Biotech Daily

Wednesday April 23, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PRANA UP 11%, QRX DOWN 80%**

*** FDA COMMITTEE 3rd STRIKE FOR QRX MOXDUO, FALLS 85%**

*** PHOSPHAGENICS ENROLS PHASE II TPM-TRETINION TRIAL**

*** BLUECHIIP SHARE PLAN FOR UP TO $1.75m**

*** BIODIEM CLOSES RIGHTS ISSUE WITH $815k**

*** UNILIFE REPORTS 'BLOGGING SHORT-SELLERS' TO US SEC**

*** IMUGENE APPOINTS DR NEIL SEGAL TO ADVISORY BOARD**

*** ACTINOGEN APPOINTS DR BRENDAN DE KAUWE EXECUTIVE CHAIRMAN**

*** CIRCADIAN CEO DR MEGAN BALDWIN STARTS ON $300k**

*** LSQ STRATEGIC RISK AND CRISIS COMMUNICATIONS WORKSHOP**

*** OBJ REQUESTS 'MATERIAL AGREEMENT' TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.7 percent on Wednesday April 23, 2014 with the S&P ASX 200 up 38.5 points to 5,517.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded.

Prana was the best, up two cents or 10.5 percent to 21 cents with 4.2 million shares traded.

Atcor climbed 8.3 percent; Reva was up 6.9 percent; Compumedics, Neuren, Oncosil and Optiscan were up more than four percent; Bionomics, Clinuvel and Phosphagenics were up more than three percent; Mesoblast, Pharmaxis and Sirtex rose more than two percent; Resmed and Tissue Therapies were up more than one percent; with CSL up 0.04 percent.

QRX led the falls, down as much as 59.5 cents or 85.0 percent to 10.5 cents, before closing down 56 cents or 80 percent to 14 cents with 31.3 million shares traded. Anteo and Osprey lost more than nine percent; Patrys was down 5.6 percent; Nanosonics fell 4.2 percent; Admedus, Antisense and Avita were down more than three percent; Prima and Starpharma shed two percent or more; Alchemia, Cochlear, Living Cell and Viralytics were down more than one percent; with Acrux down 0.3 percent.

QRX PHARMA

The US Food and Drug Administration Anesthetic and Analgesic Drug Products Advisory Committee has voted 14 to nil against approval of QRX's Moxduo dual opioid.

The FDA is expected to give its final decision by May 25, 2014 at the scheduled Prescription Drug Fee User Act (PDUFA) meeting.

Last year, QRX resubmitted its Moxduo new drug application, following a second FDA 'complete response letter' (BD: Aug 28, Nov 26, 2013).

QRX said at that time that the FDA had confirmed that the combination rule trial, Study 008, satisfied efficacy requirements and that there were no efficacy or safety issues identified in any of the studies submitted in the original NDA.

In 2012, the FDA first rejected the Moxduo application saying it required further data comparing the combination drug's 12mg morphine and 8mg oxycodone to equi-analgesic doses of its component parts, that is, either 24mg morphine alone or 16mg oxycodone alone, not just 12mg morphine alone or 8mg morphine alone (BD: Jun 27, 2012).

QRX previously said the FDA had advised it would accept the drug measured against its component parts as it was in Study 008.

Background notes to the meeting, provided by the FDA, were critical of the QRX trial design and endpoints.

"Throughout clinical drug development, the Division [of Anesthesia, Analgesia, and Addiction Products] has held milestone meetings with the applicant, including a pre-IND, end-of-phase II and pre-NDA meeting," the notes said.

"Additionally, the Division evaluated the phase III protocol, Q8003-008, under special protocol assessment but did not agree with the proposed primary efficacy endpoint and statistical approach and issued a 'no agreement letter'," the FDA notes said.

In a teleconference today QRX chief executive officer Dr John Holaday said he could not recall receiving that letter.

Dr Holaday said there had been many discussions with the FDA and there were points that had been clarified, but said the FDA had approved the company's trial designs.

"The FDA has been inconsistent in their dealings with us in this process," Dr Holaday said.

Dr Holaday said that the FDA had agreed with QRX on trial designs but "their confusion is that we have two drugs in the same category" and the FDA was wary of the precedent.

In 2008, QRX said the FDA accepted its phase III protocol designs and analyses to demonstrate Moxduo's efficacy and safety, then known as Q8003IR (BD: Aug 5, 2008).

