Biotech Daily

Thursday August 24, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MESOBLAST UP 18%; PHARMAXIS DOWN 11%**

*** TELIX H1 REVENUE UP 818% TO $220m; LOSS DOWN 86% TO $10m**

*** SDI REVENUE UP 13% TO RECORD $108m; PROFIT DOWN 3% TO $7m**

*** ALCIDION REVENUE UP 18% TO $40m; LOSS DOWN 18% TO $4m**

*** STARPHARMA REVENUE DOWN 14% TO $4m; LOSS DOWN 3% TO $16m**

*** ATOMO REVENUE DOWN 79% TO $2.5m; LOSS UP 74.5% TO $10m**

*** OPTHEA HOPES FOR $80m PLACEMENT, RIGHTS OFFER; TRADING HALT**

*** WELLCOME $5.4m FOR VAXXAS 'NEEDLE FREE' TYPHOID VACCINE**

*** ORTHOCELL: EUROPE RE-CERTIFIES STRIATE+**

*** PAINCHEK US NURSING HOME STUDY**

*** RADIOPHARM: TERTHERA TERBIUM-161 FOR PROSTATE CANCER**

*** INCANNEX PREPARES PSILOCYBIN FDA APPLICATION**

*** BCAL REQUESTS 'PLACEMENT' TRADING HALT**

*** AMPLIA AGM 16% OPPOSE PLACEMENT FACILITY**

*** ILWELLA, QUENTIN FLANNERY TAKE 9.5% OF CURVEBEAM**

MARKET REPORT

The Australian stock market was up 0.47 percent on Thursday August 24, 2023, with the ASX200 up 33.7 points to 7,182.1 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and two were untraded.

Mesoblast was the best on no news, up eight cents or 18.4 percent to 51.5 cents, with 19.5 million shares traded. Medical Developments climbed 14.8 percent; Patrys was up 11.1 percent; Paradigm improved 8.2 percent; Atomo was up 6.7 percent; Micro-X and Nova Eye were up more than four percent; Telix was up 3.6 percent; Dimerix, Imugene, Neuren, Orthocell and Polynovo rose more than two percent; Antisense, Clinuvel, Emvision, Immutep, Nanosonics and Pro Medicus were up more than one percent; with Cochlear, CSL, Cyclopharm and SDI up by less than one percent.

Pharmaxis led the falls, down 0.5 cents or 11.1 percent to four cents, with 1.1 million shares traded. Resonance retreated 7.7 percent; Genetic Signatures fell 4.85 percent; Actinogen, Kazia and Starpharma were down more than three percent; 4D Medical shed 2.4 percent; with Avita, Prescient, Proteomics and Resmed down more than one percent.

TELIX PHARMACEUTICALS

Telix says it had record revenue for the six months to June 30, 2023, up 818.3 percent to $220,834,000 with net loss after tax down 85.8 percent to $10,018,000.
Telix said revenue was primarily from sales of its Illucix prostate cancer imaging agent in the US, which launched in April 2022.
Telix chief executive officer Dr Christian Behrenbruch said “Telix has delivered an excellent result across all key financial metrics”.
“The business has demonstrated its ability to commercialize successfully, delivering an impressive $218.3 million in total revenue from Illuccix sales [in the six months to June 30, 2023] with sustained growth in demand since launch,” Dr Behrenbruch said.
“Importantly, Telix has transitioned to positive earnings on an adjusted [earnings before interest, taxes, depreciation, amortization and restructuring or rent costs] basis, signalling the profitability of our commercial organization,” Dr Behrenbruch said.
“We have a positive outlook for continued growth in commercial sales of Illuccix, based on an expanding global [prostate specific membrane antigen- positron emission tomography] imaging market, and expect to see Telix launch two new products in 2024 for brain and kidney cancer imaging, subject to regulatory approval,” Dr Behrenbruch said.
Telix said that its diluted loss per share was down 80.45 percent from 23.07 cents to 4.51 cents.
The company said that net tangible asset backing per share was down 78.4 percent from 3.33 cents to 0.72 cents.
Telix said it had cash and cash equivalents of $131,729,000 at June 30, 2023, compared to $122,608,000 at June 30, 2022.
Telix was up 35 cents or 3.6 percent to $10.14 with 2.7 million shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the year to June 30, 2023 was up 13.35 percent to $107,855,000, with net profit after tax down 3.1 percent to $7,056,000.
SDI said revenue was from sales of its dental equipment and dental aesthetics, amalgam and whitening products.
SDI chief executive officer Samantha Cheetham said the company was “very pleased with the continued revenue growth momentum over the last 12 months, resulting in record sales of $107.9 million driven by further market share gains”.
“Operating expenses are back to normalized levels with trade shows and travelling back in the calendar, following the Covid pandemic, and we have seen logistics costs slowly trending towards pre-pandemic levels,” Ms Cheetham said.
“Whilst there has been some additional costs and some inefficiencies in the short term as we support our customers, we remain confident that our strategy of meeting customer needs will continue to deliver longer term profitability for our group,” Ms Cheetham said.
The company said that sales in the Asia Pacific region were up 8.0 percent, Middle East and Africa sales rose 23.1 percent, North America was up 15.9 percent, South America was up 14.8 percent and Europe increased 11.1 percent.
The company said the final fully-franked dividend was flat at 1.75 cents for a record date of September 8, to paid on September 22, 2023.
SDI said that diluted earnings per share was down 3.1 percent to 5.94 cents, with net tangible asset backing per share up 3.6 percent to 50.98 cents.
The company said that it had cash and cash equivalents of $6,022,000 at June 30, 2023, compared to $7,013,000 at June 30, 2022.
SDI was up half a cent or 0.6 percent to 85 cents.

