Biotech Daily

Monday August 3, 2020

Daily news on ASX-listed biotechnology companies

*** JULY BDI-40 DOWN 2.4%: BIG CAPS DOWN 2.4%, ASX200 UP 0.5%**

*** TODAY: ASX EVEN, BIOTECH DOWN: PATRYS UP 7%; OSPREY DOWN 15%**

*** HATCHTECH: FDA OKAYS XEGLYZE FOR HEAD LICE (19 YEARS)**

*** ZELIRA 'OVERSUBSCRIBED' PLACEMENT RAISES $8.75m**

*** SUDA: 'OVERSUBSCRIBED' RIGHTS RAISE $3.6m; $533k PLACEMENT**

*** REDHILL: FDA ALLOWS PHASE III RHB-204 FOR NTM TRIAL**

*** PRESCIENT COMPLETES 1st PTX-200 FOR AML COHORT DOSING**

*** MEDLAB: NANABIS 60% REDUCTION IN PAIN**

*** ANTISENSE FILES ATL1102 FOR DMD FDA ORPHAN APPLICATION**

*** COGSTATE: EISAI TO LINK NOUKNOWN WITH EASIIT**

*** THC H1 RECEIPTS UP 123% TO $3.2m**

*** CRESO H1 RECEIPTS UP 314% TO $2.9m**

*** TBG H1 RECEIPTS OF $2.8m**

*** ADHERIUM RECEIPTS DOWN 22.5% TO $2.7m**

*** REGENEUS RECEIPTS OF $1.6m**

*** CANN GLOBAL RECEIPTS UP 54% TO $1.3m**

*** PERENNIAL TAKES 6% OF MICRO-X**

*** CREDIT SUISSE TAKES 9.6% OF SUDA**

*** DR PAUL COZZIE INCREASES, DILUTED TO 14.2% OF CARDIEX**

*** BARD1 FOUNDER DR IRMGARD IRMINGER-FINGER DILUTED TO 5.16%**

*** IMAGION TO RELEASE 2.5m VOLUNTARY ESCROW SHARES**

*** ESENSE APPOINTS WINTON WILLESEE DIRECTOR; NON-COMPLIANCE**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Monday August 3, 2020, with the ASX200 down 1.7 points to 5,926.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 24 fell and three traded unchanged. All three Big Caps were up.

Patrys was the best, up 0.1 cents or 7.1 percent to 1.5 cents, with 4.4 million shares traded. Prescient climbed 5.4 percent; Actinogen, Cochlear and Genetic Signatures improved more than four percent; CSL, Dimerix, Pharmaxis and Uscom rose more than two percent; Antisense, Avita, Mesoblast, Orthocell and Pro Medicus were up more than one percent; with Cynata and Resmed up by less than one percent.

Osprey led the falls, down 0.6 cents or 15.0 percent to 3.4 cents, with 44.5 million shares traded. Resonance retreated 6.45 percent; Alterity, Kazia and Universal Biosensors lost more than five percent; Impedimed, Nova (Ellex) and Oncosil fell four percent or more; Amplia, Imugene, LBT, Next Science, Paradigm and Volpara were down three percent or more; Compumedics, Opthea and Telix shed more than two percent; Clinuvel, Cyclopharm, Medical Developments and Nanosonics were down more than one percent; with Neuren, Proteomics and Starpharma down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

July told a tale of two watchlists, with the Biotech Daily Top-20 Index (BDI-20) down 4.5 percent and from mostly far lower bases, the Second 20 was up 25.6 percent.

While the benchmark ASX200 managed to edge up half a percent in July, the Biotech Daily Top-40 Index (BDI-40) fell 2.4 percent, as did the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) with the Nasdaq Biotechnology Index (NBI) down 1.7 percent.

In July, 27 of the BDI-40 companies were up, 17 by more than 10 percent and 10 by more than 20 percent. Only 12 fell, with six down by more than 10 percent.

But the large percentage rises in the Second 20 fell short of compensating for the greater losses in the Top 20.

