# Biotech Daily

Monday August 25, 2008

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECHS UP: PROTEOME UP 22%, NOVOGEN DOWN 7%**

*** PRIMA TO MEET FDA FOR CVAC CANCER TREATMENT APPLICATION**

*** CELLESTIS POSTS $2.25m MAIDEN PROFIT; SALES REVENUE UP 77%**

*** ASTRAZENECA ADOPTS BIOTA'S MEDIMMUNE RSV LICENCE**

*** RELENZA ROYALTY TUMBLE TURNS BIOTA'S PROFIT TO LOSS**

*** MEDICAL DEVELOPMENTS PROFIT DOWN 26% ON REVENUE UP 24%**

*** LABTECH PROFIT DOWN 25% TO $271k ON REVENUE DOWN 36%**

*** CSL SHARE PLAN OFFER TO RAISE UP TO $96m**

*** PROTEOME PLACEMENT RAISES $2.5m**

*** KARMELSONIX SECURES $7m FUNDS FACILITY**

## MARKET REPORT

The Australian stock market was up 1.6 percent on Monday August 25, 2008 with the All Ordinaries up 79.9 points to 5,090.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, four traded unchanged and 10 were untraded. All three Big Caps were up.

Proteome was best, up two cents or 22.22 percent to 11 cents, followed by Phylogica up 21.21 percent to eight cents and Benitec up 16.67 percent to 8.4 cents

Peplin climbed 10 percent; Agenix was up 6.25 percent; Biota, Cochlear and Neuren were up more than five percent; Impedimed, Mesoblast, Optiscan and Resmed were up more than four percent; CSL rose 2.71 percent; with Heartware up 1.64 percent.

Novogen led the falls, down 10 cents or 6.67 percent to $1.40, followed by Chemgenex and Polartechnics down four percent to 96 cents and 12 cents respectively.

Circadian, Clinuvel and Pharmaxis lost more than three percent; Psivida and Sirtex shed more than two percent; with Acrux, Avexa, Phosphagenics, Progen and Viralytics down more than one percent.

## PRIMA BIOMED

Prima has submitted a “formal request for a pre-investigational new drug application meeting” with the US Food and Drug Administration for its CVac ovarian cancer treatment.
Prima said the meeting request was “a major milestone in Prima’s commercializing process for CVac” and the meeting would take place within 60 days.
The company said it intended to secure an investigational new drug application from the FDA for the CVac cancer treatment as part of its “broader and long term goal of developing commercial cancer treatment technologies and programs”.
Prima said CVac was a therapy treatment for ovarian cancer administered post-surgery and post-chemotherapy to delay relapse and control metastases.
The company said there was a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate and there are currently no maintenance-based therapy products available.
Prima announced qualified efficacy results for CVac but the company to find funding to continue its operations.
In 2006, the company announced that 21 percent of 21 patients in the phase IIa trial at Melbourne’s Austin Hospital had either a clinical response to treatment or stabilization of their disease (see Biotech Daily; May 16, 2006)
On October 16, 2007 Martin Rogers was appointed a director of Prima and began and review and renewal of the company (see Biotech Daily of that date).
Earlier this year Prima said it had a new board, cash in the bank and a planned pivotal phase II/III trial of the ovarian cancer vaccine.
Mr Rogers told Biotech Daily at that time the company had raised $2.3 million, had $1.5 million cash in the bank with a cash burn rate of $100,000 a month (see Biotech Daily; May 14, 2008).
Prima said management had finalized the pre-IND meeting request in conjunction with the Fred Hutchinson Cancer Centre in Seattle, Washington.
The company said the meeting was “a major step in the commercialization of any new drug application, and Prima is delighted to be on the cusp of this milestone for CVac”.
Prima chairman Ata Gokyildirim said that the submission for the pre-IND meeting was the result of a lot of hard work and persistence from the Prima team and had been a long time coming but the elements had finally come together.
“We are delighted to be in a position to take this milestone step with our CVac ovarian cancer treatment, and are of the view that its eventual commercialization has the potential to add major material value to the company,” Mr Gokyildirim said.
Prima was untraded at 0.9 cents.

## CELLESTIS

Cellestis has reported its first full-year net profit after tax for the 12 months to June 30, 2008 of $2,256,000 compared to the previous year’s $2,277,000 loss.
Cellestis said total revenue climbed 72 percent to $19.6 million, with sales revenue up 76.7 percent to $18.83 million.
Cellestis reported earnings per share of 2.32 cents compared to the previous year’s loss of 2.35 cents a share.
The company had $14,141,000 in cash at June 30, 2008, but no dividend will be paid.
Cellestis climbed one cent or 0.43 percent to $2.35.

## BIOTA, ASTRAZENECA

Biota says its 2005 collaboration and licence agreement with Medimmune has been assigned to Astrazeneca.

