

Biotech Daily

Wednesday May 1, 2024

Daily news on ASX-listed biotechnology companies

- * APRIL BDI-40 UP 5% TO NEW RECORD HIGH, ASX200 DOWN 3%, BIG CAPS DOWN 1%
- * TODAY: ASX, BIOTECH DOWN: MESOBLAST UP 11%; CURVEBEAM DOWN 10.5%
- * MELODIOL Q1 RECEIPTS UP 93.5% TO \$5m; LESS THAN 1 QUARTER CASH
- * IMAGION LESS THAN 1 QUARTER CASH; 'VACATE PREMISES, STAFF CUTS'
- * ANATARA 'FIRM COMMITMENTS' FOR \$1m PLACEMENT
- * NANOSONICS FILES CORIS ENDOSCOPE CLEANER TO FDA
- * BTC: AUSTRALIAN PRESCRIBER LIST RETAINS INFUSION PUMPS
- * BTC WINS EUROSETS LANDING TGA APPROVAL
- * AUSTCO COMPLETES AMENTCO ACQUISITION
- * ONCOSIL: PANCREATIC CANCER DEVICE 'INCREASES VASCULARITY'
- * WEHI DRUG COMBINATION 'GREAT POTENTIAL' FOR BLOOD CANCER
- * DIMERIX: UK PAEDIATRIC DMX-200 PHASE III TRIAL OK
- * ANTEOTECH: ANTEOX ANODE '70% ENERGY RETENTION'
- * CAMBIUM TELLS ASX AWARE, 220% PRICE QUERY 'NEWS CONFIDENTIAL'
- * ACTINOGEN REQUESTS 'FUND RAISING' TRADING HALT
- * CAPITAL, CARRINGTON TAKE 6.4% OF BCAL
- * JARDEN BELOW 5% IN PACIFIC EDGE
- * CHIMERIC LOSES M-D JENNIFER CHOW
- * HERAMED LOSES DIRECTOR DR RON WEINBERGER

MARKET REPORT

The Australian stock market fell 1.23 percent on Wednesday May 1, 2024, with the ASX200 down 94.2 points to 7,569.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 22 were down, two traded unchanged and four were untraded. All three Big Caps fell.

Mesoblast was the best, up 11 cents or 11.1 percent to \$1.10, with 17.8 million shares traded. Clarity and Cynata climbed more than seven percent; Syntara was up 6.25 percent; Paradigm and Percheron were up more than five percent; Next Science improved 4.8 percent; 4D Medical was up 3.3 percent; Micro-X rose 2.2 percent; with Clinuvel, Genetic Signatures and SDI up by less than one percent.

Curvebeam led the falls, down two cents or 10.5 percent to 17 cents, with 315,299 shares traded. Atomo lost 6.25 percent; Nova Eye shed 5.4 percent; Dimerix, Impedimed, Proteomics and Starpharma fell four percent or more; Alcidion, Compumedics, Imugene, Medical Developments, Nanosonics and Prescient lost more than three percent; Avita, Cochlear, Immutep, Polynovo and Telix shed two percent or more; Emvision, Orthocell and Pro Medicus were down more than one percent; with CSL, Neuren, Resmed and Volpara down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top 40 Index (BDI-40) continued its record-breaking run, up a further 5.3 percent in April to a collective market capitalization of \$28,629 million, compared to the benchmark ASX200 down 2.95 percent to 7,664 points (see charts below).

In the year to April 30, the BDI-40 climbed 38.3 percent and the ASX200 rose 4.9 percent.

The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) slipped 1.1 percent in April to a collective market capitalization of \$203,289 million, with Resmed's further 9.0 percent recovery to \$48,252 million mostly compensating for CSL's 3.9 percent fall to \$133,745 million and Cochlear's 3.7 percent easing to \$21,292 million from February's record high. The three Big Caps lost 4.4 percent for the year to April 30.

April favored the BDI-20, with 11 companies up, eight down and one unchanged; while the generally smaller Second 20 had just five up, 14 down and one unchanged.

Significant increases in market capitalization by Pro Medicus (\$800 million), Telix (\$797 million) and Mesoblast (\$497 million) more than offset any falls.

Mesoblast was the best for the second month in a row, up a further 78.5 percent to \$1,130 million - the first time it has been over the billion-dollar mark since November 30, 2021. From a much lower base, Nova Eye was up 20.8 percent to \$64 million, followed by Clarity (20.2%), Resonance (19.4%), Telix (19.1%), Actinogen (17.3%) Immutep (13.1%), Cynata (11.8%), Dimerix (11.5%) and Pro Medicus (7.4%).

