

Biotech Daily

Wednesday July 1, 2009

Daily news on ASX-listed biotechnology companies

- * YEAR TO JUNE BDI-20 UP 32%; BIOTECHS RAISE \$30m/MONTH
- * TODAY: ASX DOWN, BIOTECH UP; GENETIC UP 33%, STARPHARMA DOWN 6%
- * NEUREN JUMPS 170% ON US ARMY \$17m FOR BRAIN INJURY TRIAL
- * PROGEN CHANGES BOARD, LICENCES PI-88, KEEPS JUSTUS HOMBURG
- * UNILIFE, SANOFI-AVENTIS \$30m READY-TO-FILL SYRINGE DEAL
- * SAFETY MEDICAL SELLS BAGOT PRESS FOR \$1.3m
- * VIRALYTICS OPTIONS ISSUE RAISES \$915k OF HOPED FOR \$3m
- * CE MARK FOR CATHRX'S AF DIAGNOSTIC LOOP CATHETER
- * AUSTRALIA, SOUTH KOREA GRANT TWO TISSUE THERAPIES' PATENTS
- * LINK, FREEDMAN TAKE 10% OF PRIMA
- * DIRECTOR DR ROBERT PAYNE QUITS SOLAGRAN
- * BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION

MARKET REPORT

The Australian stock market fell 2.05 percent on Wednesday July 1, 2009 with the S&P ASX 200 down 80.9 points to 3,874.0 points.

Sixteen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and seven were untraded.

Genetic Technologies was best, up 1.5 cents or 33.3 percent to six cents with 150,826 shares traded, followed by Tyrian up 19.2 percent to 3.1 cents. Benitec, Cathrx and Prana climbed 12 percent or more; Nanosonics was up 10 percent with 1.9 million shares traded; Labtech climbed eight percent; Phylogica was up 7.1 percent; Biota climbed 6.7 percent; Bionomics, Optiscan and Polartechnics were up more than four percent; Circadian and Viralytics rose more than three percent; with Heartware was up 1.7 percent.

Starpharma led the falls, down two cents or 5.9 percent to 32 cents with 192,000 shares traded, followed by Avexa and Mesoblast falling more than four percent. Resmed lost 3.7 percent; Cochlear, Living Cell and Pharmaxis shed more than two percent; Chemgenex and CSL were down more than one percent; with Cellestis down 0.3 percent.

BIOTECH DAILY TOP 40 INDEX

The 2008-'09 financial year was not bad for biotechs. While many have struggled and some have gone under, the Biotech Daily Top 40 Index (BDI-40) is 10.5 percent above the same time last year and the sector has raised about \$500 million in the last 12 months.

Biotech companies have raised more than \$184.611 million since January this year and just under \$300 million since June 30, 2008, not including significant raisings by institutions such as GBS Ventures' \$122.5 million and Brandon Capital's \$50 million.

The Top 40 Biotechs have clearly out-performed the S&P ASX 200 over 12 and 24 months and the data shows the less diversified and bigger, the better.

The three Big Caps of Cochlear, CSL and Resmed, which are not included in the BDI-20 and BDI-40 indices, were up 10.1 percent for the month of June, compared to the S&P ASX 200 up 3.6 percent. Cochlear climbed 7.5 percent, CSL was up 10.7 percent and Resmed improved 9.2 percent.

For the year to June 30, 2009, the Big Caps climbed 6.4 percent compared to the ASX 200's 24.2 percent tumble and in the two years since July 1, 2007 the Big Caps climbed 14.2 percent compared to the ASX 200's 37.0 percent fall.

While the BDI-20 retreated 2.3 percent for the month of June after six consecutive months of growth, the Top 20 biotechnology companies were up 31.5 percent for the year, while the smaller Second 20 companies reduced the overall BDI-40 rise to 10.5 percent for the year. Over two years, the BDI-20 fell 18.6 percent and the BDI-40 lost 32.5 percent compared to Australia's largest 200 companies falling 37.0 percent.

Eight of the Top 40 companies were up, of which seven were in the Top 20, 29 fell and three were unchanged. Chemgenex was best up 29.6 percent to a market capitalization of \$184 million, followed by Mesoblast (14.1%) and Sirtex (12.0%).

Genetic Technologies led the falls, down 37.0 percent to \$17 million, followed by Novogen deflating 36.9 percent after last month's 78.7 percent rise, Prana (35.9%), Polartechnics (30.8%), Clinuvel (23.4%), Peplin (22.3%), Phylogica (20.0%), Bionomics (18.5%) and Biota (12.9%).



