

# Biotech Daily

Tuesday September 1, 2015

Daily news on ASX-listed biotechnology companies

- \* AUGUST BDI-40 DOWN 4%, ASX200 DOWN 9%, BIG CAPS DOWN 4.5%
  - REVA UP 58%, GENETIC TECHNOLOGIES DOWN 28%
- \* TODAY: ASX, BIOTECH DOWN: POLYNOVO UP 10%, ANALYTICA DOWN 17%
- \* AIRXPANDERS FILES AEROFORM 510(K) SUBMISSION TO FDA
- \* USCOM COMPLETES THOR ACQUISITION
- \* BIOTECH CAPITAL LANG WALKER \$1m, BRUCE HANCOX, JON PILCHER
- \* INVION RAISES \$1m FROM UNNAMED US INVESTOR
- \* RESAPP 1st PATIENT ENROLLED AT PRINCESS MARGARET HOSPITAL
- \* SUDA REVENUE DOWN 35% TO \$5.7m, LOSS UP 64% TO \$3.4m
- \* BIOXYNE REVENUE DOWN 50% TO \$1.6m, PROFIT DOWN 83% to \$201k
- \* PHOSPHAGENICS H1 REVENUE UP 113% TO \$978k, LOSS UP 399%
- \* ANTISENSE ATL1103 PARTNER CORTENDO FILES FOR NASDAQ LISTING
- \* IMMURON APPLIES FOR US OTCQB, FULL US LISTING
- \* CANADA'S INVESTORS GROUP TAKES 7% OF ADHERIUM
- \* PRESCIENT CSO PROF SAID SEBTI WINS NATURE TRANSLATION GONG

## MARKET REPORT

The Australian stock market fell 2.12 percent on Tuesday September 1, 2015 with the ASX200 down 110.6 points to 5,096.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Polynovo was the best, up one cent or 10 percent to 11 cents with 210,000 shares traded. Antisense climbed 8.5 percent; Living Cell was up 7.9 percent; Prima was up six percent; Bionomics rose five percent; Genetic Technologies and Universal Biosensors were up more than four percent; IDT was up 3.85 percent; Pharmaxis rose 2.4 percent; with Admedus, Avita, Orthocell and Tissue Therapies up more than one percent.

Analytica led the falls, down 0.1 cents or 16.7 percent to 0.5 cents with 1.4 million shares traded. Optiscan and Nanosonics lost nine percent or more; Anteo, Cellmid and Prana fell more than six percent; both Oncosil and Sirtex fell four percent or more; Clinuvel was down 3.8 percent; Atcor, CSL, Mesoblast and Osprey shed more than two percent; with Acrux, Benitec, Cochlear, Ellex, Medical Developments, Resmed and Reva down more than one percent.

# BIOTECH DAILY TOP 40 INDEX (BDI-40)

August wasn't all doom and gloom, but it wasn't good, either. Seven of Biotech Daily Top-40 Index (BDI-40) companies were up, with just three - Prima, Reva and Sirtex - in the BDI-20, while the 31 falls ranged from small to moderate. Mesoblast lost \$195 million, but Sirtex climbed \$248 million against the trend.

The ASX200 fell 8.6 percent in August, the BDI-40 was more resilient, falling 3.7 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 4.5 percent.

But for the year to August 31, the data shows a different picture entirely (see graphs below), with the ASX200 down 7.5 percent, the BDI-40 up 3.2 percent and the Big Caps up 21.8 percent.

The three Big Caps fell a collective 4.5 percent in August, with Cochlear down 5.9 percent to \$4,877 million, CSL shedding 4.6 percent to \$42,705 million and Resmed down 3.0 percent to \$10,269 million.

Reva led the seven rises, up 57.6 percent to \$249 million following a briefing call and the appointment of Regina Groves as chief executive officer. Optiscan was up 20 percent to \$12 million, followed by Sirtex (14.3%), Ellex (13.9%), Prima (6.45%) and Cellmid (3.4%), with Analytica and Uscom looking good by not moving.

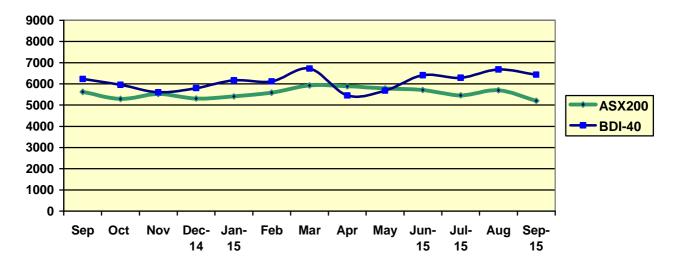
Genetic Technologies led the falls, down 28.0 percent to \$36 million, followed by Admedus (25.6%), Nanosonics (23.9%), Antisense (22.2%), Oncosil (21.7%), Benitec (21.2%), Orthocell (20.9%), Living Cell (20.0%), Viralytics (17.9%) and Anteo (17.2%).