ALCIDION GROUP

Alcidion says that revenue for the year to June 30, 2023 was up 17.6 percent to $40,400,000 with net loss after tax down 18.0 percent to $3,617,000.
Alcidion said revenue came from sales of its hospital management and patient care software in the UK, New Zealand, and Australia.
Alcidion chief executive officer Kate Quirke said “the past twelve months have been significant in validating our product positioning and sales strategy across all our markets”.
“Alcidion is pleased with the progress we have made this year and remain well positioned to support the challenges facing the healthcare system as our solutions are increasingly recognized for the innovative and scalable options they offer,” Ms Quirke said.
The company said that diluted loss per share was down 23.7 percent from 0.38 cents to 0.29 cents.
Alcidion said that its net tangible assets per share up 55.3 percent from negative 0.38 cents to negative 0.59 cents.
The company said it had cash and cash equivalents of $14,641,000 at June 30, 2023, compared to $17,339,000 at June 30, 2022.
Alcidion was unchanged at 12 cents with 2.7 million shares traded.

STARPHARMA HOLDINGS

Starpharma says revenue for the year to June 30, 2023 was down 14.1 percent to $4,208,000 with net loss after tax down 3.2 percent to $15,638,000.
Starpharma said that revenue included $2,938,000 from its Viraleze nasal spray and Vivagel sales including Vivagel BV for bacterial vaginosis and condom coatings, royalty and research revenue from commercial partners, with interest on investments of $1,269,000.
The company said diluted loss per share was constant at four cents, with net tangible asset backing per share down 33.3 percent to eight cents.
Starpharma said it had cash and cash equivalents of $35,180,000 at June 30, 2023 compared to $49,918,000 at June 30, 2022.
Starpharma fell half a cent or 3.45 percent to 14 cents with 2.2 million shares traded.

ATOMO DIAGNOSTICS

Atomo says revenue for the year to June 30, 2023 fell 79.4 percent to $2,543,716 with net loss after tax up 74.5 percent to $9,957,632.
Last year, Atomo said its $12,336,111 revenue was driven by “a substantial increase in sales of Covid-19 rapid tests which accounted for $10.4m in revenue, with more than one million tests sold in Australia” (BD: Aug 26, 2023).
Today, the company said it had $1.56 million in HIV test sakes, $390,000 from Covid-19 tests and $591,000 for other “original equipment manufacturer” sales.
“Revenue was significantly lower … as the Covid-19 pandemic passed and with it, demand ceased for Covid-19 rapid antigen and rapid antibody tests,” Atomo said.
The company said that it had taken measures to reduce operating costs and had obtained the rights from the Guipry, France-based NG Biotech to launch a rapid blood-based pregnancy test on the its Pascal platform, pending approvals.
The company said that diluted loss per share was up 73.9 percent to 1.744 cents, net tangible asset backing per share fell 45.7 percent to 2.02 cents and it had cash and equivalents of $6,470,318 at June 30, 2023 compared to $12,966,400 at June 30, 2022.
Atomo was up 0.2 cents or 6.7 percent to 3.2 cents with 10.3 million shares traded.

OPTHEA

Opthea says it hopes to raise $80 million through a $10.0 million private placement and a $70.0 million, one-for-3.07 entitlement offer, both at 46 cents a share.
Opthea said the offer price was a 23.2 percent discount to the five-day volume weighted average price.
The company said that investors would receive one option for every two shares bought, exercisable at 80 cents each by August 31, 2025.
Opthea said that the institutional component of the non-renounceable entitlement would begin today and the retail component had a record date of August 28, would open on August 31, and close September 14, 2023.
The company said the funds would be used for the clinical development of OPT-302 for wet age-related macular degeneration, including phase III clinical trials and for general corporate purposes.
Opthea said the placement would not be underwritten.
The company said that MST Financial Services Pty Ltd was the sole lead manager to the offer and sole underwriter to the entitlement offer.
Opthea requested a trading halt for the capital raising and last traded at 60 cents.

