85 percent; Alterity, Antisense, Cynata, Next Science and Resmed shed more than two percent; Amplia, Avita, Genetic Signatures, Immutep, Nova Eye, Orthocell and Telix were down more than one percent; with Clinuvel, Nanosonics, Pro Medicus and Proteomics down by less than one percent.

[BIOTECH DAILY TOP 40 INDEX \(BDI-40\)](#)

For anyone looking for stock market “certainty” or even vague consistency, January was not your month. The Biotech Daily Top-40 Index (BDI-40) slipped 0.8 percent in January but was up 8.4 percent for the year, compared to the benchmark S&P ASX200, which was up 0.3 percent in January but down 5.8 percent compared to January 31, 2020.

The cumulative market capitalization of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 3.9 percent in January, and down 8.8 percent for the year, while the Nasdaq Biotechnology Index (NBI) climbed 6.3 percent in January and soared 41.5 percent for the year.

What all this means is that the BDI-40, the Big Caps and the ASX200 are all close to their record highs, just before we locked down for Sars-Cov-2 pandemic, when the global economy allegedly collapsed, completely. Apart from the NBI, which didn't. Go figure.

Even Cannabis Corner was confounding. Despite ordinary announcements, the collective market capitalization for the 22 companies claiming to do something medical with marijuana, was up 2.7 percent in January and 18.8 percent for the year.

The Big Caps are dominated by CSL which fell 5.7 percent in January – possibly by speculation on the gazillions to be made on vaccines which have a tiny margin – while Cochlear climbed 3.5 percent to \$12,859 million, and Resmed slipped 0.04 percent for the month on yet more record revenue and profit, primarily due to efficiently switching production to ventilators for Covid-19. Go figure, again.

Twenty-three of the BDI-40 were up, 10 by more than 10 percent, with 17 down and five by more than 10 percent.

Prescient was the best, on a strong run last week on no news, up \$27 million or 62.8 percent to \$70 million. Antisense was up 37.3 percent to \$103 million, followed by Avita (34.3%), Patrys (25.6%), Pro Medicus (20.6%, to more than \$4 billion), Dimerix (21.3%), Cyclopharm (18.9%), Alterity (15.9%), Amplia (11.5%) and Orthocell (11.0%).

Polynovo led the falls, retreating 33.0 percent from last month's all-time high of \$2.6 billion to \$1.7 billion, followed by Resonance (18.7%), Nanosonics (14.7%), LBT (14.3%) Proteomics (13.3%) and Paradigm 9.9%.

On the Nasdaq, Eyepoint (Psivida) jumped 106.2 percent to \$266 million, Redhill (with Australian assets) climbed 15.9 percent to \$458 million and Queensland's Protagonist was up 3.5 percent to \$1,166 million.

In reviewing the BDI-40 and lower lists, we ask the question: is Company X better than Company Y, based on science, benefit to human health and board and management?

While there are several companies that could be demoted from the BDI-40, we err on the side of conservatism (so we don't look like fools when they announce a major deal, the day after we demote them). And the lower lists do not as yet have the scores on the board. Some are close.