Osprey was by far the best, from the third lowest market capitalization at June 30, putting on 275.0 percent to $60 million in July.

(Mesoblast was the best in the BDI-20 up $344 million but only translating to an 18.2 percent increase.)

Alterity was up 116.9 percent to $39 million, followed by Imugene (90.3%), Amplia (62.5%), Proteomics (38.5%), Universal Biosensors (28.6%), Dimerix (27.5%), Pharmaxis (26.9%), Impedimed (25.8%) and Optiscan (22.2%).

Nova Eye (Ellex) led the falls, having sold off its major revenue-earning laser and ultrasound business, falling 52.0 percent to $47 million, followed by Avita taking a $314 million hit, or 32.5 percent, on its migration to the Nasdaq, where we are told there are better valuations of companies than the ASX.

LBT fell 20.4 percent to $43 million, followed by Medical Developments (13.3%), Clinuvel (12.6%), Polynovo (10.2%) and Pro Medicus (8.8%).

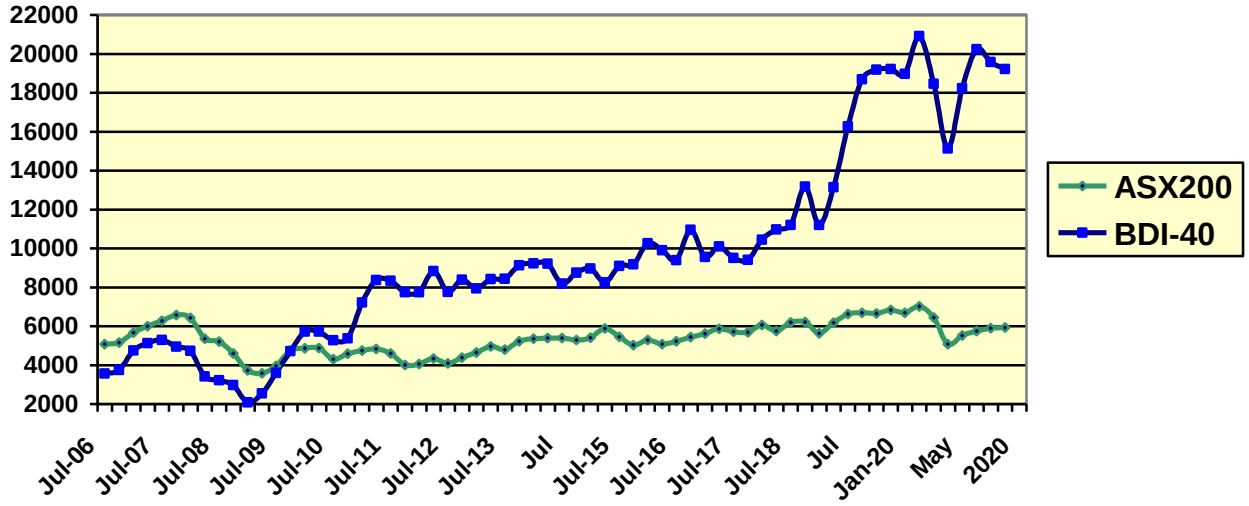
The collective market capitalization of the three Big Caps slipped 2.4 percent in July, with behemoth CSL down 4.4 percent to $124,614 million, while Resmed improved 2.7 percent to a record $40,658 million and Cochlear was up 2.3 percent to $12,691 million.

The 22 Cannabis Corner rose 9.2 percent in July to $1,066 million, down 44.2 percent for the year, and down 45.0 percent from the August 31, 2019 peak of $1,939 million.