Outside the BDI-40, the MMJ Phytotech merger and capital raising took its market capitalization up 146.7 percent to \$37 million, followed by Immuron (63.2%), Airxpanders (30.4%), Rhinomed (16.7%) and Suda (14.7%). On the Nasdaq, Biota fell 7.0 percent to \$106 million, Heartware shed 2.8 percent to \$2,084 million and Sunshine Heart slipped 1.3 percent to \$77 million.

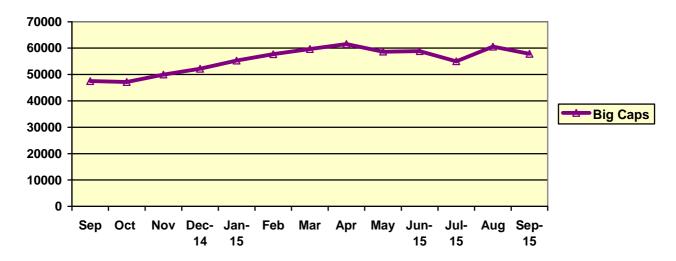
# BDI-40 v ASX200 Jun 30, 2006 to Jul 31, 2015 - Adjusted



BDI-40 (\$m) v S&P ASX 200 - Aug 31, 2014 - Aug 31, 2015



Big Caps (Cochlear, CSL, Resmed) Aug 31, 2014 - Aug 31, 2015



## **AIRXPANDERS**

Airxpanders says it has filed its 510(k) submission for the Aeroform breast tissue expander with the US Food and Drug Administration.

Airxpanders chief executive officer Scott Dodson said the submission was "a very important milestone ... as we continue to commercialize our device in Australia and prepare for entry into the US market".

The company said that Aeroform had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval and last month said its pivotal, 150-patient Xpand study had met its primary endpoint in patients that have undergone a mastectomy (BD: Aug 25, 2015).

Airxpanders said that it would benefit from existing reimbursement covering breast reconstruction procedures in the US, as well as US Federal laws such as the Women's Healthcare Act of 1998 which mandated reimbursement coverage for reconstructive procedures with a diagnosis of breast cancer.

The company said the Aeroform device used a controlled delivery of carbon dioxide to expand the tissue required for the placement of a permanent breast implant. Airxpanders was unchanged at 75 cents.

#### **USCOM**

Uscom says it has completed the acquisition of the Budapest, Hungary-based Thor Laboratories, expanding the company with 16 engineers and 10 administrative staff. In July, Uscom said it had raised \$1.55 million to acquire Thor Laboratories, which was a cash-flow positive medical device manufacturer with annual revenue of about \$500,000 and specialized in high fidelity digital Doppler technology for measurement of respiratory function (BD: Jul 20, 2015).

The company said that Thor manufactured devices with applications in the assessment of asthma, chronic obstructive pulmonary disease and other respiratory disorders, with potential applications in sleep medicine.

Uscom said the Thor devices had a range of approvals including Conformité Européenne (CE mark) and Australian Therapeutic Goods Administration, with some devices under US Food and Drug Administration submission.

Uscom said that Thor founder George Ferenczi would be a full-time employee, managing the Thor operations and contribute to an expanded product development program. The company said the acquisition was "a key strategic growth opportunity, providing additional revenue, internationally accredited manufacturing and [research and development] capabilities, distribution and a respirometric product suite". Uscom executive chairman Prof Rob Phillips said the Thor devices were Doppler ultrasound based, like the Uscom 1A ultrasonic cardiac output monitor and related to the cardiopulmonary clinical market.

"Thor will provide a high quality, approved and manufacturing base close to international markets," Prof Phillips said.

"Hungary is a European manufacturing secret, providing highly cost-effective manufacturing for the medical device companies of Germany and Switzerland," Prof Phillips said. "This is a very fortuitous partnership at exactly the right time." Uscom was untraded at 15 cents.

## **BIOTECH CAPITAL**

Biotech Capital says it has raised \$1,028,847 through the issue of 12,860,583 shares at eight cents each to the Auckland Trust Co, which is associated with Lang Walker. Biotech Capital said that the funds raised would be used for working capital. The company said that Lang Walker investments director and Neuren director Bruce Hancox and Neuren chief financial officer Jon Pilcher were appointed as non-executive directors effective from today, September 1, 2015 and director Alastair Davidson had resigned after 15 years with the company.

