Biotech Daily

Wednesday August 28, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTHEA UP 17%; ACTINOGEN DOWN 11%**

*** COGSTATE REVENUE DOWN 25% TO $32m, LOSS UP 341% TO $3.7m**

*** CLINUVEL RECORD REVENUE UP 22% TO $31m, PROFIT UP 37% TO $18m**

*** CELLMID REVENUE UP 29% TO $7.4m, LOSS UP 58% TO $6m**

*** GENETIC SIGNATURES REVENUE UP 71% TO $5m, LOSS UP 7% TO $3.5m**

*** STARPHARMA REVENUE DOWN 45% TO $2.7m, LOSS UP 39% TO $14.3m**

*** BIOXYNE REVENUE UP 4% TO $2.3m, LOSS UP 4% TO $1m**

*** BLUECHIIP REVENUE UP 83% TO $1m, LOSS UP 31% TO $3.3m**

*** COGSTATE RAISES $2.9m FROM JAPAN DISTRIBUTOR EISAI**

*** GLOBAL BRANDS BUYS PROBIOTEC CELEBRITY SLIM FOR $7m**

*** STARPHARMA DEP-CABAZITAXEL, DEP-DOCETAXEL 'EARLY EFFICACY'**

*** NOVITA 'SHORTFALL, CE MARK APPLICATION' TRADING HALT**

*** FDA GUIDANCE FOR TELIX TLX591-CDX PROSTATE CANCER IMAGING**

*** US FDA UPGRADES IDT; AUSTRALIAN MARIJUANA LICENCE**

*** PBS REIMBURSEMENT FOR MAYNE PHARMA KAPANOL MORPHINE**

*** HERAMED HERABEAT, HERACARE HAPVIDA BRAZIL ROLL-OUT**

*** MEDIGARD CANCELS $615k SOL-MILLENNIUM NOTES; CONVERTS LOANS**

*** NOXOPHARM: 'NOX66 REDUCES TUMOR SIZE; PAIN, PSA LEVELS'**

*** REGAL FUNDS TAKES 13% IN OPTHEA**

MARKET REPORT

The Australian stock market was up 0.45 percent on Wednesday August 28, with the ASX200 up 29.4 points to 6,500.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and three were untraded.

Opthea was the best, up 47 cents or 17.4 percent to $3.17 with 1.3 million shares traded. Polynovo climbed 11.1 percent; Amplia was up 9.6 percent; Pro Medicus rose 8.95 percent; Paradigm improved 5.5 percent; Patrys, Prescient and Telix were up more than four percent; Clinuvel, Compumedics and Optiscan rose two percent or more; Cochlear, Impedimed, Mesoblast and Resmed were up more than one percent; with Ellex, Medical Developments and Neuren up by less than one percent.

Actinogen led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 2.2 million shares traded. LBT lost 9.1 percent; Universal Biosensors shed seven percent; Dimerix, Genetic Signatures, Resonance and Uscom fell more than four percent; both Osprey and Starpharma were down 3.5 percent; Pharmaxis and Volpara shed two percent or more; Avita, Cynata and Nanosonics were down more than one percent; with CSL down 0.45 percent.