Avita led the falls, on a revenue warning, down \$280 million or 44.7 percent to \$347 million, followed by Syntara (24.0%), Universal Biosensors (23.9%), Paradigm (22.3%), Medical Developments (21.2%), Amplia (20.0%), Micro-X (19.4%), Percheron (17.3%), Imugene (17.1%), Opthea (16.1%) and Emvision (15.5%)

Seven of the 12 companies in Cannabis Corner fell, with five unchanged. Bioxyne lost 47.8 percent to \$12 million followed by Vitura (36.7%), Inhalerx (33.3%), Avecho (18.75%), Emyria (13.6%), Neurotech (8.9%) and Little Green Pharma (7.1%).

The collective market capitalization fell 18.1 percent to \$325 million down 33.8 percent from \$491 million a year ago, and a very long way from the \$1,945 million peak at February 29, 2021.

The Nasdaq Biotechnology Index (NBI) edged lost 6.0 percent in April to 4,162 points, down 0.6 percent for the year.

Three Australian companies which moved to the Nasdaq for "better valuations" Bionomics, Incannex and Kazia, lost 50.0 percent, 62.6 percent and 67.4 percent of their market capitalizations, respectively, in the past 12 months. Eyepoint (formerly Psivida) fell 10.4 percent to \$1,416 million in April, while Brisbane's Protagonist lost 12.0 percent to \$2,276 million and Redhill with Australian assets shed 12.5 percent to \$21 million.

Outside the BDI-40, Adalta, Argenica, Botanix, Mayne Pharma and PYC consolidated their gains in April.



BDI-40 v ASX200 Jun 30, 2006 to Apr 30, 2024- Adjusted

Big Caps \$m (Cochlear, CSL, Resmed) Apr 30, 2019 – Apr 30, 2024



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Apr 30, 2024 (Pre-Covid to date)



MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol says receipts from customers for the three months to March 31, 2024 were up 93.5 percent to \$5,014,000, compared to the previous corresponding period.

Melodiol said receipts were from sales of its marijuana-based therapeutic, food additive and "lifestyle" products, including \$1.6 million from its Windsor, Nova Scotia-based subsidiary Mernova Medical Inc and \$2.4 million from its distribution business.

The company said it had a cash burn of \$1,088,000 for the three months, with cash and cash equivalents of \$599,000 at March 31, 2024 compared to \$1,069,000 at March 31, 2023, leaving it with about 0.65 quarters cash.

Melodiol said it expected to reduce operating expenditure, increase revenues and it had "consistently demonstrated that it has various avenues by which it can draw down further capital, and a track record of utilizing these various avenues when required".

Melodiol fell 0.1 cents or 25 percent to 0.3 cents with 2.8 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has less than one quarter of cash on hand, will vacate its premises and is in "discussions with several parties looking to restructure the company".

Imagion said receipts from customers for sales of its Magsense cancer diagnostic for the three months to March 31, 2024 were up eight-fold to \$694,000, it had a cash burn of \$142,000 and cash of \$94,000 compared to \$2,563,000 at March 31, 2023.

The company said it had 0.7 quarters cash and had been reducing its staff costs since October 2023.

Imagion said it had filled recent nanoparticle manufacturing orders which had now ceased, would vacate its premises at the end of April 2024 and was focused on finding "a pathway to recapitalization and [reducing] amounts owing to creditors".

Earlier this year, Imagion said it had implemented staff and cost reductions, and that "essential personnel and infrastructure necessary to realize revenue from nanoparticle sales remains intact" (BD: Feb 29, 2024).

Today, the company said it expected \$700,00 from nano-particle sales, equipment sales and its Federal Research and Development Tax Incentive by July 2024, which was not enough to clear current creditor balances.

Imagion said it was "in discussions with several parties looking to restructure the company ... [and] to date these haven't resulted in a successful outcome and further updates will be provided should any of these discussions result in an outcome that can provide a pathway forward for the company".

Imagion was in a suspension and last traded at 7.3 cents.