Biotech Capital is a pooled development fund and its non-executive chairman Dr Richard Treagus, is the executive chairman of Neuren and former chief executive officer of Acrux. The company said that Mr Hancox had a in business in New Zealand and Australia and was formerly as general manager, group chief executive officer and chairman of Brierley Investments and was currently a director of Medical Australia as well as Neuren. Biotech Capital said that Mr Pilcher was a chartered accountant and held a degree in biotechnology from Reading University, UK

The company said that Mr Pilcher was previously the chief financial officer and company secretary of Acrux for 11 years and had experience in matters relating to the funding, growth and compliance of a registered pooled development fund.

Dr Treagus said the company was "in a good position to execute on our stated strategy of making carefully targeted investments in high-growth biotech and medical technologies". Biotech Capital was up four cents or 53.3 percent to 11.5 cents.

#### INVION

Invion says it has definitive agreements with an unnamed US institutional investor to raise \$1,001,000 is a placement of 71,500,000 million shares at 1.4 cents a share.

Invion said it would also grant the US investor 12-month options to buy up to 51.5 million shares exercisable at 1.4 cents, 12-month options to buy up to 91.5 million shares exercisable at 1.4 cents per option and five-year options to buy up to 35.75 million shares, exercisable at 1.75 cents each, subject to shareholder approval.

The company said that the New York-based HC Wainwright & Co was the exclusive placement agent, the proceeds were for working capital purposes and it was "reviewing other secondary capital raising options to enable existing shareholders to participate on similar terms to the US institutional investor".

Invion fell 0.3 cents or 16.7 percent to 1.5 cents with 6.1 million shares traded.

#### **RESAPP HEALTH**

Resapp says the first paediatric patient has been enrolled at the Perth, Western Australia-based Princess Margaret Hospital.

Resapp said that along with the Joondalup Health Campus the Princess Margaret was the second site to approve the trial of its telephone applications for the diagnosis and management of respiratory disease (BD: Aug 12, 2015).

The company said that the study would gather data to optimise the Resapp algorithms for pneumonia and asthma as well as broadening the validation to other common respiratory conditions such as bronchitis, bronchiolitis and upper respiratory tract conditions.

Resapp was up 0.1 cents or 6.25 percent to 1.7 cents with 2.6 million shares traded.

#### **SUDA**

Suda says that revenue for the year to June 30, 2015, fell 34.6 percent to \$5,728,000 with net loss after tax up 64.1 percent to \$3,367,000.

Suda said that the revenue primarily came from its wholly-owned subsidiary Westcoast Surgical and Medical Supplies which had secured a Federal Government contract for the provision of medical supplies to the detention centres which generated more than \$4 million in revenue, but generated negligible revenue for the reporting period.

The company said that net tangible asset backing per share was up 52.8 percent from 0.36 cents at June 30, 2014 to 0.556 cents at June 30, 2015, with diluted loss per share up 32.0 percent to 0.33 cents, with cash and cash equivalents of \$6,251,947 at June 30, 2015 compared to \$3,990,397 at June 30, 2014.

Suda fell 0.3 cents or 8.8 percent to 3.1 cents.

#### BIOXYNE

Bioxyne says revenue for the 12 months to June 30, 2015 was down 50.3 percent to \$1,653,274 with a net profit after tax down 83.1 percent to \$201,039.

Bioxyne said that the previous year included the sale of Hunter Immunology for \$929,607. The company said that the continuing revenue was primarily from the sale of probiotics. Bioxyne said net tangible assets per share was unchanged at one cent and diluted earnings per share was down 85.7 percent to 0.1 cents, compared to the previous year's 0.7 cents, with \$958,469 in cash and cash equivalents at June 30, 2015, compared to \$992,378 at June 30, 2014.

Bioxyne was unchanged at 1.1 cents.

#### **PHOSPHAGENICS**

Phosphagenics says revenue for the six months to June 30, 2014 was up 113.1 percent to \$978,000 with net loss after tax up 399.1 percent to \$13,900,000.

Phosphagenics said the revenue related to Vital ET a modified form of its tocopheryl phosphate mixture or TPM sold to Ashland and used as a raw ingredient in personal care products.

Phosphagenics said its diluted loss per share was up 430.0 percent from 0.20 cents at June 30, 2014 to 1.06 cents at June 30, 2015 and net tangible assets per security was up 45.8 percent from 1.18 cents at June 30, 2014 to 1.72 cents at June 30, 2015.

