Biotech Daily

Tuesday August 10, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: VIRAX UP 8%; BIONOMICS DOWN 6%**

*** FDA ADVISORY FOR ACRUX'S EVAMIST; EURO-DISTRIBUTOR FALLS**

*** CALZADA CALLS AVEXA EGM TO ROLL 'UNCOOPERATIVE' BOARD**

*** COCHLEAR: INNOVATION KEY TO RECORD PROFIT UP 19% TO $155m**

*** BIOGUIDE BRIEF: ACRUX, CALZADA, AVEXA & LOOKING AFTER NUMBER 1**

*** NANOSONICS TO LOSE CFO CHRIS GRUNDY**

*** UNNAMED BODIES PROVIDE STIRLING WITH $3.9m**

MARKET REPORT

The Australian stock market fell 1.18 percent on Tuesday August 10, 2010 with the S&P ASX 200 down 54.2 points to 4540.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and 11 were untraded.

Virax was best, up 0.6 cents or 8.1 percent to eight cents with 453,001 shares traded.

Chemgenex and Novogen climbed more than seven percent; Cathrx and Universal Biosensors were up more than five percent; Compumedics, Heartware and Phosphagenics were up four percent or more; Pharmaxis and Viralytics rose more than two percent; with Starpharma up 1.9 percent.

Bionomics led the falls, down two cents or 6.45 percent to 29 cents with 19,579 shares traded, followed by Cellmid and LBT, both down five percent to 7.6 cents and 1.9 cents, respectively.

Living Cell fell 4.55 percent; Biota was down 3.4 percent; Clinuvel, Prima and Tissue Therapies shed more than two percent; with Acrux, Alchemia, Cellestis, Cochlear and Psivida down more than one percent.

ACRUX

Acrux says the US Food and Drug Administration has issued an advisory note on unintentional exposure of Evamist, its estradiol spray for menopause symptoms.

Acrux said that on July 29, 2010, the FDA advised that in the three years since approval, it had received eight reports of adverse effects in children aged between three and five years and two reports of adverse effects in dogs, which may have been caused by unintentional exposure to Evamist through skin contact with women using the product.

Acrux posted the warning on its website on August 2, 2010, but did not post it to the ASX, nor publish a media release.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily the advisory was not financially material for the company and the notice had been posted on Acrux's website at the first opportunity.

Dr Treagus said Evamist had warnings about cross contamination but licencee KV Pharmaceutical was in discussions with the FDA regarding the prominence of the warnings.

Dr Treagus said that 200,000 prescriptions for Evamist had been issued in the US per year and agreed that about 20,000 women were using the product.

FDA Office of Drug Evaluation director Dr Julie Beitz said that women using Evamist "need to be aware of the potential risks to children who come in contact with the area of skin where this drug is applied".

"It is important that people know to keep both children and pets away from the product to minimize exposure," Dr Beitz said.

The FDA said that adverse events reported in unintentionally exposed children include premature puberty, nipple swelling and breast development in females, and breast enlargement in males.

Pets exposed to Evamist may exhibit signs such as mammary/nipple enlargement and vulvar swelling, the FDA said.

Separately, Acrux said negotiations with HRA-Pharma for the distribution of the estradiol spray in major European markets had been terminated.

Acrux said that despite "taking all reasonable efforts, HRA and Acrux were unable to reach agreement on terms and today have agreed not to proceed with the distribution agreement".

"In the absence of clear alignment on the key issue of product supply, Acrux's interests are best served by discontinuing the HRA partnership," Dr Treagus said in a media release to the ASX.

Dr Treagus told Biotech Daily that the agreement was intended to apply to France Germany and the UK.

Dr Treagus said that termination of the HRA agreement had no material financial impact on Acrux and preliminary discussions were being held with alternative partners.

Acrux said in its media release it had marketing applications for Ellavie filed with the Swedish regulatory authority, as well the Swiss regulatory authority, with review decisions for both of these applications are anticipated during the course of 2010.

Acrux said Ellavie was licensed to Vifor in Switzerland, Dream Pharma in South Korea and Aspen Pharmacare in South Africa and Australia.

Dr Treagus did not comment on approval in Australia.

