Biotech Daily

Monday October 3, 2022

Daily news on ASX-listed biotechnology companies

*** ALL INDICES FALL IN SEPTEMBER: BDI-40 7%, ASX200 7%, BIG CAPS 0.5%, NBI 2%**

*** TODAY: ASX, BIOTECH DOWN: MESOBLAST UP 8%; DIMERIX DOWN 9%**

*** LUMOS: FDA REJECTS FEBRIDX APPEAL; SARASOTA FACTORY CLOSED**

*** MESOBLAST FILES MORE FDA REMESTEMCEL-L DATA FOR GVHD**

*** ANATARA HALTS 3FDC TRIAL FOR 'INSUFFICIENT SAMPLE SIZE'**

*** PHARMAUST DOSES 1ST MONEPANTEL MND PATIENT**

*** AMPLIA: 'AMP886 INHIBITS AML, IN MICE'**

*** EPSILON: $600k MISSING FROM $1.55m PLACEMENT**

*** ACRUX RECEIVES $2.3m R&D TAX INCENTIVE; TOTAL $3.3m**

*** 4D MEDICAL 1.9m M-D PROF ANDREAS FOURAS OPTIONS AGM**

*** ASX SUSPENDS NUHEARA ON REPORT**

*** BIOSCIENCE MANAGERS DILUTED TO 19.5% OF ADHERIUM**

*** TRUDELL MEDICAL INCREASES, DILUTED TO 16.5% OF ADHERIUM**

*** VOLPARA: CEO TERI THOMAS PROMOTED TO M-D**

*** DEBORAH AMBROSINI REPLACES CANN GROUP CO SEC GERALDINE FARRELL**

MARKET REPORT

The Australian stock market fell 0.27 percent on Monday October 3, with the ASX200 down 17.3 points to 6,456.9 points. Eight of the Biotech Daily Top 40 stocks were up, 23 fell, three traded unchanged and six were untraded.

Mesoblast was the best, up six cents or 7.7 percent to 84 cents, with 1.6 million shares traded. Genetic Signatures climbed 5.7 percent, with seven shares traded; Clinuvel, Imugene and Polynovo rose more than two percent; Impedimed improved 1.6 percent; with Cochlear, Pro Medicus and Telix up by less than one percent.

Dimerix led the falls, down 1.5 cents or 9.4 percent to 14.5 cents, with 382,791 shares traded. Starpharma lost eight percent; Actinogen and Micro-X were down more than six percent; Alcidion, Emvision and Resonance retreated more than five percent; Compumedics and Next Science fell more than four percent; Neuren, Opthea, Orthocell, Pharmaxis and Proteomics were down three percent or more; Avita, Immutep, Medical Developments, Prescient and Volpara shed more than two percent; Kazia and Universal Biosensors were down more than one percent; with Antisense, CSL, Nanosonics and Resmed down by less than one percent.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

The Winter recovery stalled in the first month of Spring with both the ASX200 and the Biotech Daily Top 40 Index (BDI-40) down 7.3 percent for the month.

The year to September 30 was even worse, with the ASX200 down 11.7 percent to 6,474 points, the BDI-40 fell 27.0 percent from a collective market capitalization of $22,142 million to $16,171 million, and the Nasdaq Biotechnology Index shed 2.4 percent in the month of September, losing 25.9 percent to 3,768 points for the year.

The biotech fall is made clear in the medium-term BDI-40 v ASX200 chart (below). Throughout 2021, there was speculation that biotechnology would save the world from severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), which was partly true. Some companies did hold promise but many of the claims didn't hold up and short-term, under-informed speculators lost interest. This was equally true in the US.

At September 30, 2022, the BDI-40 was 3.4 percent below its pre-pandemic high.

Taking a slightly longer view, the ASX200 has improved 27.6 percent in the 16 years and three months since these charts began, while the BDI-40 has climbed 353.9 percent.

The collective value of the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell half a percent in September, but was up 1.1 percent for the year.

Cochlear fell 2.8 percent to $13,706 million, CSL was down 2.2 percent to $138,271 million, but Resmed was resilient, climbing 5.3 percent to $49,538 million.