COGSTATE

Cogstate says revenue for the year to June 30, 2019 was down 24.6 percent to $US21,834,374 ($A32,380,923) with net loss after tax up 341.0 percent to $US2,495,767 ($A3,701,285).
Cogstate said clinical trials sales contracts fell 24.0 percent to $US21,353,341, with healthcare contributing $US296,384 and research and development contracts contributing $US184,649.
The company said revenue was “impacted by the recent failures of Alzheimer’s disease clinical trials”.
Cogstate said net tangible asset backing per share was down 66.7 percent to six US cents, diluted loss per share was up 320.0 percent to 2.1 US cents and it had cash and cash equivalents of $US3,216,017 at June 30, 2019 compared to $US4,366,304 at June 30, 2018.
Cogstate was up 1.5 cents or 7.7 percent to 21 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the year to June 30, 2019 was up 21.8 percent to a record $31,047,776 with record net profit after tax up 37.1 percent to $18,134,160.
Clinuvel declared an unfranked dividend of 2.5 cents a share on the record date of September 5 and to be paid on September 19, 2019.
The company said revenue was from its third full year of sales of its Scenesse treatment for erythropoietic protoporphyria (EPP).
Clinuvel said commercial sales in Europe was up 24.0 percent to $26,489,000, with sales under special access schemes in Switzerland down 10.5 percent to $4,559,000.
The company said net tangible assets was up 41.2 percent to $1.158, diluted earnings per share was up 37.1 percent to 36.6 cents, and it had cash and cash equivalents of $54,268,758 at June 30, 2019 compared to $36,198,451 at June 30, 2018.
Clinuvel was up 51 cents or 1.96 percent to $26.47 with 140,221 shares traded.

CELLMID

Cellmid says total revenue for the year to June 30, 2019 was up 29.3 percent to $7,389,473, with net loss after tax up 58.3 percent to $5,909,557.
Cellmid said that sales of Advangen hair loss products were up 28.2 percent to $7,301,686, and midkine diagnostics licence fees and royalties increased 38.4 percent to $87,787.
Cellmid chief executive officer Ms Maria Halasz said the 2019 financial year was “a year of significant investment for Cellmid”.
“We have expanded our distribution channels in the US and around the world, built our [electronic] commerce and digital marketing infrastructure, and we have expanded our senior management capability for global growth.” Ms Halasz said.
“The benefit of these investments will flow through in 2019-’20 and beyond,” Ms Halasz said.
The company said that net tangible assets per share increased 50 percent to 0.09 cents, diluted loss per share was up 15.3 percent from 6.74 cents in the previous year to 7.77 cents for the year to June 30, 2019.
Cellmid said that it had cash and cash equivalents of $3,081,924 at June 30, 2019, compared to $1,607,783 at June 30, 2018.
Cellmid was up one cent or 4.35 percent to 24 cents.

GENETIC SIGNATURES

Genetic Signatures says revenue for the year to June 30, 2019 was up 71.3 percent to $4,865,908 with net loss after tax up 7.3 percent to $3,491,994.
Genetic Signatures said revenue was from sales of its test kits and consumables, including the Australian launch of its Easyscreen respiratory pathogen detect kit and GSS automation system (GS1-HT) and the first UK sales of its reagent kits.
The company said the net loss “reflects the investment in future growth”.
Genetic Signatures said its net tangible asset backing per share was down 21.2 percent to 10.16 cents, diluted loss per share was up 7.3 percent to 3.36 cents and it had cash and cash equivalents of $6,311,555 at June 30, 2019 compared to $8,954,775 at June 30, 2018.
Genetic Signatures fell five cents or 4.55 percent to $1.05.

STARPHARMA

Starpharma says revenue for the year to June 30, 2019 was down 44.6 percent to $2,708,000 with net loss after tax up 38.6 percent to $14,254,000.
Starpharma said it had revenue of $1,651,000 from licencing and royalties relating to Vivagel BV for bacterial vaginosis in Australia and Europe and the Vivagel condom in Japan, with interest of $1,057,000 and other income of $12,000.
The company said the fall in revenue was due to last year’s $2,955,000 licencing milestone payments for Vivagel BV (BD: Aug 21, 2019).
Starpharma said it spent $5,071,000 on research and development.
The company said net tangible asset backing per share was down 21.4 percent to 11 cents, diluted loss per share was up 33.3 percent to four cents, and it had cash and cash equivalents of $41,251,000 at June 30, 2019 compared to $51,319,000 at June 30, 2018.
Starpharma fell four cents or 3.5 percent to $1.10 with one million shares traded.