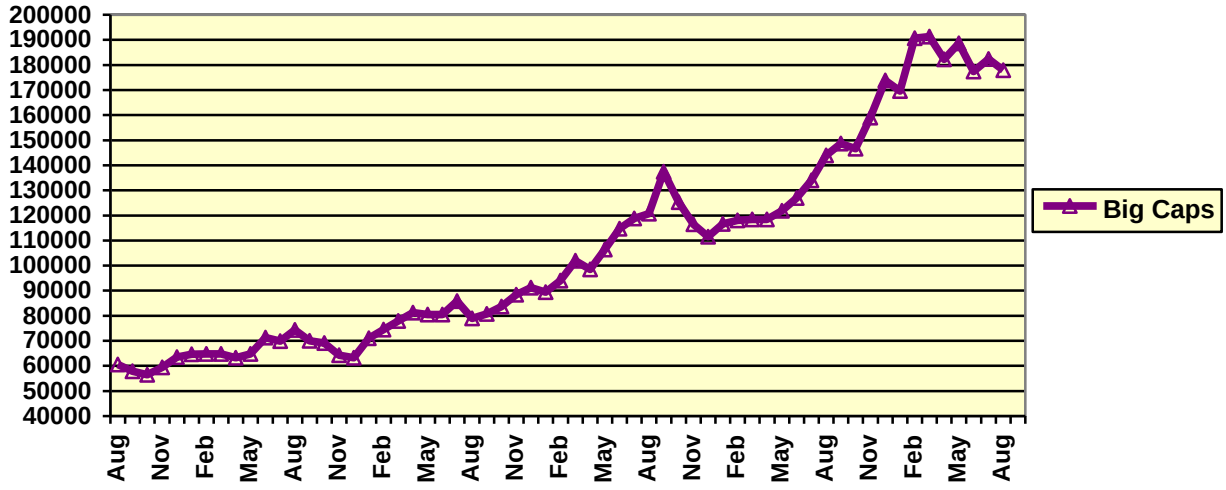
Outside the BDI-40, Aroa Biosurgery had a stunning debut, putting it straight into the Third 20 and replacing Sienna which has become part of Bard1. Cogstate, Immuron, Genetic Technologies, Mach7, Memphasys, PYC, Race and Recce all strengthened in July.

On the Nasdaq, Redhill (with Australian assets) was up 14.6 percent, Queensland's Protagonist fell 13.8 percent, with Eyepoint (Psivida) down 9.5 percent.

BDI-40 v ASX200 Ju; 31, 2006 to Jul 31, 2020- Adjusted



Five-year Big Caps $m (Cochlear, CSL, Resmed) Jul 31, 2015 – Jul 31, 2020



HATCHTECH

Hatchtech says partner Dr Reddy's Laboratories has US Food and Drug Administration approval of Xeglyze for head lice in patients six months of age and older.

Hatchtech has been developing the treatment, previously known as Deovo since 2001, and in 2005 then chief executive officer Dr Paul MacLeman told Biotech Daily the product had "100 percent efficacy in-vitro" to kill louse eggs and it would be a 10-minute treatment to be done at the same time as the head lice treatment regime, but would remove the need for a repeat treatment (BD: May 15, 2006).

The company's founding investor was Uniseed with later investments from Oneventures, GBS Venture Partners and Bluesky, with Dr Stewart Washer as chair.

Hatchtech said at that time that existing head lice treatments killed the lice, but not the unhatched eggs, requiring a second treatment seven to 10 later to kill the hatchlings.

Today, the company said the FDA had approved Xeglyze, or abametapir, lotion 0.74 percent for the topical treatment of head lice.

Hatchtech said it completed the submission to the FDA in September 2015 and at the same time sold the rights to Xeglyze to Dr Reddy's Laboratories for selected territories, including the US.

Hatchtech chief executive officer Hugh Alsop said the FDA approval was "the culmination of the journey to gain approval of the product originally developed by Hatchtech".

"This is a fantastic outcome for Dr Reddy's, Hatchtech and our shareholders," MR Alsop said.

"We are excited to finally see this product gain approval and we look forward to product launch in the US, enabling availability of this novel product for the treatment of head lice infestation," Mr Alsop said.

The company said it received an FDA "complete response letter" in August 2016, citing manufacturing deficiencies at the Dr Reddy's manufacturing plant in India, which received an FDA warning letter in November 2015.