Late last year the Australian Therapeutic Goods Administration said it would require additional supporting data that specifically compared the spray to an Australian marketed estradiol transdermal product (BD: Nov 12, 2009).

Acrux fell four cents or 1.97 percent to $1.99.

CALZADA, AVEXA

Avexa's major shareholder Calzada has requisitioned a meeting to replace the board.

With 16.06 percent of Avexa, Calzada has repeatedly requested board representation and been rebuffed by the company (BD: Jul 7, 8, 13; Aug 9, 2010).

Following the failure of the apricitabine or ATC program for HIV, the July 6, 2010 general meeting deposed the previous chairman Nathan Drona and the recently appointed director Uri Ratner and elected Steven Crowley and Bruce Hewett as representatives of investors with Bell Potter, RBS Morgans, UBS and Solomon Smith Barney.

The following day former director Joe Baini was appointed to the board, followed by Bell Potter advisor Jet Soedirdja on July 13, 2010.

Yesterday, Avexa appointed Iain Kirkwood as a director (BD: Aug 9, 2010).

In its requisition notice Calzada nominated as new directors former Peptech/Arana chief executive officer Dr John Chiplin and chief medical officer Dr David Fuller; Ausbiotech director and former Phylogica chief executive officer Dr Stewart Washer; and Calzada director Bruce Rathie, who has acted as a representative of the Commonwealth Scientific and Industrial Research Organisation on several biotechnology company boards.

In its notice to the ASX Calzada said that since the July 6 Avexa shareholders meeting it had “attempted to engage with the current board of Avexa in respect of certain concerns it has relating the composition of the Avexa board and its future direction”.

“To date, the responses received have not adequately addressed Calzada’s concerns,” the company told the ASX.

Calzada said its only option was to put these issues to Avexa shareholders and offer an alternative to the future leadership of the company.

Calzada said it intended to propose that “only one of its nominees, Calzada independent non-executive director Bruce Rathie, be appointed to the Avexa board” with the remaining positions being filled by Dr Chiplin, Dr Washer and Dr Fuller as independent non-executive directors.

Calzada said its proposed appointees “clearly underline its desire to put in place a strong and independent leadership team, with exceptional commercial and biotechnology credentials, to guide Avexa’s future direction and to enhance shareholder value”.

Calzada said it believed Avexa shareholders would share its desire for change.

Calzada said it intended to exercise its right to provide Avexa shareholders with a statement summarizing its views on this matter which would be provided to Avexa in time for it to be included in the meeting documentation to be despatched by Avexa.

Section 245D of the Corporations Act says that following a properly requisitioned meeting notice the directors must call the meeting within 21 days and the meeting must be held with two months of the requisition.

Avexa chairman Joe Baini told Biotech Daily in a media release that his company had “an outstanding team and we are committed to the independent review of the company's assets, which is already at short list stage”.

“The shareholders overwhelmingly endorsed that approach at the recent general meeting,” Mr Baini said. “I can understand Calzada's disappointment that the board declined its request for board representation,” Mr Baini said.

“That decision was made after careful consideration and in the best interests of all shareholders. Regrettably, Calzada has called for a meeting which, as things presently stand, will need to be held a month or so before the usual [annual general meeting]. We are exploring ways to avoid such duplication for the benefit of shareholders, by having one meeting rather than two,” Mr Baini said. “I am hopeful that this is achievable.”

Avexa was unchanged at 2.9 cents with 1.5 million shares traded.

Calzada fell 0.1 cents or 3.7 percent to 2.6 cents.