BIOXYNE

Bioxyne says revenue for the year to June 30, 2019 was up 3.5 percent to $2,339,524, with net loss after tax up 4.1 percent to $1,365,882.
Bioxyne said revenue was primarily from the sale of its probiotic Lactobacillus fermentum VRI-003, or PCC, with sales up 8.3 percent to $1,839,088.
Bioxyne said that diluted loss per share fell 4.5 percent from 22 cents in the previous year to 21 cents for the year to June 30, 2019.
The company said that net tangible asset backing per share was constant at 1.0 cent at June 30, 2019.
Bioxyne said it had cash and cash equivalents of $1,767,909 at June 30, 2019, compared to $3,309,904 at June 30, 2018.
Bioxyne was unchanged at two cents.

BLUECHIIP

Bluechiip says revenue for the year to June 30, 2019 was up 82.5 percent to a record $1,025,052 with net loss after tax up 30.7 percent to $3,257,996.
Bluechiip said revenue was from sales of its cryogenic marker chip, the micro electro mechanical system (MEMS), its reader and software.
The company said the revenue increase was partly due to “the three-year supply agreement worth more than $US11.6 million ($A15.9 million) with Labcon North America”.
Bluechiip chief executive officer Andrew McLellan told Biotech Daily that this year was the first time the company had exceeded $1 million in revenue.
Bluechiip said net loss was up due to an increase in external research and development to $1,486,820, an increase in business development expenses to $468,599, higher share-based payment expenses of $188,448 and higher employee benefits expenses of $1,754,842.
The company said net tangible asset backing per share was up 158.5 percent to 1.06 cents, diluted loss per share was up 3.1 percent to 0.66 cents and it had cash and cash equivalents of $3,849,113 at June 30, 2019 compared to $1,172,048 at June 30, 2018.
Bluechiip was up 0.75 cents or 5.45 percent to 14.5 cents with 2.4 million shares traded.

COGSTATE

Cogstate says it has raised $2.86 million in a placement to the Tokyo-based Eisai Co which has a 10-year agreement to distribute Cogstate technology in Japan.
Cogstate said it would raise $1.36 million at 20.308 cents a share in tranche one of the placement and $1.5 million in tranche two at the 5-day volume weighted average price to the issue date and subject to shareholder approval.
The company said the funds would be used to provide scientific, operational and technical support to launch its technology in Japan, to advance its technology and for general working capital, and it would consider a $3 million rights offer.
Cogstate said it had an exclusive, licence with Eisai to distribute and market its technology as a digital cognitive assessment tool for cognition in Japan.
The company said Eisai would pay a $US1 million upfront royalty payment and would fund necessary product development activities and a commercial team in Japan.
Cogstate said the agreement would exclude clinical trials and it would share profits with Eisai equally.

PROBIOTEC

Probiotec says the Melbourne-based Global Brands Australia will pay $6.75 million in cash for its Celebrity Slim brand weight loss products.
Probiotec said that Global Brands had paid a $1.5 million cash deposit with the balance to paid on completion, expected on September 30, 2019.
The company said it would continue to manufacture the Celebrity Slim brand on an exclusive basis.
Probiotec said it was advised by PwC and Arnold Bloch Leibler.
Probiotec was unchanged at $1.56.

