Biotech Daily

Monday February 12, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ACTINOGEN UP 19%; CYNATA DOWN 8%**

*** CSL PHASE III CSL112 CARDIAC TRIAL MISSES PRIMARY ENDPOINT**

*** NOVA EYE UNAUDITED H1 RECEIPTS UP 16% TO $10m**

*** NOVA EYE HOPES FOR $3m PLACEMENT, $5m RIGHTS OFFER**

*** TRUSCREEN RIGHTS FOR $3m**

*** ARGENICA MANUFACTURES PHASE II ARG-007 DOSES**

*** CLEO TRANSFERS CXCL10 TEST TO LABORATORY**

*** LUMOS APPOINTS HENRY SCHEIN US FEBRIDX DISTRIBUTOR**

*** TRUSCREEN WINS SAUDI ARABIA REIMBURSEMENT**

*** RHYTHM EGM 56% BACK CHAIR OTTO BUTTULA**

*** PAINCHEK REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** REGAL FUNDS DILUTED TO 8.5% OF CARDIEX**

*** CYCLOPHARM APPOINTS JASON SMITH CFO**

*** PARADIGM APPOINTS SCOTT WILLIAMS CONSULTANT; 7.5m OPTIONS**

MARKET REPORT

The Australian stock market fell 0.39 percent on Monday February 12, 2024, with the ASX200 down 29.9 points to 7,614.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Actinogen was the best, up 0.6 cents or 19.35 percent to 3.7 cents, with 4.5 million shares traded. Syntara (Pharmaxis) climbed 9.1 percent; Imugene and Pro Medicus improved more than four percent; Opthea was up 3.6 percent; Immutep and Cyclopharm rose more than two percent; Avita, Paradigm, Percheron (Antisense), Polynovo and SDI were up more than one percent; with Clarity, Volpara and Neuren up by less than one percent.

Cynata led the falls, down 1.5 cents or 7.9 percent to 17.5 cents, with 216,263 shares traded, followed by Resonance down 7.55 percent. Genetic Signatures and Medical Developments lost more than five percent; CSL, Impedimed, Micro-X and Universal Biosensors fell more than four percent; both Alcidion and Prescient were down 3.8 percent; Dimerix, Orthocell and Telix shed more than two percent; Clinuvel, Emvision, Mesoblast and Resmed were down more than one percent; with Cochlear and Nanosonics down by less than one percent.

CSL

CSL says its 18,200-patient, phase III trial of CSL112 to reduce the risk of major adverse cardiovascular events following a heart attack did not meet its primary endpoint.

In 2012, CSL said a phase I trial showed CSL112, a novel formulation of the blood plasma-derivative apolipoprotein A-I, was associated with the removal of cholesterol from arteries, and that infusions "rapidly increased the presence of key biomarkers associated with reverse cholesterol transport" (BD: Nov 6, 2012).

In 2013, the company said a phase IIa trial of CSL112 in patients with stable cardiovascular disease had shown a dramatic and rapid increase in key indicators of reverse cholesterol transport (BD: Nov 21, 2013).

In 2016, CSL said that a phase IIb safety and proof-of-mechanism study showed that CSL112 was safe, well-tolerated and removed plaque cholesterol following a myocardial infarction (heart attack) (BD: Nov 16, 2016).

Today, the company said the placebo-controlled, double-blind, randomized, 850-site, 49-country phase III trial "did not meet its primary efficacy endpoint" of a reduction in major adverse cardiovascular events at 90 days.

CSL said patients were randomized to receive four weekly doses of CSL112 or placebo within five days of beginning the trial.

The company said that, while there were "no major safety or tolerability" concerns with CSL112, the results meant it had "no plans for a near-term regulatory filing".

CSL said further analysis of the study was on-going and the primary results would be presented at the American College of Cardiology Scientific Sessions on April 6, 2024 and published in a peer-reviewed journal.

The company said it had excluded any financial contribution from CSL112 in its forward-looking estimates and statements.

CSL said it did not expect any material financial impact following the trial's conclusion.

CSL executive vice president and head of research and development Dr Bill Mezzanotte said "substantial work remains to fully analyze and understand the complete data and then to determine any development path ahead for this asset".

"[The trial was] the most ambitious study in our company's history and we are proud of the quality of the study we delivered and the enhanced capabilities we developed to do so," Dr Mezzanotte said. "We plan to apply these capabilities as well as our plasma protein platform to future unmet medical need in cardiovascular and metabolic conditions as well as those in our other strategic therapeutic areas."

