

Biotech Daily

Wednesday July 1, 2020

Daily news on ASX-listed biotechnology companies

- * 14-YEAR DATA: BIG CAPS UP 963%, BDI-40 UP 450%, ASX200 UP 16%
- * TODAY: ASX, BIOTECH UP: ALTERITY UP 871%; LBT DOWN 15%
- * TELIX: FDA TLX250-CDX RENAL CANCER 'BREAKTHROUGH' STATUS
- * LBT: JOHNS HOPKINS APAS INDEPENDENCE 'NO FALSE NEGATIVES'
- * TGA APPROVES NEXT SCIENCE BACTISURE SURGICAL LAVAGE
- * ALTERITY PLEADS SCHULTZ TO ASX 2,077% QUERY; ASX MISSES 300%
- * MACH7 RETAIL RIGHTS RAISE \$11.4m; TOTAL \$34.8m
- * ALCIDION \$560k SYDNEY MIYA PRECISION DEAL
- * AMPLIA UNDER-WRITTEN RIGHTS FOR \$4m
- * RESAPP PARTNERS WITH COVIU, PHENIX
- * MEDADVISOR, HMS INTEGRATE HEALTH PLATFORMS
- * GI DYNAMICS EXTENDS \$6.6m CRYSTAL AMBER NOTE, AGAIN
- * CRONOS LAUNCHES 2 MEDICAL MARIJUANA OILS IN AUSTRALIA
- * CRESO CEO MIRIAM HALPERIN WERNLI BELOW 5%
- * SUDA APPOINTS PHILLIP HAINS JOINT CO-SEC
- * ALISTAIR WARREN REPLACES LITTLE GREEN CO-SEC CRAIG BASSON

MARKET REPORT

The Australian stock market was up 0.62 percent on Wednesday July 1, 2020, with the ASX200 up 36.5 points to 5,934.4 points. Thirty-one of the Biotech Daily Top 40 stocks were up, five fell, three traded unchanged and one was untraded. All three Big Caps fell.

Alterity was the best (see below), closing up 14.8 cents or 870.6 percent at 16.5 cents, with 268.7 million shares traded. Actinogen climbed 27.3 percent; Osprey was up 18.2 percent; Impedimed improved 17.7 percent; Telix was up 16.8 percent, Patrys was up 9.1 percent; Paradigm rose 8.6 percent; Dimerix, Prescient and Universal Biosensors were up more than seven percent; Next Science and Volpara climbed six percent or more; Antisense, Genetic Signatures and Opthea were up more than five percent; Orthocell and Pharmaxis were up more than four percent; Cynata, Immutep, Imugene and Polynovo were up more than three percent; Kazia, Mesoblast, Neuren and Uscom rose more than two percent; with Clinuvel, Cyclopharm and Starpharma up more than one percent.

LBT led the falls, down 3.5 cents or 15.2 percent to 19.5 cents, with 4.5 million shares traded. Oncosil fell 4.35 percent; Compumedics lost 3.6 percent; Avita shed 2.4 percent; with Cochlear and Resmed down more than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Biotech Daily Top-40 Index (BDI-40) fell 4.0 percent in June, but was up 30.1 percent for the year, compared to the ASX200 up 0.2 percent in June and down 10.9 percent for the financial year.

For the 14 years since inception, the BDI-40 (which does not include the three Big Caps of Cochlear, CSL and Resmed) was up 333.8 percent, from a collective market capitalization of \$3,563 million at June 30, 2006 to \$15,455 million, last night.

By comparison, the benchmark ASX200 was up 16.2 percent for the 14-year period.

Adjusting the BDI-40 for company departures, equivalent to the ASX200 methodology, the BDI-40 was up 449.5 percent.

The collective market capitalization of the three Big Caps rose 36.0 percent for the 12 months to June 30 and 2.8 percent for the month of June.

For the 14 years, the collective market capitalization for the three Big Caps climbed 962.7 percent from \$17,156 million to \$182,316 million.

