



Biotech Daily

Wednesday August 23, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PHARMAXIS UP 15%; NANOSONICS DOWN 9%**
- * **EDITORIAL: H1, FY REPORTS \$4m MINIMUM; RDTI IS NOT REVENUE**
- * **CURVEBEAM DOWN 31% ON \$25m IMAGING SYSTEMS IPO**
- * **VITURA REVENUE UP 75% TO \$117m, PROFIT UP 128% TO \$13.8m**
- * **POLYNOVO REVENUE UP 60% TO \$66m; LOSS UP 313% TO \$5m**
- * **CURVEBEAM REVENUE \$8m; LOSS UP 509% TO \$52m**
- * **BTC SUBSIDIARIES SALES \$9.5m, LOSS TO \$10m**
- * **ARGENICA: FDA OKAYS ARG-007 STROKE TRIAL PROTOCOL**
- * **CORRECTIONS: CANN GROUP, CLEO DIAGNOSTICS**
- * **EPSILON PAYS \$4m LOAN, BORROWS \$2.85m**
- * **AVECHO REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **INVEX US PRESENDIN PATENT**
- * **ALTERITY EUROPEAN PATENT FOR IRON CHAPERONE DRUGS**
- * **AILEEN STOCKBURGER NEXT SCIENCE CHAIR, GRANT HUMMEL DIRECTOR**
- * **ANDREW COOK REPLACES ANTEO CFO, CO SEC TOM MILICEVIC**

MARKET REPORT

The Australian stock market was up 0.38 percent on Wednesday August 23, 2023, with the ASX200 up 26.8 points to 7,148.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Pharmaxis was the best, up 0.6 cents or 15.4 percent to 4.5 cents, with 1.4 million shares traded. Mesoblast climbed 10.1 percent; Next Science was up 6.9 percent; Actinogen, Emvision and Micro-X improved four percent or more; Avita rose 2.75 percent; Genetic Signatures was up one percent; with 4D Medical, Clinuvel, Cyclopharm, Opthea and Proteomics up by less than one percent.

Nanosonics led the falls, down 40 cents or 8.9 percent to \$4.10, with 1.8 million shares traded. Resonance lost 8.45 percent; Impedimed, Paradigm and Prescient fell more than seven percent; Nova Eye was down 6.25 percent; Polynovo fell 5.1 percent; Immutep and Kazia were down more than three percent; Orthocell shed 2.6 percent; Antisense, Dimerix, Medical Developments and Resmed were down more than one percent; with Cochlear, CSL, Neuren, Pro Medicus and Telix down by less than one percent.

BIOTECH DAILY FINANCIAL REPORTS POLICY

It is a mark of the sector's success that Biotech Daily has had to set a bar for reporting half-yearly and full year reports.

Initially, Biotech Daily reported the handful of companies with revenue and the smaller group with profits. In 2006, dividends were the province of the three Big Caps: Cochlear, CSL and Resmed.

With many companies reporting revenue from sales of more than \$1 million in revenue, last year we moved the benchmark to \$4 million.

Some companies need to be reminded that the Federal Research and Development Tax Incentive is NOT revenue. It doesn't matter what an accountant or auditor claims, it is deceitful to claim \$5 million in revenue when there is no product on the market.

Government grants and the Tax Incentive are not income – unless what one is trying to say is that “the business of business is business” and your company is only here for the RDTI and not to produce drugs, diagnostics or devices for human health.

Claiming the RDTI as revenue is deliberately misleading the industry and investors.

David Langsam
Editor

CURVEBEAM AI (ARTIFICIAL INTELLIGENCE)

Curvebeam AI opened down 31.25 percent at 33 cents following its \$25 million initial public offer at 48 cents a share to list on the ASX to commercialize its imaging systems. The Melbourne-based Curvebeam AI (artificial intelligence) said it listed under the code CVB and with the offer fully underwritten by Bell Potter Securities, and an indicative market capitalization of \$153.7 million.