ANATARA LIFE SCIENCES

Anatara says it has received "firm commitments" to raise \$1.0 million in a placement at four cents a share, a 3.5 percent discount to the 15-day volume weighted average price. Anatara said the funds would be used to refine product development and prepare for commercial manufacturing, strengthening its balance sheet and working capital purposes. The company said chair David Brookes and director John Michailidis had committed to take up \$60,000 and \$10,000 of the placement, respectively, subject to approval. Anatara said Taylor Collison and Candour Advisory acted as lead manager and advisor, respectively, with Taylor Collison to receive 2,000,000 options exercisable at 10 cents each within three years.

Anatara was up 0.1 cents or 2.1 percent to 4.9 cents.

NANOSONICS

Nanosonics says it has submitted a de novo application to the US Food and Drug Administration for its Coris flexible endoscope cleaning device.

Nanosonics said the submission followed a successful clinical in-use study and was "a significant step toward addressing one of the most critical challenges in instrument reprocessing".

The company said it would continue to conduct, publish and present studies on the Coris technology and progress the necessary activities required to support its commercialization during the regulatory review.

Nanosonics chief executive officer Michael Kavanagh said Coris was "designed to revolutionize endoscope reprocessing".

"By combining cutting-edge science and engineering with practical usability, Nanosonics aims to enhance patient safety and improve healthcare outcomes," Mr Kavanagh said. "Coris represents a significant opportunity for the organization and the submission to the FDA marks a pivotal moment in the company's journey," Mr Kavanagh said.

"We look forward to engaging with the FDA during the evaluation process," Mr Kavanagh said.

Nanosonics fell nine cents or 3.1 percent to \$2.83 with 718,965 shares traded.

BTC HEALTH

BTC says the Federal Government has retained infusion pumps for chronic pain management on the prescriber list status after July 1, 2024, ensuring reimbursement. BTC said remaining on the prescriber list meant private insurers were legally required to pay a defined benefit for use of the infusion pumps.

The company said subsidiary BTC Specialty Health Pty Ltd had a range of infusion pumps included on the prescriber list and had submitted full applications to the Department of Health and Aged Care, including for Rhythmic Evolution and Elasto-Q.

BTC executive chair Dr Richard Treagus said "the last three years have been challenging for the sector with changing dates, changing rules and no new products being added to the general use category over this time".

"Today's announcement is certainly a positive step and follows extensive dialogue with government focused on the need to put patient choice and access first," Dr Treagus said. "This provides greater certainty within the healthcare sector and a framework for our company to provide the latest and very best medical technologies to all Australian patients," Dr Treagus said.

BTC was untraded at 4.3 cents.

BTC HEALTH

BTC says it has Australian Therapeutic Goods Administration approval to sell its Eurosets Landing Advance for membrane oxygenation and cardio-pulmonary medical procedures. BTC said the device had a "large graphic interface and integrated data management system" and provided clinical teams with real-time monitoring of these complex and critical procedures.

BTC executive chair Dr Richard Treagus said "this advanced technology makes the lifesaving work of our healthcare professionals that much easier, ultimately helping to achieve more predictable and better patient outcomes".

"Our team is looking forward to implementing trials of Landing Advance at the major [extra-corporeal membrane oxygenation] units in the coming weeks," Dr Treagus said.

AUSTCO HEALTHCARE

Austco says it has completed its acquisition of the Brisbane-based Amentco Enterprise Group Ltd for \$5 million in up-front cash and \$2 million in scrip.

In February, Austco said it would buy the certified Nurse Call reseller and healthcare solutions provider Amentco (BD: Feb 21, 2024).

Today, the company said the shares had an issue price of 19.5 cents each, equal to the 30-day volume weighted average price prior to the settlement date.

Austco said the acquisition further increased its direct sales capability, provided "growth opportunities and enhances its range of solutions to better meet the needs of the Australian healthcare market".

Austco was unchanged at 19.5 cents with six shares traded.

ONCOSIL MEDICAL

Oncosil says a 20-patient study shows its device with chemotherapy "significantly increases the vascularity" of pancreatic tumors and decreases tumor size (p < 0.001). Oncosil said the study recruited 20 patients with unresectable, non-metastatic locally advanced pancreatic cancer undergoing standard Folfirinox chemotherapy with implantation of its device after two or three cycles of chemotherapy.

The company said 15 patients completed 12-week follow-up.

Oncosil said patients were assessed using contrast-enhanced harmonic endoscopic doppler ultrasound with high-mechanical index and computer tomography after two chemotherapy cycles and at four weeks and 12 weeks after device implantation. The company said after two cycles of chemotherapy and before device implantation all tumors showed a lower intensity of enhancement relative to surrounding normal pancreatic tissue, suggesting low vascularity, or hypo-vascularity.