The assignment of the agreement resulted in part from Astrazeneca's acquisition of Medimmune in 2007.

Astrazeneca also secured the rights to a number of Asian and Pacific territories not held by Medimmune under the original agreement and for which Biota would receive an additional $US3.5 million payment, plus future royalties.

The collaboration and license agreement was related to a series of antivirals aimed at the treatment of respiratory syncytial virus.

Biota said that under the agreement all existing milestone and royalty entitlements were preserved and its research and development program was extended.

The lead candidate BTA9881 entered phase I clinical trials in July 2007 and was being continued.

Biota's chief executive officer Peter Cook said the company was pleased to have Astrazeneca as the licencee for its respiratory syncytial virus (RSV) program on a global basis.

"Astrazeneca's tremendous track record in developing and marketing small molecule therapeutics will be of great benefit in bringing new RSV products to the market," Mr Cook said.

Astrazeneca's vice president and head of oncology and infection therapy Dr Brent Vose said the agreement was "part of a growing commitment for Astrazeneca in antiviral therapies".

Biota was up 3.5 cents or 5.11 percent to 72 cents.

## BIOTA

Biota's net loss after taxation for the 12 months to June 30, 2008 was $6,489,000 on revenue down 21 percent to $44,989,000.

In the year to June 30, 2007 Biota posted a profit of $20.2 million.

The revenue fall was primarily due to a halving of Relenza royalties from $39.8 million in 2006-'07 to $20.5 million for the year to June 30, 2008.

Diluted earnings per share was a loss of 3.4 cents a share compared to 11 cents in 2007.

No dividend will be paid, but Biota said it had cash reserves of $60.2 million at June 30, 2008.

Biota said director Barbara Gibson would retire from the board on December 31, 2008 and chairman John Grant intends retiring by June 30, 2009.

## MEDICAL DEVELOPMENTS

Medical Developments says its net profit after taxation for the 12 months to June 30, 2008 was down 26.2 percent to $891,000 on revenue up 23.9 percent to $9,296,000.

Medical Developments said the net profit after tax was "after allowing for marketing, overseas registration activities and [US Food and Drug Administration] preparedness costs of $500,000, all necessary as a platform for [fiscal year 2009] growth".

The company said it continued its "aggressive overseas growth strategy by pursuing the registration of Penthrox in new countries".

Basic earnings per share was down 23.8 percent to 1.6 cents.

Medical Developments was unchanged at 26 cents.

## LABTECH SYSTEMS

Labtech says its net profit after taxation for the 12 months to June 30, 2008 was down 25.29 percent to $271,000 on revenue down 36.29 percent to $2,274,000.
Diluted earnings per share was 0.54 cents compared to 0.90 cents in 2007.
Labtech received $1,689,000 from its licence agreement with France's Biomérieux as well as $406,000 interest and grant income of $120,000.
The company said the past year had been focused on engineering development and transfer to manufacturing of Microstreak, now called Previ Isola.
"Full commercial launch and first commercial sales [of Previ Isola] are anticipated during the second quarter of 2008-'09," Labtech said.
Labtech was untraded at 20 cents.

## CSL

CSL says that following its $1.75 billion placement to buy Talecris (see Biotech Daily; August 14, 2008) existing shareholders can acquire up to $5,000 in shares.
CSL said shareholders at the record date of August 22, 2008 would be able to buy shares at the lower of $36.75 or the volume-weighted 15 trading day average price at the September 16, 2008 offer close, minus a five percent discount.
A CSL spokeswoman told Biotech Daily that the company had 64,000 Australian and New Zealand eligible shareholders.
"Traditionally usually only 20 to 30 percent take up the opportunity and that would raise an additional equity of between $64 million and $96 million," the spokeswoman said.
CSL climbed $1.02 or 2.71 percent to $38.69 with 2.1 million shares traded.

## PROTEOME

Proteome has raised $2.5 million through the issue of 23,809,524 shares at 10.5 cents a share.
Proteome said participants included Oppenheimer Funds and other US and Australian investors. Foster Stockbroking arranged the placement.
The company said proceeds were being allocated to maintain development timelines for the leading two diagnostic programs for tuberculosis and determining wheat quality.
Proteome was up two cents or 22.22 percent to 11 cents.

## KARMELSONIX

Karmelsonix says it has a three-year $7.2 million funding arrangement with Trafalgar Capital Specialised Investment Fund.
The funding agreement was facilitated by Arbel Capital, Trafalgar's representative in Israel and Israel's IBI Investment House.
Karmelsonix said it had a standby equity drawdown facility of up to $7.2 million and a loan facility of up to $1 million as part of the $7.2 million facility for working capital and as a standby for ongoing product development and commercialization program.
Karmelsonix was unchanged at 4.8 cents.