CSL slipped 0.2 percent in June to \$130,312 million, Cochlear shed 2.4 percent to \$12,410 million, but Resmed was up \$5,492 million or 16.1 percent to \$39,594 million.

For the year to June 30, Resmed rose 60.9 percent, CSL climbed 33.6 percent and Cochlear was up 4.2 percent.

In June, 12 BDI-40 companies were up (nine by more than 10 percent), 27 fell (15 by more than 10 percent) and one was unchanged.

For the 12 months to June 30, the best performing biotech company was Opthea up 280.2 percent for the year, despite falling 20.5 percent in June. Mesoblast was up 168.1 percent for the year, followed by Genetic Signatures (119.3%) and Polynovo (64.9%). Pharmaxis was the BDI-20's worst, down 74.3 percent for the year, with Ellex down 44.1 percent.

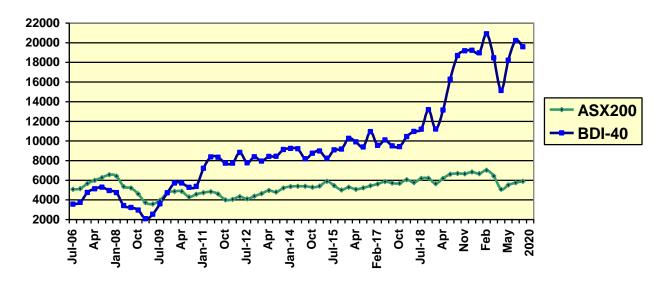
From smaller bases in the Second 20, Dimerix improved 430.8 percent to \$69 million, followed by Oncosil (190.1%), Imagene (131.0%), Kazia (104.5%) and LBT (100.0%).

Outside the BDI-40, Phylogica climbed 374.6 percent to \$337 million for the year to June 30, 2020, followed by Pharmaust up 370.0 percent to \$47 million, Imagion (320.0%), Recce (295.7%), Tali (280.0%), Memphasys (214.3%) and Mach7 (197.2%).

The 21 companies in Cannabis Corner fell a further 15.2 percent in June and down 58.9 percent for the year, with most companies falling for both the month and the year to June 30. The exceptions were Bod, Esense, Lifespot, Palla Pharma and Zelira.

On the Nasdaq, Queensland's Protagonist was up 28.3 percent in June to \$912 million and up 125.7 percent for the year, Redhill (with Australian assets) was down 9.2 percent for the month but up 30.0 percent for the year, with Eyepoint (Psivida) down 14.9 percent in June and down 44.8 percent for the year.

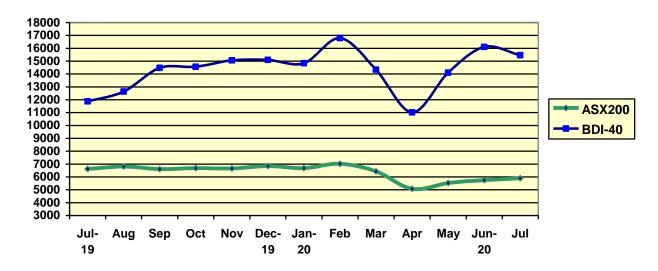
BDI-40 v ASX200 Jun 30, 2006 to Jun 30, 2020- Adjusted



Five-year Big Caps \$m (Cochlear, CSL, Resmed) Jun 30, 2015 – Jun 30, 2020



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



TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has granted breakthrough therapy designation for its renal cancer imaging product TLX250-CDx.

Telix said its TLX250-CDx used positron emission tomography (PET) imaging to determine if "indeterminate renal masses", identified through computed tomography (CT) and magnetic resonance imaging (MRI) imaging, were either clear cell renal cell cancer or non-clear cell renal cell cancer.

The company said it would be eligible for fast track designation, more frequent interactions with the FDA and the opportunity to submit a biological licence application for TLX250-CDx through a streamlined review process.