The company said it had cash and cash equivalents of \$15,832,000 at June 30, 2015 compared to \$20,679,000 at December 31, 2014.

Phosphagenics fell 0.2 cents or 11.1 percent to 1.6 cents with 3.8 million shares traded.

#### ANTISENSE THERAPEUTICS

Antisense says that ATL1103 licencing partner Cortendo AB has filed a registration statement with the US Securities and Exchange Commission to list on the Nasdaq. In May, the Trevose, Pennsylvania-based Cortendo AB agreed to pay an upfront fee of \$6.2 million and up to \$131 million for the rights to ATL1103 for endocrinology applications, including acromegaly (BD: May 15, 2015).

Today, Cortendo said the number of shares to be offered and the initial public offer price range had not been determined, but it had applied to list under the symbol 'SBBP'. Antisense was up 0.7 cents or 8.5 percent to 8.9 cents.

#### **IMMURON**

Immuron says it has applied to upgrade its American depository receipts (ADRs) program of 'pink sheets' to an over-the-counter quality B (OTCQB) listing.

Immuron said that the OTCQB listing would provide a direct link to brokers and dealers

who could provide liquidity and execution services its securities in the US.

The company said it intended to apply for a full US National Exchange listing. Immuron was up 4.5 cents or 10.8 percent to 46 cents.

# **ADHERIUM**

The Winnipeg Manitoba-based Investors Group Investment Management says it has become a substantial shareholder in Adherium with 9,535,000 shares (6.811%). The substantial shareholder notice, filed by Investors Group assistant vice-president Brad Kirk said that the shares were held by the Investors Group, the Demarais Family Residuary Trust and associated entities and the company bought 10,000,000 shares at 50 cents each on August 26 and sold 465,000 shares at 56.36 cents each on the same day. Adherium fell two cents or three percent to 64 cents.

# PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Prescient says that chief scientific officer and technology co-inventor Prof Said Sebti, has been named one of Nature Publishing's Top 20 translational researchers.

Prescient said the list examined each researcher's most-cited patent from the previous

five years and their 'H index', a score based on the impact of published work.

Prescient fell 0.7 cents or 8.75 percent to 7.3 cents.

# BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION AT AUG 31, 2015

Company \$Am	Sep-14	Aug-15	Sep-15
Cochlear	4,118	5,184	4,877
CSL	35,414	44,787	42,705
Resmed	7,955	10,592	10,269
BDI-20	000	444	405
Acrux	329	114	105
Admedus	223	164	122
Benitec	119	104	82
Bionomics	269	180	167
Biotron	31	33	31
Circadian	9	31	30
Clinuvel	107	131	130
Impedimed	84	333	305
Medical Developments	66	158	138
Mesoblast	1,608	1,314	1,119
Nanosonics	242	498	379
Neuren	157	161	143
Osprey	70	116	113
Pharmaxis	17	71	65
Prima	48	93	99
Psivida	147	165	157
Reva	54	158	249
Sirtex	1,209	1,735	1,983
Universal Biosensors	32	66	63
Viralytics	50	140	115
Second 20			
Actinogen	8	37	32
Analytica	29	8	8
Anteo	125	99	82
Antisense	22	18	14
Atcor	15	40	38
Avita	34	37	33
Cellmid	22	29	30
Compumedics	18	48	47
Ellex	38	36	41
Genetic Technologies	18	50	36
IDT	22	51	50
Living Cell	19	20	16
Oncosil	43	46	36
Optiscan	7	10	12
Orthocell	21	43	32
Polynovo (Calzada)	44	41	42
Prana	108	87	77
Starpharma	210	209	184
Tissue Therapies	96	18	17
Uscom	22	14	14

<sup>\*</sup> Biotech Daily editor, David Langsam, owns shares in Acrux, Alchemia, Admedus, Benitec, Mesoblast, Nanosonics, Neuren and non-biotechnology stocks. Through Australian Ethical Superannuation he has an indirect interest in a range of other biotechnology companies: <a href="http://www.australianethical.com.au/who-we-invest-in">http://www.australianethical.com.au/who-we-invest-in</a>. These holdings are liable to change.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: <a href="mailto:editor@biotechdaily.com.au">editor@biotechdaily.com.au</a>; <a href="mailto:www.biotechdaily.com.au">www.biotechdaily.com.au</a>; <a href="mailto:www.biotechdaily.com.au</a>; <a href="mailto:www.biote