Hatchtech said the deficiencies had "only now been resolved, paving the way for approval of the product".

Hatchtech chairman and Oneventures managing-partner Dr Paul Kelly said his company was "excited that Dr Reddy's have secured approval for Xeglyze" and while the program experienced a significant delay "we have never wavered in our support for the product or the team that has achieved this outcome".

"This is a real credit to those that have been involved in this journey over the many years and is a testament to resilience, teamwork and an unwavering focus on the issues that really matter," Dr Kelly said.

Hatchtech said that the university-backed venture capital firm Uniseed provided the initial funding for Hatchtech, which was founded in 2001 by the University of Melbourne's deputy director of the Centre for Animal Biotechnology Dr Vern Bowles.

Uniseed chief executive officer Dr Peter Devine said that Hatchtech was one of Uniseed's first investments and was "the first of our human therapeutics companies to get product approval, validating our model of facilitating early stage commercialization of research partner [intellectual property".

Hatchtech said that milestone payments associated with product approval was "a welcome return for Hatchtech's venture capital investors" including Oneventures, Queensland Investment Corp, GBS Venture Partners, Uniseed and the University of Melbourne, along with sophisticated investors.

The company said that a total $33 million was invested since the formation of the company.

Hatchtech is a private company.

ZELIRA THERAPEUTICS

Zelira says it has commitments to raise $8.75 million through an “oversubscribed” placement at 5.0 cents a share.
Zelira said the funds would be used to accelerate its plans to launch five products into global markets and to advance its planned clinical programs.
The company said Morgans Corporate was lead manager to the placement.
Zelira fell 0.2 cents or 3.4 percent to 5.7 cents with 2.5 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has raised $3.56 million through a “heavily oversubscribed” one-for-one non-renounceable pro rata entitlement offer at 2.5 cents a share.
Last month, Suda said it hoped to raise $3.56 million through the rights offer and participants would receive one free attaching option for every three shares purchased, exercisable at five cents by July 31, 2022 (BD: Jul 3, 2020).
Today, the company said it had applications for $5.2 million but top-up applications were scaled back, and options would be exercisable by June 30, 2021 at 37 cents a share.
The company said that it would place a further 21,338,159 shares at 2.5 cents a share to raise $533,453 through a placement to sophisticated investors.
Suda said that funds from the placement would be used to supplement working capital.
Suda fell 0.4 cents or eight percent to 4.6 cents with 4.1 million shares traded.

REDHILL BIOPHARMA

Redhill says the US Food and Drug Administration has approved a 125-patient, phase III study of RHB-204 for pulmonary non-tuberculous mycobacteria (NTM).
Redhill said that the FDA had approved the investigational new drug application for the trial and said that RHB-204 was “a potential first-line, oral treatment for pulmonary nontuberculous mycobacteria infections, a rare disease caused by Mycobacterium avium complex infection, with no FDA-approved first-line therapy.
The company said it had also submitted an orphan drug designation application to the FDA and RHB-204 previously was granted qualified infectious disease product (QIDP) designation and was eligible for fast-track development, new drug application priority review and a total of eight years of US market exclusivity, if approved.
Principal investigator and Portland State University professor Prof Kevin Winthrop said that non-tuberculous mycobacteria infections were “enormously challenging, resistant to most antibiotics, and can cause significant lung damage, and they are becoming more prevalent”.
Redhill said that the pivotal study at up to 50 sites in the US would evaluate RHB-204 as a first-line, stand-alone, orally-administered therapy.
The company said that the randomized, double-blind, placebo-controlled, parallel-group pivotal study would evaluate the safety and tolerability of RHB-204, patient-reported outcomes, sputum culture conversion by month-6 of treatment and patients will continue to receive treatment for 12 months from sputum culture conversion.
Redhill said that RHB-204 was a fixed-dose oral capsule containing a combination of clarithromycin, rifabutin, and clofazimine.
On the Nasdaq last Friday, Redhill was up 38 US cents or 5.03 percent to $US7.93 ($A11.10) with 1,194,304 shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has completed dosing of the first cohort of its modified phase Ib trial of PTX-200 and cytarabine for relapsed or refractory acute myeloid leukaemia.