Telix chief executive officer Dr Christian Behrenbruch said the breakthrough designation for the kidney cancer imaging product "provides Telix with the opportunity to interact closely with the FDA to expedite the registration process of TLX250-CDx, a particularly important consideration given the current phase III development status of the asset". "There is a significant unmet medical need to improve diagnosis and staging of clear cell renal cell carcinoma, which is the most common and aggressive form of kidney cancer," Dr Behrenbruch said.

Telix was up 21.5 cents or 16.8 percent to \$1.495 with 4.2 million shares traded.

LBT INNOVATIONS

LBT says an independent evaluation of its APAS Independence by the Johns Hopkins Hospital and School of Medicine achieved no false negatives.

LBT said the three-month study at the Baltimore, Maryland-based Johns Hopkins University evaluated the ability of its automated plate assessment system (APAS) Independence to identify 4,603 patient samples for methicillin-resistant Staphylococcus aureus (MRSA) compared to current manual culture plate reading.

The company said the results, to be presented as an electronic poster, titled 'Comparison of an Automated Plate Assessment System (APAS Independence) and Artificial Intelligence (AI) to Manual Plate Reading of Methicillin-resistant Staphylococcus aureus Chromagar Surveillance Cultures' on the American Society of Microbiology's ASM Microbe Online, showed that the APAS Independence with an MRSA module demonstrated high accuracy compared to manual reading and detected low-level positives missed by manual reading.

The study concluded that "compared to manual reading, the APAS demonstrates high accuracy and detected low-level positives missed by manual reading".

"In a laboratory with a moderate volume of plates [about 70 per day], modest gains in technologist time are realized," the report concluded.

"In a laboratory with high throughput MRSA cultures and/or a larger menu of chromagar cultures ... greater efficiencies may be realized," the study concluded.

LBT fell 3.5 cents or 15.2 percent to 19.5 cents with 4.5 million shares traded.

NEXT SCIENCE

Next Science says the Australian Therapeutic Goods Administration has approved its Bactisure surgical lavage for the removal of bacteria, fungus and infection from wounds. Next Science said Bactisure would be sold by its international distributor, Zimmer Biomet. The company said Bactisure washed out the surgical cavity to remove biofilm and microscopic bacteria, viruses and fungi that could cause infection. Next Science was up 7.5 cents or six percent to \$1.325.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 2,076.5 percent from 1.7 cents at last night's close to a high of 37 cents today, July 1, 2020, and noted a "very significant increase" in the trading volume.

In fact, Alterity climbed as much as 2,370.5 percent to 42 cents at 10.58am this morning, prior to a pause in trading at 11.21am, when it last traded at 32 cents.

Yesterday, the company said that the US Food and Drug Administration had agreed part of its phase II trial design for ATH434 for multiple system atrophy and the company and FDA were yet to agree on the endpoints.

Last night, Alterity was up 0.1 cents or 6.25 percent to 1.7 cents with 6.1 million shares traded.

Overnight on the Nasdaq, the company was up 61 US cents or 103.4 percent to \$US1.19 (\$A1.73) with 47.027 million US shares traded. Each US share is equivalent to 60 Australian shares, implying a closing price of 2.88 cents with 2,821.6 million shares traded.

Today, Alterity opened at three cents and climbed as high as 42 cents before the pause. Alterity re-opened at 25 cents at 3.14pm and climbed to 35 cents before closing up 14.8 cents or 870.6 percent at 16.5 cents with 268.7 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has raised \$11.4 million through the retail component of a one-for-four, non-renounceable, entitlement offer, for a total \$34.8 million raised at 68 cents a share. Last month, Mach7 said it hoped to raise \$34.8 million to buy the Waterloo, Ontario-based Client Outlook for \$CA38.5 million (\$A40.8 million), with the placement and institutional

Today, the company said it had applications for 15,555,413 shares raising \$10.7 million with a shortfall of 1,239,435 shares worth \$700,000 to be placed by the underwriter, Morgans Corporate.

Biotech Daily calculates that at 68 cents a share the company had applications for \$10,577,681 in shares with a shortfall of \$842,816.