COCHLEAR

Cochlear says its net profit after tax was up 19 percent to a record $155.2 million for the 12 months to June 30, 2010 on record revenue up six percent to $743.8 million.
Cochlear said it would pay a 60 percent franked final dividend of $1.05 per share up 11 percent on the previous year, with earnings per share up 18 percent to $2.757.
The dividend will be paid on September 23, 2010 with a record date of September 2.
Cochlear's chief executive officer Dr Chris Roberts told a teleconference that although the company made a profit of $155.2 million, the company had a "free cash flow" of $166 million, up 50 percent on the previous year.
Dr Roberts said that the company's Nucleus 5 system had a full year increase in sales of 13 percent to 21,023 units, with a 20 percent rise for the six months to June 30, 2010.
Research and development expense was $94.9 million or 12.8 percent of revenue.
Dr Roberts said the Americas were the company's main growth area with sales increasing 18 percent in constant currency and two percent in reported currency of $307.6 million.
Cochlear's chief financial officer Neville Mitchell told the teleconference that about 90 percent of revenue was in foreign currency with about 50 percent of expenditure in foreign currency providing "a natural hedge" against currency fluctuations.
Mr Mitchell said the company had total debt of $113.9 million at June 30, 2010 of which $72.8 million related to the company's new headquarters at Macquarie University, which would be retired when the University bought back the building on completion this year.
Dr Roberts paid tribute to the innovations and the team behind the Nucleaus 5 product.
Dr Roberts said there were more than 50 innovations incorporated in the Nucleus 5 device, including manufacturing processes and changes to the global supply chain (see Biotech Daily: Apr 14, 2010).
Cochlear fell $1.42 or 1.99 percent to $69.86.

MARC SINATRA'S BIOGUIDE BRIEF: ACRUX, CALZADA, AVEXA

ACRUX

I don't particularly like being late with an opinion, but unfortunately, I don't check Acrux's website everyday, so I found out 10 days after the fact that there are some safety concerns regarding Acrux's Evamist product for menopausal women.

Evamist has been linked with reports of children showing signs of premature puberty and mammary/nipple enlargement along with vulvar swelling in dogs. The theory is that accidental transference of the topically applied Evamist is the cause.

While the problem can probably be resolved with a more prominent warning on the packaging, the FDA will continue to monitor these accidental transferences.

The issue is: why didn't Acrux see the FDA's announcement regarding Evamist as material?

Given the company is all about topical application of drugs, unintentional transference is an issue that could affect a large part of their current and future product lines.

To me, that risk factor falls pretty well into the category of material information. If Acrux didn't think it was material, why publish the notice at all?

I think they were trying to have a bet each way.

CALZADA, AVEXA

Years ago, when I first started investing, I told a broking client advisor that I had held on to some shares for too long and missed a good profit-making opportunity.

He replied: You should have come to me for advice; I timed it perfectly and made a killing.

I later found out that he had only sold a small portion of his shares in the company and didn't fare much better than me in the overall investment return.

Client advisors, like most of us, trade on the perception that we are right and have a tendency to take actions post-fact to justify our positions when we are wrong. And when they are wrong they come under immense pressure from the clients they have advised.

With this in mind, it is interesting to note that the main organizers in the successful push to oust Avexa's former board are client advisors.

While I have believed for a while that Avexa's drug apricitabine was moribund, the new board doesn't seem to think so.

And despite a pending review of the drug's development prospects, the company seems to be giving the impression that development of the drug will continue - given its swift moves to appoint executives and expand the board.

While I originally didn't believe that Avexa's major shareholder, Calzada, should be automatically given a seat on the board, I am beginning to change my mind.

The goings on at Avexa seems to me to be more of a face-saving exercise than anything else - at the moment - and the appointment of a director from Calzada would probably be a good thing for Avexa's shareholders.

Given the conflicts of interest any Calzada representative would have, obviously, this isn't a perfect solution, but given Avexa's board seems to be more beholden to the further development of apricitabine than anything else, any different point of view is likely to be beneficial.

While it may not be in Avexa's shareholders best interests to replace the whole of the existing board with those nominated by Calzada in their general meeting requisition announced today, the appointment of some of them may be the thing that gets Avexa thinking about its future, more than saving face for those who backed it.

Marc Sinatra
Analyst

NANOSONICS

Nanosonics says chief financial officer and company secretary Chris Grundy, has resigned effective from October 1, 2010.
Nanosonics said Mr Grundy cited his personal circumstances as not aligning with the company's imminent plans to expand its operations in Europe and the US.
Nanosonics was unchanged at 62 cents.

STIRLING PRODUCTS

Stirling says that an unnamed group will provide a “mezzanine” funding facility worth $2.1 million.

The company said unnamed sophisticated investors would provide loans for a further $1.8 million.

Stirling was up 0.1 cents or 10 percent to 1.1 cents with 27.9 million shares traded.