Biotech Daily Top 40 (\$m) v S&P ASX 200 2008-09

BIOTECH DAILY TOP 40 CHANGES

Clinuvel's afamelanotide is in phase III trials and the company will be promoted to the Biotech Daily Top 20, replacing Arana which has been all but acquired by Cephalon. Antisense, which has a \$100 million deal with Israel's Teva, will move up to the Top 20 replacing Cytopia which has taken a share price battering and Compumedics will be promoted to the Second 20. Compumedics is tightly-held - mostly by its founder David Burton - but Biotech Daily likes companies that make very high-tech products in Australia and sell them offshore.

NEUREN

Neuren says US Army has approved \$US14 million (\$A17.3 million) in new funding for a collaborative phase II clinical trial of NNZ-2566 for traumatic brain injury.

Neuren climbed as much as 170.8 percent to 6.5 cents on the news.

The company said the US Army collaboration began in 2004 when NNZ-2566 was at an early pre-clinical stage.

The company said the funds would be provided through a cooperative agreement in which Neuren would be reimbursed for direct costs incurred in conducting the trial and in preparing for a possible pivotal trial if the results of the phase II study were positive. Neuren said that with the earlier funding award to the program through the Geneva Foundation in January 2008, the US Army has approved total funding for the NNZ-2566 program of \$US18.7 million, representing non-dilutive funding of nine cents per share. The company said that a part of the earlier funding had been used for clinical trial preparations including initial drug supply.

Neuren said the US Army funding followed US Food and Drug Administration approval for the phase II trial and fast track designation which accelerated the drug development review and approval process.

Neuren said it was in the final stages of preparing the phase II trial which would be conducted at up to 12 trauma centres in the US and expected to begin patient enrolment in October 2009.

Neuren chief executive officer Larry Glass said the funding enabled Neuren to accelerate clinical development of NNZ-2566 "at a pace that simply would not have been possible without the Army's continued support and at no cost to existing shareholders".

"The funding was peer reviewed by an independent panel of experts from the US Army, the National Institutes of Health, the Department of Veterans Affairs and leading experts in traumatic brain injury research and treatment," Mr Glass said.

"Their approval and the Army's support reflect the potential that NNZ-2566 holds as a potential treatment for traumatic brain injury," Mr Glass said.

"This is an exciting and hopeful time, not just for the company, but also for our uniformed and civilian colleagues and collaborators in both scientific and clinical settings," he said. "We are about to begin an ambitious program, one which we hope will impact the devastating consequences of traumatic brain injury in civilian and military populations alike," Mr Glass said

The agreement is between the US Army and Neuren's wholly owned US based subsidiary.

Neuren said it was seeking direct investment to the US subsidiary to support the NNZ-2566 program and other programs and would make a share plan offer to shareholders. Neuren climbed 2.9 cents or 120.8 percent to 5.3 cents with 231.4 million shares traded.

PROGEN

Progen has licenced its liver cancer drug PI-88 and restructured its board, including the appointment of a new chairman and retained chief executive officer Justus Homburg. Progen said the moves would strengthen the company and drive development of its anticancer products, but the changes also deflect a July 17, 2009 proposed board coup. Progen said it had appointed four independent and experienced board members including incoming chairman Stuart James and non-executive directors Dr Julie Cherrington, Dr John Chiplin and Dr Gordon Schooley.

Mr James was managing director of Colonial State Bank and Mayne Group; Dr Chiplin was the chief executive officer of Peptech/Arana; Dr Cherrington was a director of Chemgenex and Dr Schooley was an executive at several pharmaceutical companies. Chairman Stephen Chang, managing director Justus Homburg and director Dr Wolf Hanisch have resigned, but Mr Homburg continues as chief executive officer.

Last month a group of Progen investors requisitioned a meeting to be held on July 17, 2009 to remove the then existing three directors and replace them with directors believed to represent Taiwanese interests (BD: Jun 10, 2009).

The meeting resolutions called for the removal of Mr Homburg, Mr Chang and Dr Hanisch, replacing them with Thomas James Burt, Heng Hsin Tang and Joe Yeh-Chiao Lin. A statement by the nominated replacement candidates focused on the need to unlock the value in PI-88 Progen's drug for liver cancer.

A phase III trial of PI-88 was halted in 2008 triggering a demand from major investors for a return of funds raised for the trial along with a series of board spills, attempted mergers hostile mergers and failed mergers (BD: Jul 23, Dec 1, 2008; Mar 9, 27, 2009).