Mach7 confirmed Biotech Daily's calculations.

rights offer raising \$23.4 million (BD: Jun 10, 12, 2020).

Mach7 was up 3.5 cents or 3.6 percent to \$1.005 with 1.7 million shares traded.

ALCIDION GROUP

Alcidion says it has an initial one-year \$560,000 deal with Sydney Local Health District for its Miya Precision patient management system.

Alcidion said that Sydney LHD serviced the centre and inner west of Sydney at five hospitals, including the Royal Prince Alfred and Concord Hospitals.

The company said the Miya Precision platform supported integration of devices and electronic medical record data to monitor patients, and for Sydney LHD's virtual hospital, Royal Prince Alfred virtual, which was currently used to support Covid-19 patients in home isolation.

Alcidion said Sydney Local Health District would have the right to extend the contract for a further one year.

Alcidion was up one cent or 6.9 percent to 15.5 cents with 3.7 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it hopes to raise \$4 million through a fully-underwritten, three-for-five, prorata, non-renounceable entitlement offer at 10 cents a share.

Amplia said the offer price was at a 19.6 percent discount to the 10-day volume weighted average price to June 30, 2020 and a 20 percent discount to the last closing price of 12.5 cents on June 30.

The company said the record date would be July 3, 2020 and the offer would include an institutional entitlement offer, which would open today and close tomorrow July 2, with a retail offer, opening on July 8 and closing on July 28.

Amplia said eligible retail shareholders would be able to apply for up to 100 percent of their entitlement under the shortfall.

The company said Taylor Collison would receive 2,000,000 options as the underwriter, exercisable at 20 cents a share within three years.

Amplia said the funds would be used for preclinical studies, for a phase I trial of AMP945, for drug capsule manufacture, intellectual property and licences and for working capital. Amplia requested a trading halt pending the outcome of the capital raising.

Trading will resume on July 3, 2020 or on an earlier announcement.

Amplia last traded at 12.5 cents.

RESAPP HEALTH

Resapp says it has two-year service and software agreements with telehealth providers Coviu Global and Phenix Health for its Resappdx-EU respiratory diagnostic.

Resapp said both agreements would allow the company to provide the Resappdx-EU diagnostic through the Coviu internet-based telehealth platform from July 9, 2020 and through the Phenix telehealth application from July 6 through the Apple App Store.

The company said its Resappdx-EU used the patient's smartphone to record and analyze cough sounds.

Resapp said it would receive a per test licence fee of between \$5 and \$10 through both agreements and would make Resappdx-EU available for Android mobile phones this year. The company said that more than 22,000 health professionals used the Coviu platform, a spinout from the CSIRO's Data61.

Resapp was unchanged at 17.5 cents with 3.2 million shares traded.

MEDADVISOR

Medadvisor says it has a three-year agreement with the Irving, Texas-based Health Management Systems (HMS) for a secure digital communication product.

Last year, Medadvisor said HMS Holdings had become substantial in the company with 220,000,000 shares or 12.8 percent (BD: oct 11, 2019).

Today, the company said the agreement would allow it to integrate its health programs platform with HMS' Eliza health engagement product, to enable healthcare organizations to communicate and deliver better messages.

Medadvisor said it would broaden the HMS US health programs from traditional interactive voice response to include secure digital functionality, including the use of internet-based content, short message service (SMS) messaging and other content.

The company said it expected to generate revenue for each secure digital message sent on behalf of HMS' clients.

Medadvisor said the new product would go live by January 2021.

Medadvisor was up 5.5 cents or 11.0 percent to 55.5 cents with 1.9 million shares traded.

GI DYNAMICS

GI Dynamics says it has further extended the maturity date of its \$US5,000,000 (\$A6,595,767) Crystal Amber Fund convertible note from June 29 to July 31, 2020. In May and June, GI Dynamics said Crystal Amber repeatedly extended the maturity date and said that if funding was not secured it "would need to cease operations" and delist from the ASX (BD: Jun 15, 2017; May 4, 18, Jun 17, 2020).