VAXXAS

Vaxxas says that London's Wellcome has granted $5.4 million for initial studies and a phase I trial for a potential 'needle-free' second generation typhoid vaccine.
Vaxxas said the funds from the charitable foundation Wellcome, previously known as the Wellcome Trust, were to trial the delivery of the typhoid vaccine using its high-density microarray patch (HD-MAP) platform technology.
The company said that the project was expected to be completed within two years.
Vaxxas said that the typhoid vaccine formulation used to coat the HD-MAP would be based on an approved typhoid conjugate vaccine that was jointly developed by its collaborator, the Pangyo, South Korea-based SK Bioscience, and the Seoul-based International Vaccine Institute, a United Nations Development Programme initiative.
The company said that the typhoid vaccine candidate used in these studies would be formulated to be stable at higher temperatures than required for needle and syringe vaccination.
Vaxxas said that improved thermostability of vaccine products was "a key potential benefit offered by [its] HD-MAP platform and has the potential to reduce the cost and complexity of cold-chain distribution and storage, which are both significant barriers to vaccine accessibility in lower- and middle-income countries".
The company said that HD-MAP had "the potential benefit of requiring less training to administer and even self-administration … [and] success in this endeavor has the potential to increase global access to the typhoid vaccine".
Vaxxas said that typhoid fever was a life-threatening systemic infection caused by the bacterium Salmonella enterica serovar Typhi, usually spread through contaminated food or water, with about nine million people infected by the disease each year and about 110,000 people dying each year, mostly in lower income countries, "and disproportionately children, where water quality and hygiene are compromised".
Wellcome senior research manager Pierre Balard said that "to help protect more people at risk from deadly diseases like typhoid fever, new vaccine innovations are needed to improve access and ensure equitable coverage".
"Vaxxas' HD-MAP is an important step in this direction," Mr Balard said.
Vaxxas is a private company.

ORTHOCELL

Orthocell says the European Medical Device Regulations has re-certified its Striate+ dental membrane for bone and tissue regeneration.

Orthocell said the European Union originally approved Striate+ in 2017, as Celgro, but the company was required to apply for re-certification for it to be sold in the 30 European Economic Area member countries.

Orthocell chief executive officer Paul Anderson said “re-certification to the [Medical Device Regulations] is a significant milestone for the company as it confirms Striate+, manufactured by the company in Western Australia, complies with the more stringent safety and efficacy standards now in place in the EU”.

“Additionally, it enables Biohorizons, our marketing and distribution partner, to continue to execute their plans to enter the EU market without restriction,” Mr Anderson said.

“We look forward to working with Biohorizons to launch Striate+ in the EU and expand into multiple EU countries,” Mr Anderson said.

Orthocell was up one cent or 2.6 percent to 39 cents.

PAINCHEK

Painchek says it will begin a 100-patient study of its Paincheck Adult software at US nursing homes for a US Food and Drug Administration de-novo application.

Painchek said the study was scheduled to begin in September 2023, and it expected to submit its de-novo regulatory clearance application to the FDA by January 2024, with regulatory clearance and US market entry possible by July 2024.

The company said the study would be conducted with Oaknoll Christian Retirement Services and include recruitment at sites in Iowa, Illinois and Missouri, with the clinical research organization Donawa Lifesciences to oversee the project, conduct data evaluation and write the clinical report to the FDA.

Painchek said the study would be held at between five and 12 nursing homes and recruit residents with moderate to severe dementia unable to self-report their pain.

The company said that two assessors would test residents pain comparing Painchek to the Abbey pain scale, with performance evaluated on the agreement of 600 matched paired pain assessments obtained using the two tests.

Painchek chief executive officer Philip Daffas said the trial was “a relatively short clinical study, but sufficient in size, 100 participants, to generate high quality evidence, and it is the last step in completing the FDA requirements”.

“We are confident that this will result in Painchek receiving FDA clearance as the protocol has been reviewed by the FDA multiple times over a one-year period and the clinical study process is consistent with our previous peer reviewed published Australia-based clinical studies that led to TGA and CE mark clearance,” Mr Daffas said.

“This next stage is important to the company as the US is the largest aged care market in the world and FDA regulatory clearance would provide Painchek with access to a market than is three times the size of our existing regulatory cleared markets in Australia, New Zealand, UK and Canada combined,” Mr Daffas said.