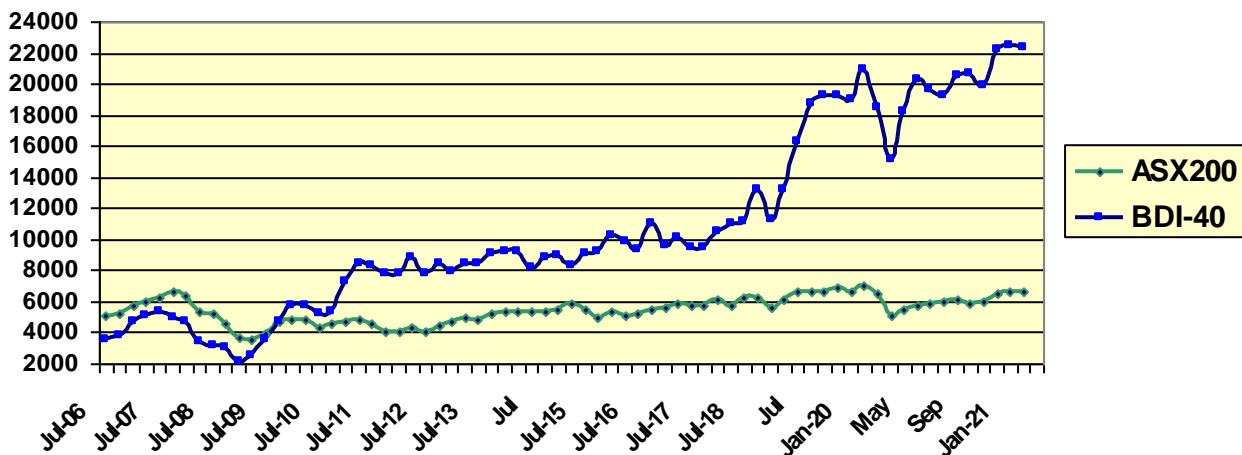
The elephants in the room are Mesoblast and Starpharma. Both have spent two decades attempting to show their respective technologies, stem cells and dendrimer anti-microbials, have efficacy for human health, but with very little reward for shareholders.

Mesoblast had a US FDA GvHD knockback and two trials showing that the original mesenchymal precursor cells and the Osiris-acquired mesenchymal stem cells did not meet the primary endpoints for cardiac failure and Covid-19 related Ards, respectively; while Starpharma has been looking for a use for SPL7013 since before Biotech Daily started in 2005. Mesoblast earns income from the Osiris drug for GvHD and Starpharma has revenue from condom coatings and as a continuous use against bacterial vaginosis. Both companies have made significant deals with major pharmaceutical companies.

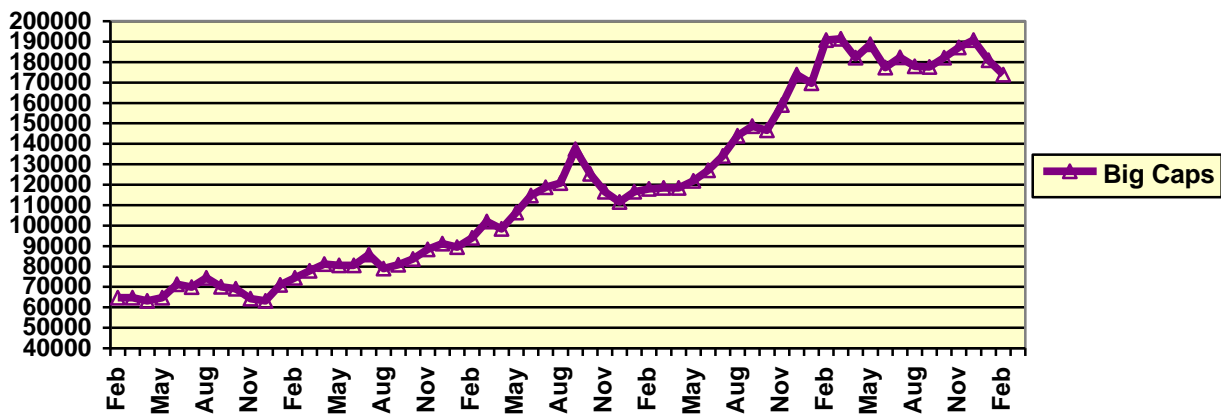
If there was a drug development company near phase III that could displace them from the Top 20 to the Second 20, that would happen, but both maintain their rankings in the Top 20 because there is no competition. And that says more about drug development in Australia than either company. We remain impressed with their boards and management and determination to prove that they have something that benefits humankind.

Contenders for promotion include Alcidion, Micro-X, Emvision and Control Bionics.