STARPHARMA

Starpharma says efficacy signals have been observed in clinical trials of dendrimer enhanced product (DEP) cabazitaxel and docetaxel.
Starpharma said both DEP-cabazitaxel and DEP-docetaxel had been showing “promising interim results”, with several patients dosed with DEP-cabazitaxel showing efficacy signals in tumors including prostate, ovarian and pancreatic cancer.
In January 2018, Starpharma said it had approval for a 35-patient, open-label, phase I/II dose-escalation trial for DEP-cabazitaxel to evaluate the safety, tolerability and pharmacokinetics of DEP-cabazitaxel, to define a recommended phase II dose and to determine the anti-tumor efficacy of the product (BD: Jan 31, 2018).
In September 2017, Starpharma said its phase I trial of DEP-docetaxel showed “encouraging signs of efficacy” and it would proceed to a 52-patient phase II trial in lung and prostate cancer, starting with DEP-docetaxel as a monotherapy and in combination with Nintedanib (BD: Sep 22, 2017).
Today, Starpharma said patients treated with DEP-cabazitaxel or DEP-docetaxel showed a “notable” lack of bone marrow toxicity in addition to other signs of efficacy, with several patients with a variety of tumor types dosed with DEP-cabazitaxel showing a decrease in specific tumor biomarkers, such as prostate-specific antigens.
Starpharma chief executive officer Dr Jackie Fairley said the company was “very pleased with these early observation for DEP-cabazitaxel, particularly for those patients who have had long-standing stable disease and reduced bone marrow toxicity which often results in significant side-effects … with [cabazitaxel alone] therapy”.
“The fact that we are seeing efficacy in a variety of tumors such as prostate, pancreatic and ovarian is extremely promising,” Dr Fairley said.
“The growing body of clinical data from our DEP-docetaxel and DEP-cabazitaxel products demonstrates the compelling advantages for patients and for our commercial partners,” Dr Fairley said.
“The commercial utility of the DEP platform is also evidenced by our partnerships, including with Astrazeneca, and we look forward to them taking their first DEP candidate AZD0466 into the clinic later this year,” Dr Fairley said.

NOVITA HEALTHCARE

Novita Healthcare has requested a trading halt pending an announcement regarding a “book build for shortfall shares … [and] its CE Mark application”.
Yesterday, Novita said its five-for-11 rights issue at one cent a share raised $485,796 of a hoped-for $2 million and would seek to place the shortfall (BD: Aug 27, 2019).
Trading will resume on August 30, 2019 or on an earlier announcement.
Novita last traded at one cent.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has provided guidance for its new drug application for TLX591-CDx for prostate cancer.
Telix said the pre-new drug application meeting “provided clear manufacturing and clinical guidance” to have its 68-galium-prostate specific membrane antigen (PSMA) preparation kit TLX591-CDx, which was marketed as Ilumet, approved for prostate cancer in the US.
The company said the FDA agreed that its application would rely on the drug master file submitted in July 2018, and since referenced by multiple US and European investigational new drug applications.
Telix said the FDA clarified the product stability data it would need to support an application, consistent with its current data capture activity, and agreed with its proposed manufacturing validation plan.
The company said the FDA and Telix agreed that the new drug application (NDA) would be under the 505(b)(2) pathway in reference to previous approvals and would be partly based on supporting literature.
Telix said the FDA agreed that its rationale for the proposed dose was acceptable.
Telix US head Dr Bernard Lambert said the company appreciated “the clear guidance in relation to our NDA as we prepare our final package for submission”.
“Telix is currently preparing to file a [drug master file] amendment to include the company’s new US-based manufacturer of record, with the FDA’s requested stability and validation data,” Dr Lambert said. “This will be followed by the NDA submission itself.”
Telix was up 5.5 cents or 4.1 percent to $1.405 with 1.4 million shares traded.