The FDA background notes said it had "never before approved a combination drug product that is composed of two drugs from the same pharmacologic class".

"Indeed, it is contrary to the purpose for which the Combination Rule was created, which was to assure that the combination of two fixed-dose drugs provides some benefit to patients that could not be obtained by prescribing the individual components alone," the FDA said.

The advisory committee was asked to vote on whether QRX had provided evidence that Moxduo was safer than morphine and oxycodone when these drugs were used individually and at comparable doses.

The committee was asked to vote on whether Moxduo should be approved for the treatment of moderate to severe acute pain and if not discuss whether there were additional studies to support approval in the future.

"We will press-on – we have a great drug," Dr Holaday said.

QRX fell as much as 59.5 cents or 85.0 percent to 10.5 cents, before closing down 56 cents or 80 percent to 14 cents with 31.3 million shares traded.

PHOSPHAGENICS

Phosphagenics says it has completed enrolment for its 54-patient phase II clinical trial of tocopheryl phosphate mixture or TPM tretinoin for acne vulgaris.

Phosphagenics said the three month, randomized, double-blind study would examine the efficacy of TPM-tretinoin against a commercial tretinoin formulation and was expected to be completed by July, with results by October, 2014.

The company said that previous studies demonstrated a significant increase in the delivery of trentinoin into the skin compared to a commercially available product as well as substantially deeper penetration of the drug, with less irritation to the skin and surrounding application area.

Phosphagenics said that tretinoin was most commonly prescribed by dermatologists for topical treatment of acne, but it caused adverse skin irritation in many patients and led to a large number of those patients withdrawing from treatment.

The company said that as a result, products often contained a less than optimal amount of tretinoin to reduce irritation but this led to a decrease in efficacy.

Phosphagenics said the global market for acne prescription and over-the-counter products was estimated at $3 billion a year, with the market for tretinoin more than $200 million in sales in the US market alone and that market could potentially be increased significantly with a superior product.

Phosphagenics chief executive officer Harry Rosen said that dermatological products and particularly those with active ingredients that needed to penetrate deeply into the skin but caused irritation “lend themselves perfectly to this technology”.

“The size of the acne market and the low cost of registering dermatological products justifies the allocation of our expertise and efforts in this area,” Mr Rosen said.

“If we can replicate our initial studies in this phase II trial and beyond, it would result in a substantially superior product with better efficacy for patients and less skin irritation,” Mr Rosen said.

Phosphagenics was up 0.3 cents or 3.4 percent to 9.1 cents.

BLUECHIIP

Bluechiip hopes to raise up to $1,750,000 through a share plan at five cents a share

Bluechiip said shareholders eligible at the record date of April 22, 2014 would be able to apply for parcels of shares from $2,000 to $15,000.

The company said the offer would open on May 1 and close on May 23, 2014.

Bluechiip said the funds would be used to provide working capital to support sales and business development activities of its storage tracking systems.

Bluechiip was unchanged at 5.4 cents.

BIODIEM

Biodiem says it has closed its rights issue raising the full amount available of $815,000 at 5.5 cents a share, although it had applications for $972,094 in shares.

Biodiem chief executive officer Julie Phillips told Biotech Daily that the company had received applications for more than $699,000 of new shares, including more than $300,000 of shortfall applications and expected to exceed the total maximum subscription amount of $815,000 (BD: Apr 10, 2014).

Ms Phillips said that 6,151,157 options had been exercised at eight cents each raising $492,093.

Biodiem is a public unlisted company.