BDI-40 v ASX200 Jun 30, 2006 to Jan 31, 2021- Adjusted



5-Year Big Caps \$m (Cochlear, CSL, Resmed) Jan 31, 2016 – Jan 31, 2021



MICRO-X

Micro-X says it has raised \$30.5 million in a placement at 34 cents a share and hopes to raise a further \$2.5 million through a share purchase plan at the same price. Micro-X said the funds would be used to expand the US market, sales and marketing infrastructure, insourcing x-ray tubes, strengthen its balance sheet and reduce commercialization risks.

The company said that the record date for the share plan was January 29, it would open on February 4 and close on February 17, 2021.

Micro-X said that Morgans Corporate and Hawkesbury Partners were the joint lead managers to the placement.

Micro-X fell two cents or 5.4 percent to 35 cents with 1.4 million shares traded.

REDHILL BIOPHARMA

Redhill says the independent data safety monitoring board “unanimously recommended to continue” for its phase II/III study of opaganib for Covid-19.

Redhill said that the board made its recommendation following a pre-scheduled futility review of unblinded efficacy data from the first 135 patients treated in the study and safety data from the first 175 patients.

Redhill medical director Dr Mark Levitt said opaganib was an oral, sphingosine kinase-2 inhibitor “with demonstrated antiviral, anti-inflammatory, and anti-thrombotic activity”.

“The positive and unanimous DSMB recommendation is a significant milestone in the progress of our development program for Covid-19 disease,” Dr Levitt said.

“together with the positive results from the phase II study, this unanimous DSMB recommendation to continue the global phase II/III study suggests we are heading in the right direction from both a safety and efficacy perspective,” Dr Levitt said.

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

Redhill closed on the Nasdaq on Friday down 40 US cents or 4.54 percent at \$US8.42 (\$A11.01) with 665,612 shares traded.

ALTHEA GROUP HOLDINGS

Althea says receipts from customers for the six months to December 31, 2020 was up 203.9 percent to \$4,696,000, compared to the previous corresponding period.

Althea said that receipts from customers for its marijuana products for the three months to December 31, 2020 was up 191.4 percent to \$2,623,000.

The company said it had cash equivalents of \$8,967,000 at December 31, 2020 compared to the \$22,359,000 at December 31, 2019.

Althea was up one cent or 2.3 percent to 45 cents with 1.6 million shares traded.

TBG DIAGNOSTICS

TBG says customers receipts for the 12 months to December 31, 2020 was up 119.2 percent to \$7,335,000 compared to revenue from the corresponding prior period.

TBG said that the revenue was from the sale of Covid-19 antibody test kits as well as its human leukocyte antigen (HLA) genotyping kits

The company said it had cash equivalents of \$3,777,000 at December 31, 2020 compared to the \$5,205,131 at December 31, 2019.

TBG was in an ASX suspension and last traded at 27 cents.

[THC GLOBAL GROUP \(FORMERLY THE HYDROPONICS CO\)](#)

THC says receipts from customers for the 12 months to December 31, 2020 was up 46.3 percent to \$6,916,000 compared to the corresponding prior period.

THC Global said its receipts from customers from the sales of its marijuana products and hydroponics equipment for the three months to December 31, 2020 was down 12.7 percent to \$1,632,000.

The company said it had cash equivalents of \$6,968,000 at December 31, 2020 compared to the \$3,555,000 at December 31, 2019.

THC was up 1.5 cents or 6.8 percent to 23.5 cents.

[CARDIEX](#)

The ASX says it suspended Cardix following a “failure to lodge the relevant periodic report by the due date” with the company filing its quarterly report shortly after.

Cardix said its receipts from customers for the six months to December 31, 2020 fell 0.3 percent to \$2,296,000 compared to its half yearly revenue from the corresponding prior period.

The company said its revenue came from the sales of its Sphygmocor central blood pressure and arterial stiffness monitor and wearable devices to measure blood pressure.