Oncosil said that at four and 12-weeks post-device implantation "vascularity increased significantly in the treated tumors".

The company said historical data showed no changes in vascularity in response to chemotherapy alone and the longest diameter of the primary tumors decreased from a median of 32mm pre-implantation to 24mm post-implantation (p < 0.001).

Oncosil said at 12 weeks following implantation local disease control rate was 100 percent, with five patients having their tumours down-staged, three patients undergoing surgical resection to remove the primary tumor, one patient pending surgery and one patient refusing surgical treatment.

The company said the study conducted at the Royal Adelaide Hospital in South Australia was believed to be the first study to show increased vascularity within pancreatic primary tumors, which may increase the concentration of chemotherapy agents within the tumor. Oncosil said the results were presented by the Royal Adelaide Hospital's Dr Amanda Lim at the Annual Scientific Meeting of the Australian and New Zealand Society of Nuclear Medicine in Christchurch, New Zealand from April 26 to 28, 2024.

Oncosil managing-director Nigel Lange said it was "an important study that further explains the mode of action of Oncosil.

"In addition to delivering a tumoricidal dose of radiation therapy inside the primary pancreatic tumor that leads to significant tumor shrinkage and prolonged local disease control, this study demonstrates that the Oncosil device substantially increases vascularity within the tumor, which may in turn increase the concentration of chemotherapy agents that are widely acknowledged as otherwise being sub-optimal in this devastating disease," Mr Lange said.

Oncosil was unchanged at 0.5 cents with 24.1 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says a combination of venetoclax and a Sting agonist has shown "great potential as a future treatment" for acute myeloid leukaemia. The Institute said researchers tested standard-of-care venetoclax with the immunotherapy 'cyclic guanosine monophosphate-adenosine monophosphate synthase-stimulator of interferon genes' and found the combination eradicated blood cancer cells in-vitro. WEHI said the stimulator of interferon genes, or Sting, agonist immunotherapy drugs were used to attack solid tumors, but its study used them to directly target mechanisms within the cancer cells, stimulating the natural processes that caused the cells to die. The Institute said the research showed the drug combination was "notably successful against the more aggressive and difficult-to-treat forms" of acute myeloid leukaemia and may also change the way Sting agonist drugs are used to treat other cancers. WEHI said the combination showed high promise in blood cancer samples that were driven by a mutated p53 protein, and when working effectively, the protein prevented the

formation of cancerous cells, but when it was mutated could "significantly boost a person's risk of developing cancer".

WEHI said the study, titled 'Putting the STING back into BH3-mimetic drugs for TP53mutant blood cancers" was published in the journal Cancer Cell, with the full article available at: <u>https://www.sciencedirect.com/science/article/pii/S1535610824001284</u>. The Institute said researchers expected the results to be used in an acute myeloid leukaemia trial by Melbourne's Aculeus Therapeutics, led by Dr Mark Devlin.

DIMERIX

Dimerix says the UK Medicines and Healthcare Products Regulatory Agency (MHRA) has approved it to enrol children in its phase III trial of DMX-200 for kidney disease. Dimerix said following approval of its paediatric investigation plan it would open its phase III study of DMX-200 for focal segmental glomerulo-sclerosis (FSGS) kidney disease in children between the ages of 12 and 17 in the UK.

In March, Dimerix said that an interim analysis of the first 72 randomized patients in the 286-patient trial its phase III focal segmental glomerulo-sclerosis (FSGS) trial showed that DMX-200 reduced proteinuria more than placebo (BD: Mar 11, 2024).

Dimerix said the data "suggests a statistically significant and clinically meaningful result in reducing proteinuria at the end of the study may be possible".

Today, Dimerix said it had previously had trial approval from the European Medicines Agency (EMA) and the US Food and Drug Administration, with FSGS "one of the leading causes of end stage renal disease in children".

The company said the approval was "a major achievement towards potentially treating children with FSGS kidney disease globally".

Dimerix chief medical officer Dr David Fuller said it was pleasing that the MHRA paediatric investigation plan aligned with the European EMA plan and the FDA advice.

"Our single, phase III clinical study, having ... passed its first efficacy interim analysis is now being rapidly expanded to include new adult and paediatric sites," Dr Fuller said. Dimerix fell 1.5 cents or 4.5 percent to 32 cents with eight million shares traded.