Last November, Prescient said it would expand its trial following a third complete response after it found overlapping drug interactions between PTX-200 and cytarabine, which were not present in a previous phase Ib trial of PTX-200 for acute myeloid leukaemia as a single agent (BD: Nov 27, 2019).

Today, the company said the modifications included maintaining the day one PTX-200 dose, removing days eight and 15 and delaying the start of the cytarabine five-day continuous infusion to days three to seven of a 21-day cycle.

Prescient said no dose limiting toxicities were observed in the three patients enrolled and dosed with 25mg/m2 of PTX-200.

The company said it would progress to the next dose level of 35mg/m2.

Prescient was up 0.3 cents or 5.4 percent to 5.9 cents with 5.2 million shares traded.

MEDLAB CLINICAL

Medlab says data from its observational study of Nanabis for pain has shown an average 59.5 percent reduction in pain in 432 patients.

Medlab said Nanabis included an equal combination of tetrahydrocannabinol (THC) and cannabidiol (CBD), optimized with its drug delivery platform, Nanocelle.

The company said data showed that the 432 enrolled patients averaged four sprays of Nanabis per day and the reduction in pain included patients treated from one month to three months.

Medlab said that the observational study hoped to enrol up to 2,000 patients who paid a reduced amount for access to the marijuana-based Nanabis.

The company said that of the patients enrolled, 15 percent had cancer-related pain and 85 percent non-cancer-related pain.

Medlab chief executive officer Dr Sean Hall said it was “significant that the body of evidence on the safety, tolerability and efficacy of Nanabis is growing”.

“We are looking to formally submit our multi-centred phase III trials protocol to the US, UK and Australian regulatory authorities this calendar year,” Dr Hall said.

“The confirmation of the performance of our product through these real-world trials encourages us to continue to push ahead aggressively with our ultimate objective of a drug registration for Nanabis,” Dr Hall said.

Medlab was up half a cent or 3.7 percent to 14 cents.

ANTISENSE THERAPEUTICS

Antisense says it has submitted an orphan drug designation application to the US Food and Drug Administration for its ATL1102 for Duchenne muscular dystrophy.

Antisense said orphan drug designation could be granted for the treatment of rare diseases that affected fewer than 200,000 people in the US and included tax credits towards the cost of clinical trials, a waiver of US prescription drug filing fees and orphan product exclusivity for seven years upon marketing authorization.

The company said it expected to submit an orphan drug designation application to the European Medicines Agency by October 2020.

Antisense was up 0.1 cents or 1.3 percent to 7.9 cents with 1.1 million shares traded.

COGSTATE

Cogstate says Tokyo's Eisai will link its Nouknow brain health self-assessment tool to the Easiit application for dementia by September 2020.
Last year, Cogstate said Eisai would distribute its technology in Japan, and in March, said Eisai would launch the Nouknow "digital brain performance tool … for self-assessment of brain health" that month (BD: Aug 28, 2019; Mar 23, 2020).
Today, the company said that in conjunction with Dena Co, the Easitt application aimed to eliminate the lack of understanding about brain health decline mitigation through readjustments in lifestyle.
Cogstate was up three cents or 5.6 percent to 57 cents.

THC GLOBAL GROUP

THC says receipts from customers for the six months to June 30, 2020 were up 122.9 percent to $3,168,000 compared to the previous corresponding period.
THC said receipts from customers for the three months to June 30, 2020 rose 237.2 percent to $1,949,000.
The company said revenue was primarily from its Canadian hydroponics equipment and cultivation business, but also from sales of its Canndeo medical marijuana and from manufacturer agreements for Cannatrek and Medleaf Therapeutics.
THC said it had cash and cash equivalents of $9,039,000 at June 30, 2020 compared to $5,689,000 at June 30, 2019.
THC fell one cent or 3.5 percent to 27.5 cents.