Cardix said it had cash and equivalents of \$3,322,000 at December 31, 2020 compared to the \$1,137,681 at December 31, 2019.

Cardix last traded at 8.4 cents.

[POLYNOVO](#)

Polynovo says it has appointed the Padua-based Medival SRL as its Novosorb BTM wound treatment distributor in Italy.

Polynovo said that Italy was the fourth largest medical device market in Europe with a value of about \$US10 billion.

The company said that Medival had “an established customer base throughout Italy” accessing about 1,500 plastic surgeons, with 25 representatives and a dedicated product manager.

Polynovo managing-director Paul Brennan said that the Italian market was “very sophisticated, and we think it will value innovative, quality medical technologies like ours”.

“The country is important both geographically and commercially and is a major step forward in our European strategy,” Mr Brennan said.

Polynovo was up four cents or 1.5 percent to \$2.67 with 4.4 million shares traded.

[PALLA PHARMA](#)

Palla says UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for its Norway production facility.

In December 2020, Palla said the Agency wanted more information to approve its Norwegian codeine manufacturing site.

Today the company said it had received approval for its combination 30mg codeine phosphate and 500mg paracetamol tablets and caplets.

Palla fell four cents or 5.8 percent to 65 cents.

OSTEOPORE

Osteopore says has a collaboration with Terumo Technologies to promote and distribute their respective regenerative products in the Asia-Pacific region.

Osteopore said the Lakewood, Colorado-based Terumo Blood and Cell Technologies had specialized equipment to extract concentrated bone marrow for bone regeneration.

The company said it would combine its technology with Terumo's to provide "a biomimetic structure to guide bone tissue formation".

Osteopore was up half a cent or one percent to 50 cents.

NYRADA

Nyrada says it has a collaboration with Walter Reed Army Institute of Research and the University New South Wales to test its lead compound for brain injury.

Nyrada said the collaboration would evaluate its unnamed compound in a preliminary study of its mechanism of action on mitochondrial calcium dynamics, an "important determinant of cell fate" which could trigger or prevent cell death after traumatic brain injury.

The company said a second study in an unnamed animal model would evaluate the neuroprotective compound "in a controlled cortical impact" study.

Nyrada said that the preliminary baseline assessment would allow it to develop "the most optimal study design to test its preclinical drug candidate".

The company said it previously demonstrated that its lead pre-clinical neuroprotection compound "blocks calcium build-up in cells and shows excellent brain penetration".

The company said Dr Deborah Shear and Prof Gary Housley would lead the studies at the Walter Reed Hospital and at Sydney's University of New South Wales, respectively.

Nyrada was up one cent or 2.6 percent to 40 cents with 1.6 million shares traded.

ANATARA LIFESCIENCES

Anatara says its randomized, placebo-controlled, poultry challenge trial of ANR-pf for necrotic enteritis has been "successful".

Anatara said the study, titled 'Efficacy of ANR-pf on the performance of broilers subject to subclinical and necrotic enteritis challenges' showed that over the experimental period of 35 days, treatment with ANR-pf in water provided benefit when compared to untreated birds in weight gain ($p = 0.007$), feed intake ($p = 0.039$), lesion scores in both the jejunum ($p = 0.040$) and ileum ($p = 0.035$) and oocyst shedding ($p < 0.05$).

Anatara chief executive officer Steve Lydeamore said that "while this was an initial study, the results we have seen are extremely encouraging and point to a potentially commercially valuable product for development".

"Further work to optimize the dose and dosing regimen will help to cement the product's value," Mr Lydeamore said.

Anatara fell 1.5 cents or 7.1 percent to 19.5 cents.

DORSAVI

Dorsavi has requested a trading halt "pending an announcement in relation to the placement of shares forming part or all of the shortfall".

Trading will resume on February 3, 2021 or on an earlier announcement.

Dorsavi last traded at 3.6 cents.

BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt pending “an announcement in relation to the results of the BTX1801 phase IIa antimicrobial study”.