CSL closing down $14.76 or 4.8 percent at $290.24 with 959,198 shares traded.

NOVA EYE

Nova Eye says unaudited receipts from customers for the six months to December 31, 2023 were up 16.2 percent to $US6,620,000 ($A10,145,000).

Nova Eye said sales of its glaucoma surgical devices in the US were up 65.0 percent to $US5,050,000 with sales in Western Europe down 5.7 percent to $US1,255,000 and sales in China down 70.0 percent to $315,000.

The company said its marketing investment in the US following the launch of its Itrack in May 2023 had led to increased sales but caused decreased sales in other regions.

The company said its loss before interest, taxation, depreciation, and amortization was down 56.2 percent to $4,179,000 compared to the previous corresponding period.

The company said it had cash and cash equivalents of $2,612,000 at December 31, 2023, compared to $2,635,000 at December 31, 2022.

Nova Eye last traded at 27.5 cents (see below).

NOVA EYE MEDICAL

Nova Eye says it hopes to raise $8.0 million through a $3.0 million placement and a $5.0 million, one-for-eight, non-renounceable rights offer, at 21.0 cents a share.
Nova Eye said the offer price was a 24.2 percent discount to the 10-day volume weighted average price of 27.7 cents.
The company said the institutional component of the rights offer would open on February 12 and close on February 14, and that the retail component had a record date of February 14, would open on February 19 and close on March 8, 2024.
Nova Eye said the funds would be used for its glaucoma business, including expanding sales of its Itrack canaloplasty devices to Europe and the US, as well as product development.
Separately, the company requested a trading halt in “relation to a proposed capital raising” with trading expected to resume on February 14, 2024.

TRUSCREEN GROUP

Truscreen says it hopes to raise $NZ2.8 million ($A2.63 million) through a one-for-three, renounceable rights offer at 2.0 NZ cents (1.88 Australian cents) a share.
Truscreen said the offer was for shareholders on the record date of February 20, would open on February 21 and close on March 13, 2024.
The company did not state how the funds would be used.
Truscreen fell 0.3 cents or 10.7 percent to 2.5 cents.

ARGENICA THERAPEUTICS

Argenica says it has manufactured ARG-007 doses for its 92-patient, phase II trial for acute ischaemic stroke, with dosing expected to begin next month.
Argenica said the primary endpoint of the double-blinded, randomized, placebo-controlled, single-dose study would test the safety of ARG-007 in acute ischaemic stroke patients, and that if achieved it would “pave the way … to progress towards a pivotal phase III trial”.
The company said the trial was also designed to “generate preliminary signals of efficacy on the ability of ARG-007 to reduce brain tissue death following stroke and endovascular thrombectomy”.
Argenica said it would only recruit patients with a “diagnosed large vessel occlusion stroke” eligible for endovascular thrombectomy, which would allow it to assess the ability of ARG-007 on brain injury caused by clot blockages and protecting against the secondary injury caused to brain cells following clot removal.
The company said large vessel occlusion strokes accounted for “close to 40 percent of all acute ischaemic strokes” and were responsible for 60 percent of post-stroke dependency, as well as 90 percent of mortalities after stroke.
Argenica said the study would be conducted at 10 Australian trial sites with dedicated stroke care units capable of performing endovascular thrombectomy.
The company said that following treatment patients would be assessed for “key safety outcomes” as well as “infarct volume and functional outcomes” by standard assessments.
Argenica’s chief executive officer Dr Liz Dallimore said “achieving successful scale up [of the] manufacturing of ARG-007 for our upcoming phase II trial is a huge milestone for the company”.
Argenica was up two cents or 3.45 percent to 60 cents.

CLEO DIAGNOSTICS

Cleo says it has transferred its CXCL10 ratio test for measuring immune process changes to detect tumors to a “more rigorous laboratory environment”.
Last year, Cleo raised $12 million at 20 cents a share to list on the ASX to commercialize its blood tests for ovarian cancer (BD: Aug 22, 2023).
Today, the company said the transfer would help it deliver “reproducible and reliable results” in preparation for its US Food and Drug Administration 510k application.
Cleo said CXCL10 related to the “core technology” for its ovarian cancer detection test.
The company said it was finalizing a tender process for the selection of an antibody manufacturer and hoped to announce a partner by April, 2024.
Cleo was unchanged at 18 cents.