CRESO PHARMA

Creso says receipts from customers for the six months to June 30, 2020 were up 314.0 percent to $2,948,000 compared to the previous corresponding period.
Creso said receipts from customers for its Cannqix food additives, Mernova medical marijuana and its anibidiol animal health products for the three months to June 30, 2020 rose 154.7 percent to $1,505,000.
The company said it had cash and cash equivalents of $3,281,000 at June 30, 2020 compared to $3,580,000 at June 30, 2019.
Creso fell 0.1 cents or 3.2 percent to three cents with 1.7 million shares traded.

TBG DIAGNOSTICS

TBG says receipts from customers for the six months to June 30, 2020 were $2,816,000.
Last year, TBG said revenue for the six months to June 30, 2020 was up 21.2 percent to $1,558,390 but had no equivalent Appendix 4C (BD: Aug 30, 2019).
On March 17, the company was suspended from the ASX following its share price climbing as much as 1,053.8 percent to 30 cents, closing at 27 cents before the halt, and on March 18, the company said that TBG Xiamen had Conformité Européenne (CE) Mark approval for Covid-19 diagnostic test kits (BD: Mar 17, 18, 2020).
Today, the company said it had $1.3 million in revenue for the three months to June 30, 2020 from sales of its high-resolution human leukocyte antigen (HLA) sequence-based typing products and received $127,000 from its TBG Xiamen Covid-19 test kits.
TBG said it had cash and cash equivalents of $4,099,000 at June 30, 2020.
TBG remained in an ASX suspension and last traded at 27 cents.

ADHERIUM

Adherium says receipts from customers for the year to June 30, 2020 were down 22.5 percent to $2,731,000 compared to the previous corresponding period.
Adherium said receipts from customers for its adherence technology sensor sales, engineering services and clinical trial services for the three months to June 30, 2020 fell 89.7 percent to $139,000.
The company said it had cash and cash equivalents of $4,584,000 at June 30, 2020 compared to $763,000 at June 30, 2019.
Adherium was unchanged at three cents.

REGENEUS

Regeneus says receipts from customers for the year to June 30, 2020 was $1,639,000.
Regeneus said receipts were from a non-refundable milestone payment from Japan's Kyocera Corp, following its stem cell Progenza for knee osteoarthritis passing due diligence.
The company said it had cash and cash equivalents of $982,000 at June 30, 2020 compared to $255,000 at June 30, 2019.
Regeneus was up one cents or 9.1 percent to 12 cents.

CANN GLOBAL

Cann Global says receipts from customers for the year to June 30, 2020 were up 54.4 percent to $1,346,000 compared to the previous corresponding period.
Cann Global said receipts were from sales of its hemp seed products.
The company said it had cash and cash equivalents of $7,417,000 at June 30, 2020 compared to $5,188,000 at June 30, 2019.
Cann Global was unchanged at half a cent with 7.2 million shares traded.

MICRO-X

Sydney's Perennial Value Management says it has become increased its substantial holding in Micro-X from 18,676,430 shares (5.23%) to 22,739,288 shares (6.37%).
Perennial said that between May 18 and July 29, 2020 it bought and sold shares with the largest purchase on July 7 of 11,425,195 shares for $1,542,401 or 13.5 cents a share and the sole sale also on July 7 of 13,327,813 shares for $1,799,255 or 13.5 cents a share.
Micro-X was unchanged at 17.5 cents with one million shares traded.

SUDA PHARMACEUTICALS

Credit Suisse Holdings says it has become a substantial shareholder in Suda with 13,599,427 shares or 9.56 percent.
The Sydney-based Credit Suisse said that on June 26 it bought 20,000 shares for $600 and sold them on June 30 for $640 and on July 29 it acquired 13,599,427 shares for $1,118,867 or 8.2 cents a share.
Suda fell 0.4 cents or eight percent to 4.6 cents with 4.1 million shares traded.