Today, GI Dynamics said Crystal Amber had ceased negotiations with potential investors, but had an ongoing interest in financing the company.

GI Dynamics was unchanged at 0.3 cents with 1.4 million shares traded.

CRONOS AUSTRALIA

Cronos says it has launched two Adaya medical marijuana oil products in Australia through the Australian special access scheme.

Cronos said the products included a 600 milligrams (mg) in 30 millilitre (ml) tincture with equal quantity cannabidiol (CBD) and tetrahydrocannabinol (THC) product and a 780mg in 30ml 1:25 high CBD product, to be distributed through its distribution network of pharmacies and hospital pharmacies.

The company said it intended to launch a further two Adaya products by September 30, 2020, including a CBD only product, Adaya CBD 100 3,000mg in 30ml and a THC only product, Adaya THC 26 with 1,300mg in 50ml.

Cronos was up 1.25 cents or 18.4 percent to 8.05 cents.

CRESO PHARMA

Creso chief executive officer Miriam Halperin Wernli says her 12,800,000 shareholding has been diluted below five percent and she has ceased to be a substantial shareholder. The Baar, Switzerland-based Ms Wernli said that she was diluted on June 2, 2020 in the \$2,137,000 placement at six cents a share (BD: Jun 1, 2020).

Creso was up 0.4 cents or 12.9 percent to 3.5 cents with 5.7 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has appointed The CFO Solutions' Phillip Hains as joint company secretary with Joseph Ohayon and changed the address of its registered office.

Suda said Mr Ohayon continued as chief financial officer.

Suda was unchanged at 3.7 cents.

LITTLE GREEN PHARMA

Little Green Pharma says Alistair Warren will replace company secretary Craig Basson effective from today.

Little Green said Mr Warren had worked as the company's general counsel since January 2018 and as a lawyer since 2004.

The company said Mr Warren was previously with law firm Freehills, now Herbert Smith Freehills and was in-house legal counsel for BHP in Singapore, Chile and Australia. On his Linkedin page, Mr Warren said he held a Bachelor of Laws and Bachelor of Arts from the University of Western Australia and a Graduate Diploma of Applied Economics from Murdoch University.

Little Green was up half a cent or 1.4 percent to 35.5 cents.

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

Company \$Am	Jul-19	Jun-20	Jul-20
Cochlear	11,915	12,708	12,410
CSL	97,511	130,544	130,312
Resmed	24,613	34,102	39,594
BDI-20			
Avita	785	1,013	966
Clinuvel	1,680	1,119	1,267
Compumedics	108	89	74
Cyclopharm	101	122	111
Cynata	127	74	71
Ellex	76	71	98
Genetic Signatures	140	272	307
Immutep	85	90	76
Medical Developments	347	517	458
Mesoblast	706	2,143	1,893
Nanosonics	1,683	2,101	2,050
Neuren	115	169	127
Opthea	167	799	635
Paradigm	269	652	708
Pharmaxis	101	35	26
Polynovo	1,018	1,712	1,679
Pro Medicus	2,601	2,922	2,750
Starpharma	518	415	419
Telix	271	349	325
Volpara	359	347	342
Second 20			
Actinogen	11	21	25
Alterity (Prana)	25	19	18
Amplia (Innate)	4	9	8
Antisense	19	36	36
Dimerix	13	45	69
Impedimed	44	80	62
Imugene	58	147	134
Kazia	22	44	45
LBT Innovations	27	37	54
Next Science	434	264	226
Oncosil	33	71	96
Optiscan	27	21	18
Orthocell	78	66	58
Osprey	33	18	16
Patrys	27	14	13
Prescient	15	20	22
Proteomics	28	31	39
Resonance	42	80	67
Universal Biosensors	39	39	35
Uscom	19	33	32

^{*} 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: http://www.australianethical.com.au/who-we-invest-in. These holdings are liable to change.

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