Biotech Daily

Wednesday August 15, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: FACTOR UP 12.5%; GENETIC SIGS DOWN 7%**

*** CSL RECORD REVENUE UP 15% TO $10.5b, PROFIT UP 29% TO $2.4b**

*** REDHILL RAISES $35m, MOST FOR AUSTRALIAN TECHNOLOGIES**

*** VISIONEERING $9m PLACEMENT, SHARE PLAN FOR $3m MORE**

*** PARADIGM CLAIMS '60% REDUCTION IN OSTEO-ARTHRITIS PAIN'**

*** FDA OKAYS PHARMAXIS ARIDOL PLANT; $2m US SALES A YEAR**

*** ACTINOGEN: XANAMEM ALZHEIMER'S TRIAL 75% ENROLLED, MINDMATE**

*** CANN SUPPLIES 1st PATIENTS AURORA MEDICAL MARIJUANA**

*** AUSTRALIAN PATENT FOR RESAPP RESPIRATORY DIAGNOSTIC**

*** REGAL FUNDS REDUCE TO 8% OF PRESCIENT**

*** REGAL REDUCES BELOW 5% OF AVITA**

*** ROBERT PETERS TAKES 18% OF MEMPHASYS**

MARKET REPORT

The Australian stock market was up 0.47 percent on Wednesday August 15, 2018 with the ASX200 up 29.4 points to 6,329.0 points. Nine of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Factor Therapeutics was the best, up 0.6 cents or 12.5 percent to 5.4 cents with 2.1 million shares traded. CSL climbed 6.4 percent; Airxpanders, Polynovo and Uscom were up more than three percent; Cochlear and Pro Medicus rose more than two percent; Actinogen and Resmed were up more than one percent; with Cynata, Medical Developments and Neuren up by less than one percent.

Genetic Signatures led the falls, down four cents or 6.9 percent to 54 cents with 52,900 shares traded. Ellex, LBT and Orthocell fell four percent or more; Clinuvel was down 3.55 percent; Avita, Benitec, Dimerix, Immutep, Oncosil and Universal Biosensors shed two percent or more; Prescient, Starpharma, Telix and Volpara were down more than one percent; with Mesoblast and Sirtex down by less than one percent.

CSL

CSL says that revenue for the year to June 30, 2018 was up 14.7 percent to $US7,587.9 million ($A10,507.8 million) with net profit after tax up 29.3 percent to $US1,728.9 million ($A2,394.2 million).

CSL said that sales were up in all regions, except Australia which fell 18.6 percent to $US691.5 million, while US sales revenue was up 21.7 percent to $US3,521.8 million.

In a media release CSL chief executive officer Paul Perreault said the launch of the cardiac drug Haegarda provided "a transformational therapy for patients with hereditary angioedema".

"Our global commercial rollout of Idelvion provides haemophilia B patients with a new standard of care," Mr Perreault said.

"Approval of our immunoglobulin product Privigen for the US, and Hizentra for the US and EU, provides patients with a convenient treatment for [chronic inflammatory demyelinating polyneuropathy], a debilitating peripheral nerve disorder," he said.

Mr Perreault said there was "tightness in supply of our key raw material, plasma" and the company opened 27 new US collection centres "a growth rate unmatched in the industry" taking the global total to 206 plasma collection centres.

He said that influenza subsidiary Seqirus "delivered on its commitment to achieve profitability just three years after the business was formed" with the Holly Springs, North Carolina influenza vaccines facility quadrupling the number of Flucelvax Quadrivalent doses produced this season for the US market compared to last year.

Mr Perreault said that CSL acquired Calimmune for its gene therapy platform, the transplant franchise was progressing and CSL112 for cardiovascular disease was in a phase III clinical trial.

The company said Privigen sales were up 13 percent, Hizentra sales rose 12 percent at "constant currency", with Idelvion "fast becoming the standard-of-care for haemophilia B".

CSL said its specialty products sales improved 24 percent at constant currency, driven by Kcentra and the launch of Haegarda, with Seqirus seasonal influenza vaccine sales up 53 percent and the influenza vaccine Fluad for people over 65 years sales up 142 percent.

CSL said it was ranked among the world's top 50 employers by Forbes Magazine, with 22,220 employees, a 15 percent increase over last year.

Mr Perreault said CSL expected "strong demand for CSL's plasma and recombinant products [with] continued margin expansion … forecast as the mix of plasma therapies shift towards higher value products and specialty and recombinant products grow [but] new entrants into the factor VIII market will continue to intensify competition".