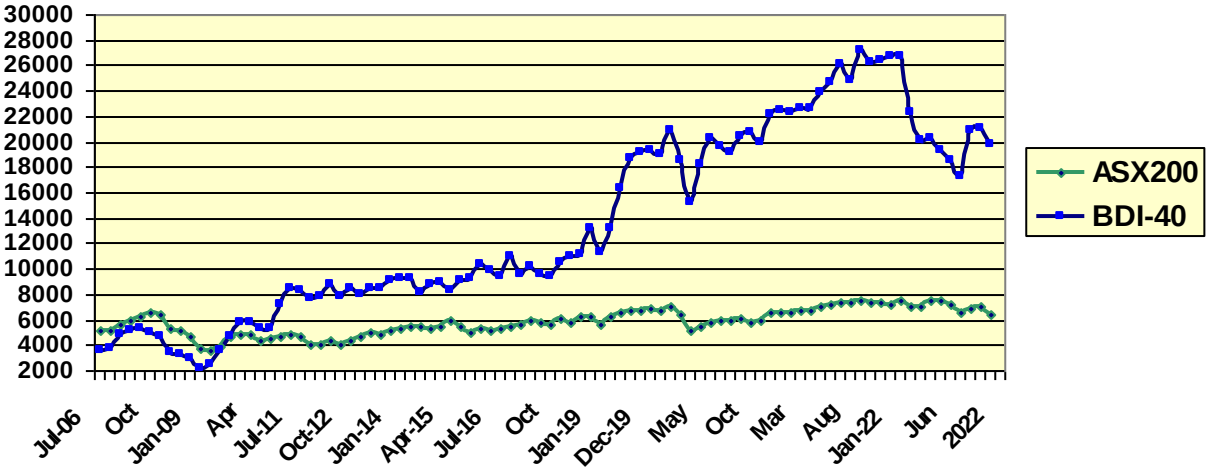
In September, 13 of the BDI-40 companies were up, with just three up by more than 10 percent; while 24 companies fell, 14 down by 10 percent or more and four companies down by more than 20 percent.

Micro-X was the percentage best, up $25 million or 45.45 percent to $80 million, but Neuren added $126 million or 17.3 percent to $853 million, followed by: Actinogen (14.3%), Dimerix (8.5%), Uscom (7.1%), Orthocell and Polynovo (both up 6.5%), Proteomics (5.45%); Amplia (5.3%), Paradigm (4.1%) and Medical Developments (3.6%).

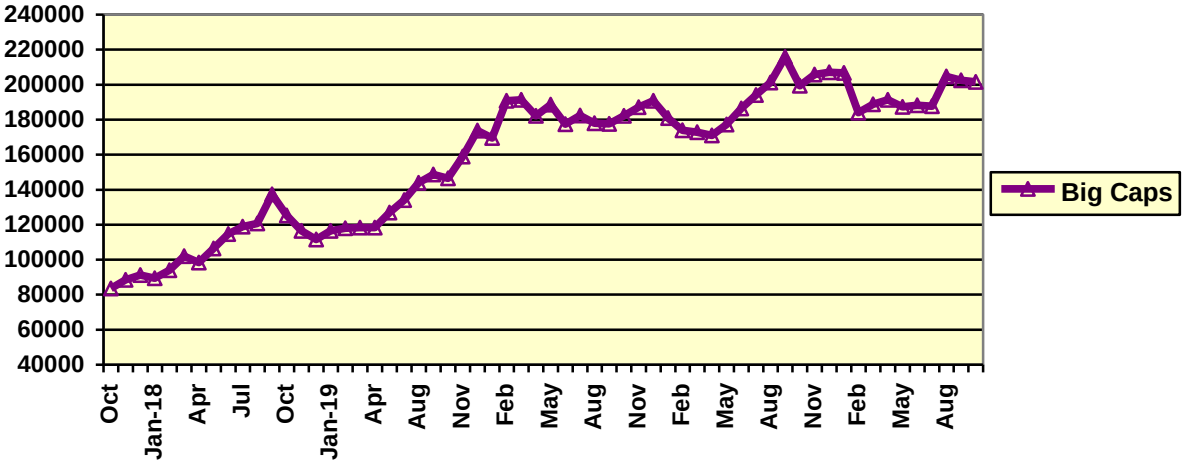
Patrys was the percentage worst, down $15 million or 26.8 percent to $41 million, but Telix lost $479 million or 24.7 percent to $1,462 million on withdrawing the Illuccix European market application, with Imugene losing $365 million or 23.9 percent to $1,160 million, followed by: Kazia (20.6%), Oncosil (19.3%), Resonance (18.75%), Next Science (17.7%), Nanosonics (15.0%), Immutep (14.2%), Volpara (13.0%), Emvision (12.2%) and Alcidion 12.0%).