ANTEOTECH

Anteotech says its high silicon anode using its Anteox technology has achieved 1,000 charge and discharge cycles with more than 70 percent energy retention. Anteotech was up 0.3 cents or 14.3 percent to 2.4 cents with nine million shares traded.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium has told the ASX that the information regarding its placement announced on April 5, 2024 was material and "remained confidential until its release".

The ASX asked whether the placement stayed confidential prior to its announcement and what could explain "the significant increase in the price of its securities after the release of the merger completion announcement and prior to the ... placement announcement". Last month, the then Regeneus said it completed its Cambium Medical Technologies LLC, merger and raised \$3.48 million at 0.6 cents a share (BD: Apr 5, 2024).

Today, the ASX said the company's share price increased 220 percent from 0.5 cents at the close of trading on April 4, 2024 to a high of 1.6 cents a share on April 5, 2024. Cambium said the merger was a "protracted process dating back over a year" with the process communicated in announcements since April 2023 (BD: Apr 28, 2023) Cambium was unchanged at 0.8 cents.

ACTINOGEN MEDICAL

Actinogen has requested a trading halt pending a "fund raising" announcement. Trading will resume on May 3, 2024, or on an earlier announcement. Actinogen last traded at 3.8 cents.

BCAL DIAGNOSTIC

Capital Property Corporation Pty Ltd says as trustee for Carrington Trust it has increased its holding in Bcal from 10,750,302 shares (5.2%) to 16,193,425 shares (6.4%). Canberra's Capital Property said it bought shares between February 21, 2022 and April 22, 2024, with the largest purchase 788,661 shares for \$82,809, or 10.5 cents a share. Bcal fell 0.1 cents or 1.1 percent to 9.1 cents.

PACIFIC EDGE

The Wellington, New Zealand-based Jarden Securities Ltd says it has ceased its shareholding in Pacific Edge after selling Harbour Asset Management Ltd. Jarden said it had previously held 124,296,760 shares (15.332%) of Pacific Edge through Harbour Asset, which it sold to Firstcape Group Ltd on April 30, 2024. Pacific Edge was up 0.4 cents or 5.3 percent to eight cents.

CHIMERIC THERAPEUTICS

Chimeric says managing-director Jennifer Chow will resign, effective from May 24, 2024. Chimeric said the board acknowledged "the major contributions made by Ms Chow said it would announce "further changes to its executive team in the short term". Chimeric fell 0.3 cents or 10 percent to 2.7 cents with 11.6 million shares traded.

<u>HERAMED</u>

Heramed says executive director and former chair Dr Ron Weinberger has resigned, effective immediately.

According to Commsec, Heramed will be below the three-director minimum required by the Corporations Act 2001 for a public company.

Heramed was in a suspension and last traded at 1.7 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT APR 30, 2024

Company \$Am	Apr 30, 2023	Mar 31, 2024	Apr 30, 2024
Cochlear	16,395	22,106	21,292
CSL	146,640	139,138	133,745
Resmed	49,528	44,285	48,252
BDI-20	49,520	44,200	40,252
Avita	586	627	347
Clinuvel	995	720	754
	28	48	46
Compumedics		40 169	
Cyclopharm	197 29	34	165
Cynata Constia Signatures	29 108	34 127	38 130
Genetic Signatures			
Immutep Madical Devalopments	233	452	511 41
Medical Developments	86	52	
Mesoblast	649	633	1,130
Nanosonics	1,708	833	885
Neuren	1,810	2,705	2,452
Nova Eye	40	53	64
Opthea	332	490	411
Polynovo Dro Modiaus	1,149	1,512	1,415
Pro Medicus	6,442	10,834	11,634
SDI Store harman	96	101	102
Starpharma	196	52	52
Syntara Pharmaxis	44	25	19
	3,342	4,176	4,973
Volpara	201	289	291
Second 20	054	054	005
4D Medical	251	254	235
Actinogen	116	75	88
Alcidion	123	68	72
Amplia	20	15	12
Atomo	19	20	20
Clarity	191	724	870
Curvebeam	87	66	61
Dimerix	31	165	184
Emvision	122	220	186
Impedimed	331	186	170
Imugene	803	768	637
Micro-X	50	62	50
Next Science	146	95	90
Orthocell	74	82	81
Paradigm	285	121	94
Percheron	54	75	62
Prescient	78	44	42
Proteomics	107	151	143
Resonance	20	31	37
Universal Biosensors	54	46	35

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

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