LUMOS DIAGNOSTICS

Lumos says it has expanded its deal with Henry Schein Medical to include distributing its Febridx finger-prick blood test for infection identification in the US.
Last year, Lumos said it had received US Food and Drug Administration clearance to market its Febridx rapid, point-of-care, finger-prick, blood test to differentiate bacterial from viral respiratory infections (BD: Jul 3, 2023).
In July and August, the company said the New York-based Henry Schein Medical would sell Febridx in Spain, Portugal and the Netherlands (BD: Jul 18, Aug 16, 2023).
Lumos did not disclose commercial terms of the agreement.
Lumos fell 0.2 cents or 2.4 percent to 8.1 cents with 34.1 million shares traded.

TRUSCREEN GROUP

Truscreen says its Saudi Arabia distributor Bettalife has obtained reimbursement for its cervical screening device by “most health insurance companies in the country”.
Truscreen said the reimbursement meant that women with insurance that opted for its non-invasive optical-electrical device as opposed to conventional pap-smear, would receive Truscreen at a cheaper price, making it more accessible and cost-effective.
Truscreen chief executive officer Dr Beata Edling said “this approval will benefit women in Saudi Arabia and contribute to the continued success and expansion of Truscreen in the region”.

RHYTHM BIOSCIENCES

Rhythm says 56.17 percent of its extraordinary general meeting supported executive chair Otto Buttula as a director, with 43.83 percent voting for his removal.
Last year, Rhythm said it received a section 249D shareholder requisition for an extraordinary general meeting to remove Mr Buttula as a director (BD: Dec 15, 2023).
The notice from Daniel Eddington, Julie Eddington, DJ Holdings, Jawaf Enterprises, Julia Hall, Anthony Hall, Loumea Investments and Richard Vom said the parties had become substantial with 5.3 percent to requisition the removal of a director.
Today, Rhythm said 57,180,982 votes (43.83%) were in favor of removing Mr Buttula as a director, with 73,268,550 votes (56.17%) against.
According to its most recent notice, the company had 221,142,589 shares on issue, meaning that the 57,180,982 votes in favor of Mr Buttula’s removal amounted to 25.9 percent of the company, sufficient to requisition extraordinary general meetings.
Rhythm was unchanged at 12.5 cents.

PAINCHEK

Painchek has requested a trading halt pending an announcement “regarding a proposed capital raising”.
Trading will resume on February 14, 2024, or on an earlier announcement.
Painchek last traded at 3.4 cents.

CARDIEX

Sydney’s Regal Funds Management says its 25,047,077 share-holding in Cardiex has been diluted from 12.59 percent to 8.51 percent.
Last week, Cardiex said its one-for-2.87 entitlement offer at 8.0 cents a share raised $4 million, taking the total raised with the placement to $8 million (BD: Feb 7, 2024).
Regal Funds said it had acquired 25,047,077 shares on February 6, 2024 for $2,003,766 or 8.0 cents a share in the entitlement offer (BD: Feb 9, 2024).
Cardiex was in a suspension and last traded at 13.5 cents.

CYCLOPHARM

Cyclopharm says it has appointed Jason Smith as chief financial officer, effective from February 26, 2024.
Cyclopharm said Mr Smith had held financial roles at Cochlear during the past 15 years, including as Asia Pacific director of financial planning and analysis.
According to his Linkedin profile, Mr Smith held a Bachelor of Accounting from Western Sydney University and a Master of Business Administration from Macquarie Business School.
Cyclopharm was up 4.5 cents or 2.5 percent to $1.82.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed the Perth’s Scott Williams as a business development consultant, “mostly remunerated” with 7,500,000 options.
Paradigm said that Mr Williams, through his company Fiftyone Capital Pty Ltd, would help it execute “one or more regional pharmaceutical deals for injectable pentosan polysulfate sodium, which are intended to provide non-dilutionary funding for its clinical programs".
The company said it would issue Mr Williams 2,500,000 options exercisable at 65.0 cents each within two years of issue, 2,500,000 options exercisable at $1.00 each and 2,500,000 exercisable at $1.35 each following it entering into at least one binding commercial agreement by July 31, 2025.
Paradigm was up half a cent or 1.45 percent to 35 cents.