Cannabis Corner looked good with the collective market capitalization of the 11 companies up 13.8 percent to $1,161 million, but that hid the fact that eight fell, one was untraded and all the improvement was Cronos (on sales, revenue, profit and a dividend) up $143 million or 59.6 percent to $383 million and Incannex up $61 million or 17.0 percent to $419 million (on no revenue, a $14.9 million loss, but inclusion into the ASX300).

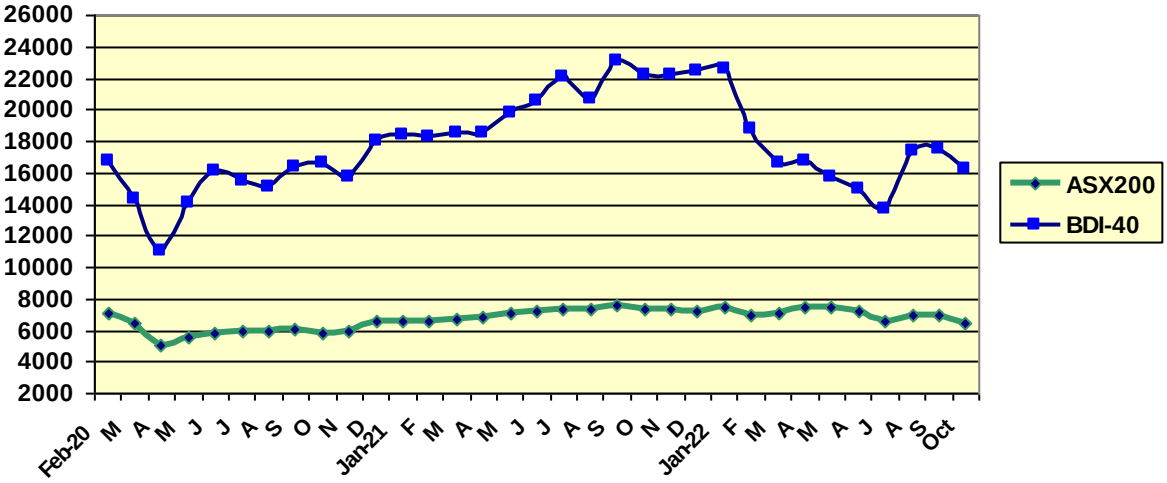
BDI-40 v ASX200 Jun 30, 2006 to Sep 30, 2022- Adjusted



Big Caps $m (Cochlear, CSL, Resmed) Sep 30, 2017 – Sep 30, 2022



BDI-40 ($m) v S&P ASX 200 – Jan 31, 2020 – Sep 30, 2022 (current, raw data)



LUMOS DIAGNOSTICS

Lumos says the US Food and Drug Administration has upheld its decision not to grant 510(k) clearance to market Febridx, and it has closed its Sarasota Facility.

In August, Lumos said it had filed an appeal to the FDA over the decision not to grant 510(k) clearance to market its Febridx finger-prick blood test to differentiate bacterial from viral infections in the US (BD: Aug 8, 2022).

In July, the company said the FDA decided not to grant approval to its Febridx finger-prick blood test to differentiate bacterial from viral infections, saying that the test "did not demonstrate substantial equivalence to the predicate device" citing concerns with possible risks associated with false negative viral infection results (BD: Jul 11, 2022).