Today, Progen said the new board ensured compliance with Nasdaq listing requirements. The company said the restructure meant that first three resolutions of the July 17 meeting would not be put to shareholders, but the latter three resolutions would.

After the market closed yesterday, Progen said its wholly-owned subsidiary Pharmasynth has licenced liver cancer drug PI-88 or muparfostat to the US-based Global Transbiotech. Progen said the agreement resulted from negotiations based on the terms sheet agreed by the parties and announced in May (BD: May 18, 2009.

Progen will retain the development and commercialization rights of muparfostat in Australia, and Pharmasynth will provide the technical and manufacturing support to Global Transbiotech to develop and commercialize muparfostat elsewhere in the world, with an initial focus on Taiwan, China, Hong Kong and Singapore.

Mr Homburg said the partnership would provide "significant financial opportunity for the Progen Group through cost effective access for muparfostat to global markets".

"In addition to assuming all further costs associated with the development and commercialization of muparfostat outside of Australia, Global Transbiotech will make milestone payments of about \$US5 million to Pharmasynth, as well as royalties on muparfostat sales," he said.

Progen said it had completed several phase II clinical trials of muparfostat, with strong signs of efficacy in delaying the recurrence of hepatocellular carcinoma, following surgery to remove liver cancer tumors.

Progen said it was undertaking a phase II clinical trial of muparfostat in combination with dacarbazine to treat patients with advanced melanoma and had agreed to assign the patent portfolio associated with its drug transporter technology, obtained in the Cellgate acquisition (BD: Feb 4, 2008), to the US-based KAI Pharmaceuticals.

The company made no mention of a \$2 million payment due to Taiwan's Medigen on licencing PI-88.

Progen was untraded at 85 cents.

UNILIFE MEDICAL SOLUTIONS

Unilife says it has an industrialisation agreement with Sanofi Winthrop Industrie, a whollyowned subsidiary of Sanofi-Aventis to commercialize its Ready-to-Fill Syringe.

Unilife says Sanofi-Aventis paid to \$16.4 million (€10 million) for the exclusive right to negotiate for the purchase of the syringe system also known as the Unilife Prefilled Syringe and to bear the costs of its industrialization subject to the signing of the agreement and the completion of agreed quarterly milestones.

The company said the agreement together set the terms of an on-going relationship, including Sanofi-Aventis' commitment to complete the funding of the \$30.4 million (€17 million) Ready-to-Fill Syringe industrialization program begun by Unilife one year ago. Both parties have agreed to extend Sanofi-Aventis's exclusive right to negotiate for the purchase of the RTFS to June 30, 2014.

Sanofi-Aventis will provide Unilife a list of therapeutic drug classes where it intends to market injectable drug products, which are either currently available from them or in their development pipeline.

Unilife has retained the right to enter into agreements with other pharmaceutical companies which may seek to use the Ready-to-Fill Syringe with injectable drug products marketed in Unilife Therapeutic Drug Classes.

Sanofi-Aventis will receive a five percent royalty on revenue generated from sales of the Ready-to-Fill Syringe to other pharmaceutical companies up to \$600 million

Unilife has the right to an access fee from other companies for the right to negotiate for the purchase of the Ready-to-Fill Syringe for use with a Unilife Therapeutic Drug Class. Unilife will pay Sanofi-Aventis 70 percent of any access fees received up to €14.286 million or June 30, 2014, whichever comes earlier.

Sanofi-Aventis will have a 10 year extension of its right to purchase the Ready-to-Fill Syringe for use for a designated therapeutic class should both parties sign a Supply Agreement prior to July 1, 2014.

This extension will be reduced to five years if Sanofi-Aventis does not sell at least 20 million units of the Ready-to-Fill Syringe for use with an injectable drug product to be marketed for this therapeutic class in at least one of the first five years of agreement. Unilife is not required to commit more than 30 percent of its annual capacity of the Ready-to-Fill Syringe to Sanofi-Aventis, allowing adequate capacity for other customers. Unilife said its industrialization program was ahead of schedule and expected to be completed by the end of 2010.

Unilife said it had received a milestone payment of \$3.5 million and had received a total of \$9.5 million in quarterly milestone payments since the commencement of the RTFS industrialization program.

Unilife chief executive officer Alan Shortall said the agreement put the company "in a strong position to … become a global leader in the fast-growing pharmaceutical market for prefilled safety syringes".

Unilife was up 3.5 cents or 11.3 percent to 34.5 cents with 2.2 million shares.

SAFETY MEDICAL PRODUCTS

Safety Medical has sold its wholly owned subsidiary Bagot Press including goodwill, inventory, plant and equipment for \$1.3 million.