Mr Perreault said the company planned to open 30 to 35 new collection centers and forecast "a modest increase in plasma costs, tempering overall margin growth".

He said he expected next year's net profit after tax to be $US1,880 million to $US1,950 million "at constant currency" a growth 10 percent to 14 percent.

CSL said that a final unfranked dividend of 93 US cents per share, up 29.2 percent compared to the previous year, would be paid on October 12, 2018, to shareholders at the record date of September 12, 2018, following the unfranked interim dividend of 79 US cents a share paid on April 13, 2018.

CSL said that its net tangible asset backing per share was up 8.2 percent from $US4.65 to $US5.03, with diluted earnings per share up 30.0 percent to $US3.809.

The company said that research and development spending increased 8.8 percent to $US702.4 million compared to the previous year, and was 9.3 percent of total revenue the same as the previous year, and it had $US814.7 million in cash and cash equivalents at June 30, 2018, compared to the previous corresponding period's $US844.5 million.

CSL climbed $12.89 or 6.4 percent to $214.58 with 1,460,922 shares traded.

REDHILL BIOPHARMA

Redhill says it has raised $US25 million ($A34.6 million) through an underwritten offer of 4,166,667 American depositary shares at $US6.00 a share.

Redhill said that the funds would be used with its existing cash and cash equivalents to fund clinical development programs, including preparations for a second phase III study of RHB-104 for Crohn's disease, begin a pivotal phase III study of RHB-204 for non-tuberculous mycobacteria (NTM) for commercial operations including Talicia, or RHB-105 for Helicobacter pylori, launch preparations, acquisitions and general corporate purposes.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, Redhill said that New York's Ladenburg Thalmann & Co was the sole book-running manager for the offer.

Redhill fell 0.7 US cents or 1.15 percent to $US6.00 with 367,276 shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it hopes to raise $11.86 million in a private placement and a share purchase plan.

Visioneering said it had commitments from sophisticated and professional investors to raise $8,856,000 through the issue of 49,200,000 Chess depositary interests (CDIs) at 18 cents a CDI.

The company said it would offer a share plan for existing holders at the record date of August 14, 2018 to subscribe for up to $15,000 in additional CDIs at 18 cents a CDI capped at $3.0 million.

Visioneering said the funds would be used for the continued development of sales and marketing in the US; the launch into geographies outside the US through local distribution agreements, build inventory to meet growing sales, new product development including toric and multifocal toric lenses and general working capital.

The company said Canaccord Genuity (Australia) was the lead manager to the placement.

Visioneering fell three cents or 14.3 percent to 18 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says 25 osteo-arthritis patients treated with injectable pentosan polysulfate sodium under a special access scheme had an average 60.5 percent reduction in pain.

Paradigm said that the result could be "attributed to a vast proportion of the patients undergoing a six-week treatment period replicating the same dosing regimen of the phase IIb osteo-arthritis clinical trial, suggesting a greater response compared to a three or four week treatment period.

The company said the 25-patients results improved the average pain reduction in the total 100 patients treated under the Australian Therapeutic Goods Administration special access scheme from 50.3 percent to 52.9 percent.

Paradigm said that of the 100 patients treated, 85 responded with both a reduction in joint pain and an improvement in knee function.

The company said that patients' self-reported pain scores were reduced by more than 52.9 percent and function was improved 67 percent on average, from baseline pain scores in 100 patients with knee osteo-arthritis and concurrent bone marrow lesions.

Paradigm was up six cents or 7.4 percent to 87.5 cents.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has approved its Sydney manufacturing facility to produce the asthma diagnostic product Aridol for the US.
Pharmaxis said the approval followed an onsite FDA inspection of the Pharmaxis manufacturing facility in Sydney where the company manufactured Aridol for Europe, Australia and South Korea as well as Bronchitol for Europe, Australia and Russia.
The company said it would relaunch Aridol in the US later in 2018 through exclusive distribution partner the Brantford, Ontario-based Methapharm which had experience in the sales channels and specialist centres that conducted respiratory testing.
Pharmaxis said that Aridol had sales, except the US, of $2 million a year the addition of the US "offers an opportunity to at least double that revenue".
The company said that Aridol was approved by the FDA to identify bronchial hyper-responsiveness, as part of a physician's assessment of asthma in patients six years of age and over, which was sold in the US until its withdrawal from the market in 2013 as part of "a corporate restructuring" (BD: Oct 6, 2010; Jun 3, 2013).
Pharmaxis said that US market research suggested there was "a strong need for objective tests to aid physicians in diagnosing asthma and that Aridol's mechanism of action and ease of use will be highly valued by respiratory specialists".
Pharmaxis chief executive officer Gary Phillips said that Aridol was "proven to be a valuable diagnostic aid in respiratory function laboratories in many global markets".
Pharmaxis was unchanged at 32 cents.