Today, Lumos said it was able to file a new Febridx application to the FDA but "based on the feedback received from the FDA, this is likely to require further investment and time to generate additional data before a new application could be submitted".

The company said that as a result, it would "direct its efforts for commercializing Febridx in markets where it has been already been granted clearance, while primarily focusing on growing its development services and contract manufacturing business … [and did not] intend to further invest in activities directed towards securing US clearance for Febridx".

Lumos chief executive officer Doug Ward said "clearly this is a disappointing outcome for Lumos as we believe there is a significant need and opportunity for Febridx in the US".

"However, we are committed to ensuring that investment and expenditure is closely aligned to achieving commercial outcomes for Lumos," Mr Ward said. "This means focusing our efforts on building our services and manufacturing businesses and selling our own [point-of-care] diagnostic products in markets where they are cleared," Mr Ward said.

Separately, Lumos said it had completed the closure of its Sarasota, Florida facility as part of its cost reduction program, relocating to its Carlsbad, California offices.

Lumos said that it was able to negotiate termination of the lease with a single payment of $US300,000 ($A462,600) that relieved more than $US3.1 million in future costs.

Lumos fell 0.8 cents or 13.3 percent to 5.2 cents with five million shares traded.

MESOBLAST

Mesoblast says it has filed data to the US Food and Drug Administration supporting its remestemcel-L for children with steroid-refractory acute graft-versus-host disease.

In 2020, Mesoblast fell as much as 44.7 percent to $2.81 on news that the FDA required a further trial of remestemcel-L for graft-versus-host disease (BD: Oct 2, 2020).

At that time, the company said it had received a complete response letter (CRL) from the FDA that "recommended that [it] conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L for ... graft-versus-host disease" and had identified a need for further scientific rationale to demonstrate the relationship of potency measurements to the product's biologic activity.

Today, Mesoblast said it had "an active dialog" with the FDA and the new submission was a "major milestone".

The company said remestemcel-L had FDA fast track and biologics priority review status.

Mesoblast chief executive Prof Silviu Itescu said "the submission summarizes controlled data providing further evidence of remestemcel-L's ability to save lives".

"The improved process controls we have put in place to assure robust and consistent commercial product, together with a potency assay that predicts consistent survival outcomes, makes remestemcel-L a compelling treatment," Prof Itescu said.

Mesoblast was up six cents or 7.7 percent to 84 cents with 1.6 million shares traded.

ANATARA LIFE SCIENCES

Anatara says it has halted its 100-participant randomized, controlled study of 3FDC in adults with moderate anxiety, stress and depression due to an insufficient sample size.
In February, Anatara said it would start the study of 3FDC in adults with moderate anxiety, stress and depression, to be conducted by the CSIRO in Adelaide (BD: Feb 17, 2022).
Today, the company said "the sample size required to detect a signal in this study may be higher than initially proposed to reach a reliable outcome" and that while it was "common for anxiety and depression trials to have high placebo responses, the board of Anatara have elected to halt the study on the balance of outcome probability rather than considering a commitment to significant future costs".
Anatara said there were no safety or tolerance concerns with 3FDC components to date.
The company said 3FDC was a subset of three components of the pineapple stem bromelain-based "gastro-intestinal re-programming", or Garp, compound being investigated for irritable bowel syndrome.
Anatara was unchanged at 5.9 cents.

PHARMAUST

Pharmaust says it has dosed the first of 12 patients in its phase I/II trial of monepantel for motor neurone disease and has ethics approval for amendments to its study protocol.
Pharmaust said the trial would assess the safety and tolerability of monepantel in patients living with motor neurone disease, or Lou Gehrig's disease or amyotrophic lateral sclerosis, and with concurrent animal studies, would determine whether monepantel should proceed to larger phase II studies.
In 2020, the company said it received an $881,085 grant for a phase I trial of monepantel for motor neuron disease from the charity Fight MND (BD: Sep 21, 2020).
Today, Pharmaust said it had received the third Fight MND instalment worth $173,035 and ethics approval had been granted to make a "few small amendments to the clinical study protocol to refine the study design and accelerate recruitment".
Pharmaust was unchanged at 7.5 cents.