According to its website Bagot Press is an Adelaide printing company specifically providing services to the bio-pharmaceutical sector including pharmacy dispensing labels, prescription folders, business cards, leaflets, catalogues and stationery items. Safety Medical was unchanged at 6.4 cents.

VIRALYTICS

Viralytics says about 900 shareholders have subscribed for 91,484,219 options at one cent per option, raising \$914,842.19.

Viralytics said the shortfall of \$2,106,542.41 or 210,654,241 new options could be issued within three months from the close of the offer to disclosure exempt parties, including sophisticated and professional investors

The company said it had previously announced a \$US6 million convertible notes facility with La Jolla Cove Investors Inc and said the first monthly tranche of \$US250,000 occurred on June 15, 2009.

Viralytics was up 0.1 cents or 3.03 percent to 3.4 cents.

<u>CATHRX</u>

Cathrx says it has Conformitée Européenne (CE) Marking for its advanced diagnostic, 'loop' catheter for atrial fibrillation.

Cathrx said the loop catheter was "designed to be one of the most advanced catheters of its kind on the market in Europe".

Cathrx chief executive officer Neil Anderson said the loop catheter was "designed and purpose built for electro-physiologists treating atrial fibrillation".

"The ability for the catheter's stylet to be withdrawn when required is a key safety feature," Mr Anderson said.

Cathrx said that all of its diagnostic catheters were approved for sale in Europe within the time required to achieve its sales projections.

The company said regulatory efforts were directed towards achieving CE Mark approval for its therapeutic catheters.

Cathrx was up five cents or 12.5 percent to 45 cents.

TISSUE THERAPIES

Tissue Therapies says Australia and South Korea have granted "two more of the family of Vitrogro patents".

The company said they added to the multiple Vitrogro patents granted in the US, Australia, New Zealand and South Africa.

Tissue Therapies said the Vitrogro intellectual property position had been strengthened by a new international patent application that further defined and protected the ways in which Vitrogro accelerates wound healing.

Tissue Therapies was unchanged at 16 cents.

PRIMA BIOMED

Link Traders and Laurence Stephen Freedman have become substantial shareholders in Prima with a holding of 40,961,539 shares or 9.74 percent.

Mr Freedman is a director of Link Traders.

Prima fell 0.2 cents or four percent to 4.8 cents with 6.1 million shares traded.

<u>SOLAGRAN</u>

Solagran says Dr Robert Payne has resigned as a director and company secretary. Dr Payne was appointed on February 23, 2009.

Solagran was up half a cent or 5.6 percent to 9.4 cents.

BIOTECH DAILY'S TOP 40 WITH MARKET CAPITALIZATION

Company ¢Am		lum 00	May 00
Company \$Am	Jul-09	Jun-09	May-09
Cochlear CSL	3,234	3,006	2,786
	19,402	17,519	20,772
Resmed Top 20	3,809	3,488	4,021
Acrux	181	188	96
Alchemia	57	59	50 57
Antisense	21	22	24
Avexa	78	87	42
Bionomics	53	65	61
Biota	209	240	257
Cellestis	290	278	269
Chemgenex	184	142	101
Clinuvel	85	111	88
Heartware	274	289	306
Impedimed	58	63	62
Living Cell	43	43	43
Mesoblast	113	99	103
Novogen	53	84	47
Peplin	160	206	182
Pharmaxis	517	492	426
Phosphagenics	90	93	113
Sirtex	187	167	160
Starpharma	70	66	52
Universal Biosensors	145	181	126
Second 20			
Benitec	9	11	8
Bone Medical	18	18	11
Cathrx	20	23	29
Circadian	33	36	38
Compumedics	22	25	19
Cytopia	6	7	10
Genera	28	33	22
Genetic Tech	17	27	17
Labtech	12	13	15
Nanosonics	78	80	33
Optiscan	5	6	5
Phylogica	12	15	12
Polartechnics	18	26	29
Prana	25	39	41
Progen	21	20	65
Psivida	38	39	39
Sunshine Heart	15	15	20
Tissue Therapies	13	15	16
Tyrian	6	8	6
Viralytics	10	11	11

* Biotech Daily editor, David Langsam, owns shares in Alchemia, Biota, Chemgenex and Cytopia as well as non-biotechnology stocks. Through Australian Ethical trusts, he has an indirect interest in Cochlear, CSL, Genera and Pharmaxis. These holdings are liable to change at any time.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: <u>editor@biotechdaily.com.au</u> <u>www.biotechdaily.com.au</u>