Last year, Botanix said it had begun recruitment for an up-to 60 patient trial phase IIa, antimicrobial study of its nasal, synthetic cannabinoid BTX1801 to prevent surgical site infections (BD: Aug 12, 2020).

Trading will resume on February 3, 2021 or on an earlier announcement.

Botanix last traded at 14.5 cents

SUDA PHARMACEUTICALS

Suda shareholders passed all six extraordinary general meeting resolutions but with 36.2 percent opposition against the company’s employee share option plan.

Suda said that the plan was passed with 34,572,013 votes (63.80%) in favor and 19,618,270 votes against (36.20%).

According to the company’s most recent appendix 2A application for quotation of securities, it had 383,544,877 shares on issue, meaning the vote against the employee share plan amounted to 5.11 percent of all shares on issue, sufficient to call extraordinary general meetings.

Suda was up 0.2 cents or 4.65 percent to 4.5 cents with 4.4 million shares traded.

LBT INNOVATIONS

LBT says chair Kate Costello will retire by October 2021 with director Caroline Popper retiring in May 2021.

LBT said it had “commenced an active process of board renewal”.

LBT fell half a cent or 4.8 percent to 10 cents.

ADHERIUM

In an appendix 3Z final director’s interest notice, Bryan Mogridge says that he retired as a director from Adherium, effective from January 29, 2021.

Adherium said Mr Mogridge was appointed as a non-executive director in July 2015.

Adherium was up 0.1 cents or 4.55 percent to 2.3 cents with 2.7 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed chimeric antigen receptor therapy (CAR-T) “pioneer” Cindy Elkins as a non-executive director.

Chimeric said Ms Elkins was formerly the chief information officer at Juno Therapeutics.

Chimeric was unchanged at 32 cents with 5.3 million shares traded.

EMYRIA

Emyria says it has appointed consultant psychiatrist Dr Richard Magtengaard to its medical advisory board.

Emyria said Dr Magtengaard was currently the director of the military trauma recovery program at two Perth mental health facilities and a member of the St John Ambulance expert advisory group.

Emyria fell half a cent or 4.2 percent to 11.5 cents with 2.1 million shares traded.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JANUARY 31, 2021

Company \$Am	Feb-20	Jan-21	Feb-21
Cochlear	13,781	12,425	12,859
CSL	140,926	128,840	121,433
Resmed	36,014	39,622	39,607
BDI-20			
Avita	1,355	530	712
Clinuvel	1,330	1,103	1,091
Compumedics	119	89	81
Cyclopharm	94	201	239
Cynata	112	95	96
Ellex	122	51	48
Genetic Signatures	165	287	271
Immutep	131	269	259
Medical Developments	657	464	472
Mesoblast	1,595	1,322	1,363
Nanosonics	2,055	2,417	2,062
Neuren	283	147	148
Opthea	926	648	660
Paradigm	831	576	519
Pharmaxis	45	37	35
Polynovo	1,950	2,565	1,719
Pro Medicus	2,483	3,560	4,294
Starpharma	434	635	611
Telix	375	1,060	1,102
Volpara	394	360	373
Second 20			
Actinogen	39	30	29
Alterity	18	63	73
Amplia	5	26	29
Antisense	33	75	103
Dimerix	25	47	57
Impedimed	66	135	144
Imugene	143	474	498
Kazia	46	146	152
LBT Innovations	37	35	30
Next Science	484	243	239
Oncosil	123	98	106
Optiscan	15	63	66
Orthocell	88	83	92
Osprey	11	36	34
Patrys	20	43	54
Prescient	21	43	70
Proteomics	25	83	72
Resonance	82	107	87
Universal Biosensors	32	77	81
Uscom	19	25	24

* Biotech Daily editor, David Langsam, owns shares in Acrux, Alcidion, Alterity, Amplia, BTC Health, Cochlear, Cynata, 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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