AMPLIA THERAPEUTICS

Amplia says AMP886 inhibits acute myeloid leukaemia activity and reduces tumor growth, in mice.
Amplia said that AMP886 could inhibit both focal adhesion kinase (FAK) and FMS-like tyrosine kinase 3 (FLT3), which were clinically validated targets for chemotherapy, and that inhibiting FTL3 and FAK together could help overcome disease rebound.
The company said there was a dose dependent reduction in tumor growth following treatment with AMP886, and that twice-daily 37mg/kg AMP886 was more effective in reducing acute myeloid leukaemia cell growth than once daily 50mg/kg venetoclax.
Amplia said that the combination of AMP886 and venetoclax improved mouse survival more than either AMP886 alone or venetoclax alone.
Amplia chief executive officer Dr John Lambert said "the impressive results we are reporting today tell us that there may be a clinical rationale to include AMP886 as part of new treatment regimens for unmet needs in [acute myeloid leukaemia]".
"With an eye to expanding Amplia's clinical development pipeline, further experiments are already underway with AMP886 to build on this data and establish a scientifically solid foundation for initiation of formal development of AMP886," Dr Lambert said.
Amplia was untraded at 10.5 cents.

EPSILON HEALTHCARE

Epsilon says it has not received $500,000 of $1,550,005 raised in its placement at 2.75 cents a share and that an application worth $99,995 was not executed.
In September, Epsilon said it had “firm commitments” to raise up to $1.65 million in a placement at 2.75 cents a share, with three attaching options for every four shares bought, exercisable at five cents within three years (BD: Sep 2, 2022).
Today, the company said that one firm applicant had not provided the funds or executed documents in respect of $99,995, and as a result, on September 9 it issued 56,363,821 shares worth $1,550,005.
Epsilon said that it was yet to receive $500,000 of the $1,550,005 placement, equivalent to 18.1 million shares, and that it was “pursuing that applicant for the amount owed to the company”.
Epsilon said that it would find a replacement investor for the applicant and that it would receive and apply the replacement investor’s proceeds against the $500,000 it was owed.
The company said that it expected to complete the share sale in “the coming weeks” but that it would not absolve that applicant from its liability.
Epsilon was untraded at 2.2 cents.

ACRUX

Acrux says it has received $2,293,419 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program for its subsidiary.
Last week, Acrux said it had received $983,422 from the Federal Government Research and Development Tax Incentive program and that it expected an additional research and development incentive for its overseas activities (BD: Sep 26, 2022).
Today, the company said it had received a total incentive of $3,276,840 in relation to research and development for the year to June 30, 2022.
Acrux fell 0.1 cents or 1.75 percent to 5.6 cents.

4D MEDICAL

4D Medical says its annual general meeting will vote to issue up-to 1,850,914 options to managing-director Prof Andreas Fouras, exercisable at 95 cents each, within four years.
4D said the 1,850,914 options were part of Prof Fouras’ long-term incentive plan, and the 95 cents exercise price was a 100 percent premium to the 30-day volume-weighted average price of shares preceding June 30, 2022 and would vest on the condition that Prof Fouras remain employed by 4D until June 30, 2025.
4D Medical said shareholders would vote to elect Evonne Collier, John Livingston and Julian Sutton as directors, adopt the remuneration report and approve the 10 percent placement facility.
The meeting will be held at Melbourne Connect Superfloor, The Forum, 700 Swanston Street, Carlton on November 3, 2022 at 10am (AEDT).
4D Medical fell two cents or 3.45 percent to 56 cents.

NUHEARA

The ASX says Nuheara has been suspended from quotation due to its failure to lodge its relevant periodic report by the due date, effective from today.
Nuheara last traded at 21 cents.