CARDIEX

Dr Paul Cozzie says he has increased and been diluted in Cardiex from 109,515,392 shares (14.54%) to 119,082,059 shares (14.22%).
The South Bexley, New South Wales-based Dr Cozzie said that between June 12 and July 31, 2020 he acquired 9,386,667 shares for $262,900 or 2.8 cents a share.
Last month, Cardiex said it had raised $2.5 million through a placement to sophisticated investors at 3.0 cents a share (BD: Jul 27, 2020).
Cardiex fell 0.2 cents or 5.4 percent to 3.5 cents with 2.2 million shares traded.

BARD1 LIFE SCIENCES

Bard1 executive director Dr Irmgard Irminger-Finger says she has increased and been diluted from 112,652,737 shares (8.24%) to 123,600,000 shares (5.16%).
The Geneva, Switzerland-based Dr Irminger-Finger said that on November 22, 2019 she acquired 347,663 shares on-market for $11,729 or 3.37 cents a share and on October 1 and 23, 2019, acquired 10,599,600 shares through a beneficiary deceased estate.
Dr Irminger-Finger said she was diluted in the implementation of the Bard1 scheme of arrangement to acquire Sienna Cancer Diagnostics (BD: Jul 29, 2020).
Bard1 was unchanged at 3.1 cents with 4.2 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it will release 2,500,000 shares from voluntary escrow on August 9, 2020.
According to Imagion's most recent Appendix 2A, the company had 761,780,156 shares on issue, including the 2,500,000 voluntary escrow shares.
Imagion fell 0.4 cents or 7.8 percent to 4.7 cents with 13.8 million shares traded.

ESENSE-LAB

According to an Appendix 3X, Esense has appointed Winton Willesee as a director.
Esense did not file a separate announcement, but included the appointment in an announcement to the ASX titled 'Update Regarding Voluntary Suspension' filed shortly before the market closed last Friday.
The announcement said the company was not in compliance with its articles of association requiring a minimum of four directors and Israel Companies Law requiring at least two 'external' directors.
Esense said it did not have "any external directors that comply with the requirements of the [Israel] Companies Law.
The company said it would call an extraordinary general meeting to elect two external directors.
Esense was in a suspension and last traded at 1.8 cents.

Biotech Daily Top 40 with Market Capitalization At Jul 31, 2020

Company $Am	Aug-19	Jul-20	Aug-20
Cochlear	12,718	12,410	12,691
CSL	104,050	130,312	124,614
Resmed	27,236	39,594	40,658
BDI-20			
Avita	814	966	652
Clinuvel	1,592	1,267	1,107
Compumedics	128	74	78
Cyclopharm	96	111	119
Cynata	183	71	73
Ellex	90	98	47
Genetic Signatures	109	307	349
Immutep	71	76	88
Medical Developments	375	458	397
Mesoblast	736	1,893	2,237
Nanosonics	1,653	2,050	1,960
Neuren	153	127	148
Opthea	190	635	646
Paradigm	284	708	719
Pharmaxis	89	26	33
Polynovo	1,058	1,679	1,507
Pro Medicus	3,186	2,750	2,507
Starpharma	489	419	410
Telix	351	325	330
Volpara	349	342	334
Second 20			
Actinogen	10	25	26
Alterity (Prana)	22	18	39
Amplia (Innate)	6	8	13
Antisense	21	36	38
Dimerix	16	69	88
Impedimed	74	62	78
Imugene	90	134	255
Kazia	25	45	53
LBT Innovations	27	54	43
Next Science	547	226	243
Oncosil	42	96	91
Optiscan	24	18	22
Orthocell	67	58	64
Osprey	31	16	60
Patrys	25	13	15
Prescient	19	22	22
Proteomics	25	39	54
Resonance	41	67	69
Universal Biosensors	43	35	45
Uscom	19	32	30

* 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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