“In parallel to the FDA de novo process, we continue to work with our existing US-based partners ensuring there is a pre-planned pathway for rapid entry into the US market upon receipt of FDA regulatory clearance,” Mr Daffas said.

Painchek was up 0.1 cents or 3.45 percent to three cents.

RADIOPHARM THERANOSTICS

Radiopharm says the Breda, Netherlands-based Terthera BV will supply it terbium-161 isotopes for the development and trial of a prostate cancer treatment.

Radiopharm said the terbium-161 isotope (Tb-161) would be linked to a proprietary monoclonal antibody to form RAD-402 and target KLK3 expression, which was highly expressed in prostate cancer cells.

The company said Tb-161 was a "highly promising isotope for targeted cancer treatment due to its unique characteristics of radiation emitted" and it had shown "excellent bioequivalence … presenting a biodistribution comparable to currently used radio-lanthanides".

Radiopharm said it would begin a phase I, dose-escalating trial to evaluate the safety and efficacy of RAD-402 in patients with advanced prostate cancer by the end of 2024.

The company said did not disclose the commercial terms of the deal but said "the costs associated with the purchase of Tb-161 are not material in relation to [Radiopharm's] annual budgeted expenditure and will be met from existing funds".

Radiopharm said the initial order was expected by December 31, 2023 and the contract would last for three years from August 28, 2023 with a possible extension of two years and no material preconditions.

Radiopharm managing-director Riccardo Canevari said the company had "decided to leverage a different mechanism of action by targeting KLK3, and the combination with Tb-161 is unique and highly promising".

"Tb-161 has shown superior preclinical results in comparison with Lu-177, which may translate into higher absorbed doses in micro-metastatic disease, with less kidney toxicity," Mr Canevari said.

"This novel radio-pharmaceutical has the potential to become the first KLK-based [diagnostic and therapeutic] option for individuals with advanced prostate cancer,' Mr Canevari said.

Radiopharm was up 0.2 cents or 2.3 percent to nine cents.

INCANNEX HEALTHCARE

Incannex says subsidiary Psychennex Pty Ltd has begun its investigational new drug application to the US Food and Drug Administration for its psilocybin therapy.

Incannex said it had begun drafting an application in preparation for the receipt of final clinical trial results for its psilocybin-assisted psychotherapy development program, expected between October 2023 and April 2024.

In March, the company said that a data safety monitoring board review of 37 patients in its phase II trial of psilocybin for generalized anxiety disorder recommended no changes (BD: Mar 15, 2023).

Today, Incannex chief executive officer Joel Latham said that beginning the investigational new drug application preparation "demonstrates our confidence in the utility of the … therapy".

"The interim analysis and the progress made by Dr [Paul] Liknaitsky and his team at Monash University has empowered us to fast-track various strategic business decisions to hasten the development of the therapy," Mr Latham said.

"Our organization is consistently fortifying its position as a frontrunner within the psychedelic research sector, and we eagerly anticipate the results from our phase II trial upon its completion," Mr Latham said.

Incannex was unchanged at 9.4 cents with 2.3 million shares traded.

BCAL DIAGNOSTICS

Bcal has requested a trading halt pending an announcement “concerning a share placement”.
Trading will resume on August 28, 2023 or on an earlier announcement.
Bcal last traded at 11.5 cents.

AMPLIA THERAPEUTICS

Amplia says its annual general meeting voted up-to 16.11 percent in opposition to the approval of its 10 percent placement facility.
Amplia said that 13,964,568 votes (16.11%) opposed the placement facility, with 72,701,491 votes (83.89%) in favor.
The company said that all the other resolutions, including its remuneration report, the re-election of chair Dr Warwick Tong as a director and the issue of 2,500,000 options to managing-director Dr Chris Burns, were passed with more than 99 percent support (BD: Jul 24, 2023).
According to its most recent filing, Amplia had 194,005,784 shares on offer, meaning the 13,964,568 votes against the placement facility amounted to 7.2 percent of the total shares on offer, sufficient to requisition extraordinary general meetings.
Amplia was untraded at eight cents.

CURVEBEAM AI

Sydney’s Ilwella Pty Ltd and director Quentin Flannery say they have become substantial in Curvebeam with 30,370,856 shares or 9.49 percent.
Ilwella said that on August 15 it acquired 4,166,667 shares for $2,000,000 or 48 cents a share.
Yesterday, Curvebeam listed on the ASX following its $25 million initial public offer at 48 cents a share to commercialize its imaging systems (BD: Aug 23, 2023).
Curvebeam was up 5.5 cents or 16.2 percent to 39.5 cents with 1.8 million shares traded.