ADHERIUM

Bioscience Managers Translation Fund 1 says it has been diluted in Adherium from 500,000,000 shares or 23.52 percent to 19.52 percent.
Bioscience Mangers said it was diluted due to the issue of shares on September 26, 2022.
Earlier this month, Adherium said it had commitments for a $13.5 million placement at 0.5 cents a share, including “cornerstone investments” from the London, Ontario-based Trudell Medical, Melbourne’s Bioscience Managers Translation Fund 1, and another unnamed “significant institutional investor” (BD: Sep 16, 2022).
Last week, Regal Funds said it had become a 9.15 percent substantial shareholder in Adherium (BD: Sep 29, 2022)
Adherium fell 0.05 cents or 9.1 percent to 0.5 cents with eight million shares traded.

ADHERIUM

Trudell Medical says it has increased and been diluted in Adherium from 165,364,179 shares or 19.47 percent to 423,080,272 shares or 16.51 percent.
The London, Ontario-based Trudell said that on May 7, 2021 it bought 257,333,333 shares for $3,860,000 in a placement at 1.5 cents a share, and on November 26, 2021 it received 382,760 shares in lieu of directors’ fees, worth $6,720 or 1.75 cents a share (BD: Mar 18, 2021).
According to Commsec data, Adherium director George Baran is the executive chair of Trudell Medical.
The company said that it was diluted on September 26, 2022 due to the issue of shares (see above).

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has appointed chief executive officer Teri Thomas as its managing-director, effective from October 1, 2022.
In April, Volpara said Ms Thomas had been appointed chief executive officer, replacing founder Dr Ralph Highnam (BD: Apr 21, 2022).
The company said at that time that Ms Thomas had worked for Epic Health for 20 years and other companies in the healthcare industry.
Volpara said Ms Thomas was a US citizen living in New Zealand and would spend about 25 percent of her time in each country.
The company said that Ms Thomas held a Bachelor of Arts in Zoology from the University of Wisconsin at Madison, and a Master of Nursing Science from the Hamilton, New Zealand-based Waikato Institute of Technology.
Volpara fell 1.5 cents or 2.7 percent to 54 cents.

CANN GROUP

Cann Group says chief financial officer Deborah Ambrosini will replace company secretary Geraldine Farrell, effective from October 25, 2022.
Last year, Cann Group said it had appointed Ms Ambrosini as its chief financial officer replacing Greg Bullock (BD: Aug 25, 2021).
The company said at that time that Ms Ambrosini had most recently worked for Acrux as chief financial officer and company secretary.
Cann Group was up half a cent or two percent to 26 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT SEPTEMBER 30, 2022

Company $Am	**Oct-21**	**Sep-22**	**Oct-22**
Cochlear	14,404	14,097	13,706
CSL	130,713	141,400	138,271
Resmed	54,257	47,046	49,538
BDI-20			
Avita	614	231	208
Clinuvel	2,048	997	901
Compumedics	74	46	43
Cyclopharm	156	133	133
Cynata	83	48	45
Genetic Signatures	207	139	126
Immutep	468	247	212
Kazia	207	34	27
Medical Developments	369	140	145
Mesoblast	1,077	630	582
Nanosonics	1,864	1,244	1,057
Neuren	261	727	853
Nova Eye	57	38	31
Opthea	474	462	475
Pharmaxis	59	42	43
Polynovo	1,253	867	923
Pro Medicus	5,488	5,689	5,552
Starpharma	540	255	255
Telix	1,608	1,941	1,462
Volpara	298	161	140
Second 20			
Actinogen	209	140	160
Alcidion	372	184	162
Amplia	26	19	20
Antisense	118	61	57
Atomo	201	37	34
Dimerix	75	47	51
Emvision	230	123	108
Impedimed	187	125	112
Imugene	2,622	1,525	1,160
Micro-X	152	55	80
Next Science	265	198	163
Oncosil	38	57	46
Orthocell	98	77	82
Paradigm	493	338	352
Patrys	79	56	41
Prescient	168	118	118
Proteomics	94	110	116
Resonance	41	32	26
Universal Biosensors	137	57	55
Uscom	21	14	15

* Biotech Daily editor, David Langsam, owns shares in Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, 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.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au; www.biotechdaily.com.au; twitter: @biotech_daily