UNILIFE CORP

Unilife says it has requested the US Securities and Exchange Commission to take action against “short sellers and their associates for stock manipulation and illicit gains”
The company said the request followed “a series of malicious blogs containing false and misleading information published over recent months by short sellers on the Seeking Alpha website”.
Unilife said it “categorically refutes any allegations of wrong-doing by the company, its directors, officers and management”.
The company said that most of the allegations related to a wrongful termination lawsuit by a former employee who was terminated ‘for cause’ and the related SEC review of the matter, which Unilife first disclosed more than 18 months ago and has repeated in subsequent regulatory filings and earnings calls (BD: Jan 24, 2014).
Unilife said it had “refuted these allegations, declined a settlement offer by the plaintiff, and expects to prevail should the case proceed to trial”.
Unilife said it had co-operated fully with the SEC in its review, provided extensive information and responded to all questions and did not believe that there were any grounds for any action to be taken against the Company.
The company said it never paid anyone to publish articles about it, no officer had sold stock since the company listed on the Nasdaq in 2010, with the chief executive officer Alan Shortall and the chief operating officer Dr Ramin Mojdeh having bought more than $4 million in stock in recent years.
Unilife said the departure of the chief financial officer was not due to a resignation but part of a long-term succession plan (BD: Mar 19, 2014).
The company said that Mr Shortall had never been a director or officer of a company that has failed, or gone bankrupt and Unilife had been through numerous due diligence processes conducted by multiple global pharmaceutical customers, investors, analysts, financial auditors and regulatory bodies.
Unilife said it encouraged the SEC to act quickly to address these illegal actions by the relevant short sellers and their associates.
Unilife fell four cents or 6.2 percent to 60.5 cents with 2.5 million shares traded.

IMUGENE

Imugene says it has appointed New York-based Memorial Sloan Kettering Cancer Center oncologist Dr Neil Segal to its scientific advisory board.
Imugene said that Dr Segal’s research focussed on the development of new therapies and ways to use the immune system to treat cancer.
The company said its recently acquired HER-Vaxx vaccine aimed to activate the patient’s immune system to produce its own antibodies (BD: Oct 23, 2013).
Imugene said that Dr Segal had clinical expertise in colorectal, pancreatic, bile duct and other gastrointestinal cancers.
The company said that Dr Segal held a Doctorate of Medicine and Philosophy from University of the Witwatersrand in South Africa.
Imugene was up 0.1 cents or 9.1 percent to 1.2 cents.

ACTINOGEN

Actinogen says that executive director Dr Brendan de Kauwe has been appointed executive chairman (BD: Feb 13, 2014).
Actinogen was untraded at three cents.

CIRCADIAN TECHNOLOGIES

Circadian says chief executive officer Dr Megan Baldwin will receive a base salary of $300,000 with eligibility for a further $150,000 in short-tem incentives.
Circadian said the incentives were subject to key performance indicators and Dr Baldwin would be entitled to long term incentive through a proposed employee option plan.
Circadian promoted Dr Baldwin earlier this year following the departure of former chief executive officer Robert Klupacs from the company (BD: Dec 3, 2013; Feb 21, 2014).
Circadian said that Dr Baldwin had more than 18 years experience focusing on angiogenesis and therapeutic strategies for cancer and ophthalmic indications.
The company said Dr Baldwin joined Circadian in 2008 and was previously the head of preclinical research and development as well as Opthea chief executive officer, developing OPT-302, or VGX-300, for wet age-related macular degeneration.
Circadian said that prior to joining the company Dr Baldwin held research and commercial roles at Roche (formerly Genentech) in San Francisco.
The company said that Dr Baldwin completed her Doctorate of Philosophy in medicine at the Ludwig Institute for Cancer Research affiliated with the University of Melbourne.
Circadian was untraded at 17 cents.

LIFE SCIENCES QUEENSLAND.

Life Sciences Queensland says that an Asia Bio-Business workshop on May 5, 2014 in Brisbane will discuss risk communication strategies and evaluate their effectiveness.
Life Sciences Queensland said it was hosting the interactive one-day workshop to be conducted by the Singapore-based Asia Bio-Business, which would focus on developing effective communication skills for leaders when dealing with risk, uncertainty and low trust situations; including mitigating risk and addressing controversy and crisis.
Life Sciences Queensland said that the workshop would offer a valuable learning experience for commercialization managers, scientists who might engage with the public, policy makers, startups or corporate communications managers.
Asia Bio-Business said that the workshop “takes a unique approach that provides clients with science-based solutions and tested ways to communicate risk, influence stakeholders and guide them towards the best possible decisions for the long-term benefit of clients”.
The Strategic Risk and Crisis Communications Workshop will be held at the Queensland University of Technology, Brisbane, Queensland.
Registration is from 8:30am and the workshop includes morning tea, afternoon tea and lunch.
For more information and to register go to: http://tinyurl.com/mz2mqoq.

OBJ

OBJ has requested a trading halt “pending an announcement by the company in relation to a material agreement”.
Trading will resume on April 28, 2014 or on an earlier announcement.
OBJ last traded at four cents.