ACTINOGEN MEDICAL

Actinogen says its Xanadu, phase II trial of Xanamem for mild Alzheimer's disease is 75 percent enrolled with 131 of the planned 174 patients enrolled.
Actinogen said it added five US sites in July and had partnered with dementia application developer the Glasgow, Scotland-based Mindmate to identify potential patients.
The company said that Mindmate's health and lifestyle application was used by more than one million people with Alzheimer's disease, dementia, brain injury and other forms of cognitive decline.
Actinogen said it was "on-track to enrol the final patient by the end of this calendar year and expects to report the top-line trial data [by July] 2019".
Actinogen was up 0.1 cents or 1.8 percent to 5.7 cents.

CANN GROUP

Cann says it has supplied the first Australian patients with Aurora cannabis oil through the Australian Therapeutic Good Administration's special access scheme.
Cann said it had imported the first products Aurora 1:1 Drops comprising an equal ratio of tetrahydrocannabidiol and cannabidiol from its 22.9 percent owner and partner the Vancouver, British Columbia-based Aurora.
The company said that Cann would import additional supplies of cannabis oil from Aurora in several different formulations.
Cann said that patients would have access to the medicinal cannabis oils after approval for treatment through the TGA's special access scheme or authorized prescriber scheme.
Cann chief executive officer Peter Crock said the supply of product to patients in Australia was "an important milestone" in the company's plans to be a fully integrated medicinal cannabis company.
Cann fell 10 cents or 3.5 percent to $2.73.

RESAPP HEALTH

Resapp says IP [intellectual property] Australia has granted a patent covering the use of a cough sound-based audio processing pipeline for diagnosing respiratory disease.
Resapp said that patent titled 'Method and Apparatus for Processing Patient Sounds' protected "a key component" of its Resappdx smartphone application for diagnosing acute respiratory disease until March 28, 2033.
The company said that the patent was the second member of the patent family to be accepted, following the recently received allowance from the US Patent and Trademark Office, with patent applications covering similar subject matter pending in Europe, Japan, China and South Korea.
Resapp chief executive officer Dr Tony Keating the company was pleased to have "a strong patent position in both Australia and the United States, two of our target markets for commercialization".
"With patents from this family also pending in other major target markets, including Europe and China, we are creating a robust intellectual property position as we move closer to regulatory approval and market entry," Dr Keating said.
Resapp said it had filed or had exclusive licence to three other patent applications which are at either provisional or Patent Cooperation Treaty application stage.
Resapp was up half a cent or 2.9 percent to 18 cents with 2.8 million shares traded.

PRESCIENT THERAPEUTICS

Regal Funds Management has reduced its substantial holding in Prescient from 18,365,241 shares (8.78%) to 16,431,910 shares (7.76%).
The Sydney-based Regal Funds said that it bought and sold shares between May 17, 2017 and August 10, 2018.
Prescient fell 0.1 cents or 1.2 percent to 8.4 cents.

AVITA MEDICAL

Regal Funds Management says it has reduced its substantial holding in Avita from 61,869,979 shares (5.88%) to below substantial (BD: Mar 23, 2018).
Regal said it made several large purchases including 15,109,600 shares for $755,480 or five cents a share, with several large purchases sold on the same day and most sales fewer than one million shares, with the most recent large sale 1,045,123 shares for $94,166 or 9.00 cents a share/
Avita fell 0.2 cents or 2.3 percent to 8.5 cents.

MEMPHASYS

Robert Peters and Peters Investments say they have increased their substantial holding in Memphasys from 650,000,000 shares (12.723%) to 1,000,000,000 shares (18.32%).
Mr Peters said that he acquired the 350,000,000 shares on August 9, 2018 at 0.1 cents a share in the recent two-part placement which raised $1 million (BD: May 25, 2018).
Memphasys was unchanged at 0.1 cents with one million shares traded.