IDT AUSTRALIA

IDT says the US Food and Drug Administration has upgraded it from ‘official action indicated’ to ‘voluntary action indicated’ and has won an Australian marijuana licence.
IDT said it received an FDA warning letter in May 2018 and received the FDA upgrade following an inspection from May 20 to 31, 2019 (BD: May 29, 2018).
The company that the FDA concluded the inspection was closed and the classification would be restored from official action indicated back to voluntary action indicated.
IDT said that prior to receiving the May 2018 FDA warning letter it maintained a voluntary action indicated inspection classification and the voluntary action classification meant that “the FDA’s assessment of any pending marketing applications referencing IDT’s facility will no longer be directly impacted”.
The company said the FDA confirmed that further correspondence, including details of the closeout for the warning letter, dated May 23, 2018, would be forthcoming.
IDT chief executive officer Dr David Sparling said the company would “continue working hard to meet the commitments we have made to the FDA and we will stand-by for what we hope to be a positive outcome on the status of the warning letter”.
Dr Sparling told Biotech Daily “there are some companies that have ‘no action indicated’ status but most companies operate as ‘voluntary action indicated’”.
Separately, IDT said the Federal Office of Drug Control had granted its first Medicinal Cannabis Manufacturing Permit under the Narcotic Drugs Act 1967.
The company said that the permit allowed it to manufacture and store cannabis extract in quantities specified by the permit.
IDT said it manufactured active pharmaceutical ingredients and finished dose forms and with the permit and its Schedule 8 and 9 Poisons Licence, it paved the way to ramp-up medical cannabis manufacturing.
IDT was unchanged at 14.5 cents with 2.3 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says the Australian Pharmaceutical Benefits Scheme has approved its Kapanol morphine drug for pallative care chronic breathlessness for reimbursement.
Mayne Pharma said that from September 1, 2019 eligible palliative care patients taking 10mg and 20mg Kapanol sustained release capsules for their advanced chronic breathlessness, would be reimbursed through the Pharmaceutical Benefits Scheme.
The company said the new indication on the PBS palliative care schedule, was in addition to Kapanol's use in chronic severe disabling pain unresponsive to non-opioid analgesics.
Mayne Pharma fell one cent or 2.2 percent to 45 cents with 6.8 million shares traded.

HERAMED

Heramed says its Herabeat foetal heart rate monitors and Heracare Pro software are fully operational across multiple Hapvida Saude hospitals in Brazil.
Last month, Heramed said it had integrated its Herabeat and accompanying internet cloud-based pregnancy monitoring software, Heracare Pro, into the Fortazela, Brazil-based Hapvida's electronic medical record system (BD: Jul 1, 2019).
Today, the company said its technology was being used by Hapvida medical professionals and patients for a scalability and potential pilot trial.
Heramed chief executive officer David Groberman said that "having multiple Herabeat monitors and Heracare subscriptions deployed and operational across Hapvida's network marks a significant achievement for Heramed".
Mr Groberman said the broader pilot trial with Hapvida would use Heracare Pro and Herabeat "to provide cost-effective and more accurate pregnancy monitoring".
Heramed was up two cents or 12.5 percent to 18 cents.

MEDIGARD

Medigard says it will extinguish Sol Millennium Medical's $615,000 convertible notes and will convert director loans of $496,000 into about 35 million shares.
Medigard said with Sol-Millennium it had agreed for the convertible note to be extinguished with the transfer of intellectual property to Sol-Millennium relating to the existing license agreement, the issue of 5,000,000 shares to Sol-Millennium and the cancellation of the prior licence agreement.
The company said the transactions would remove all debt and simplify the structure of Medigard and places it in a stronger position to work with the ASX to have trading reinstated.
Medigard was in an extended suspension and last traded at two cents.

NOXOPHARM

Noxopharm says interim three-month results of its 11-patient study of Veyonda or NOX66 with radiotherapy for prostate cancer has reduced tumor size and pain.
Noxopharm said it administered a single, 15-day course of 1,200mg of Veyonda daily, with low-dose radiotherapy, to assess tumor size, prostate specific antigen levels and pain.
The company said six of 11 men (55%) had reduced prostate specific antigen (PSA) levels and five of 11 men (45%) had reduced pain.
Noxopharm said two of eight suitable men for radiographic assessment reduced overall tumor size by at least 30 percent, with six men remaining progression free.
Noxopharm fell 6.5 cents or 14.3 percent to 39 cents.

OPTHEA

Regal Funds Management say it has increased its holding in Opthea from 28,838,514 shares (11.55%) to 32,051,888 shares (12.83%).

The Sydney-based Regal said that on August 23, 2019, it bought 3,213,374 shares for $8,676,110 or $2.70 per share on.

Opthea was up 47 cents or 17.4 percent to $3.17 with 1.3 million shares traded.