Earlier this month, the company said that it “develops and manufactures natural bilateral weight bearing [computed tomography] devices, providing point-of-care medical imaging” intended to develop software as a service (BD: Aug 1, 2023).

Curvebeam said at that time that it had a co-marketing and distribution partnership with Stryker Corp, and its Hirise computed tomography (CT) imaging equipment was US Food and Drug Administration cleared, Australian Therapeutic Goods Administration approved and had Conformité Européenne (CE) mark.

The company said its bone density module for was targeted for submission by July 2024. Curvebeam managing-director Greg Brown told Biotech Daily that manufacturing was based in Hatfield Pennsylvania, with the corporate office in Melbourne, and most of the artificial intelligence for the imaging systems had been developed at the University of Melbourne.

“While disappointed on the first day of trading, I feel it does not reflect our growth investment opportunity,” Mr Brown said.

“We remain very confident in our future and I remain very confident in my own significant cash investment into the business,” Mr Brown said.

Curvebeam climbed as high as 37 cents before closing down 14 cents or 29.2 percent at 34 cents with 5.7 million shares traded.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Vitura says revenue for the year to June 30, 2023 was up 75.2 percent to \$117,343,633 with net profit after tax up 128.3 percent to \$13,809,389.

Vitura said it would pay a fully-franked one cent dividend, equal to the previous year, for shareholders on the record date of September 5, on September 28, 2023.

The company said \$115,298,613 of its revenue was from sales of its medical cannabis products, \$1,578,741 from its medical consultation fees and \$466,279 from the sale of non-medical or consumer products in Australia and Asia.

Vitura said that medical cannabis product sales were up 78 percent.

The company said administrative expenses increased 48 percent to \$3.7 million, information technology costs were up 226 percent to \$1.6 million and personnel expenses rose 20 percent to \$13.8 million, with finance costs down 49 percent to \$225,476.

Vitura said that the gross margin fell 2.5 percent to 33.7 percent for sales of its 260 medicinal cannabis and consumer products sold through its Canview online platform.

The company said it would focus on the expansion of its digital health platform business (Canview), increase revenue through the sale and distribution of medical marijuana products and other lines, including psychedelics, and integrate and expand its two medicinal cannabis clinic businesses, CDA Clinics and Cannadoc Health.

Vitura said diluted earnings per share rose 95.2 percent to 2.42 cents, net tangible asset backing per share was up 45.1 percent to 4.99 cents, with cash and cash equivalents of \$18,849,050 at June 30, 2023 compared to \$16,077,031 at June 30, 2022.

Vitura fell 4.5 cents or 10.3 percent to 39 cents with 1.6 million shares traded.

POLYNOVO

Polynovo says revenue for the year to June 30, 2023 was up 59.5 percent to \$66,111,094 with net loss after tax up 312.9 percent to \$4,924,539.

Polynovo said revenue from its Novosorb biodegradable wound treatment in the US was up 44.4 percent to \$51.8 million, Australia and New Zealand were up 48.7 percent to \$4.8 million and "other countries" increased 266.5 percent to \$8.7 million.

The company said that employee expenses rose 84.1 percent to \$39.4 million, corporate and administrative expenses were up 67.3 percent to \$17.4 million with research and development expenses up 29.2 percent to \$7.4 million.

Polynovo chair David Williams and chief executive officer Swami Raote said that sales growth and geographical market penetration reflected that Novosorb BTM and Novosorb MTX were "being accepted by surgeons as the next generation dermal substitute".

"Unprompted, more surgeons are writing about the product in journals and presenting their experiences at conferences," Mr Williams and Mr Raote said.

The company said it expected "strong revenue growth" particularly from the US, UK, Australia, New Zealand, India, and Hong Kong, with distributor markets of Germany and Canada to continue to perform well, and distributors appointed in Spain and France.

"Further applications for [US Food and Drug Administration] 510(k) clearances are expected in [2023-'24] allowing expansion of our Novosorb MTX and BTM product portfolio," the statement said.

The company said that revenue to the US Biomedical Advanced Research and Development Authority (BARDA) was down 12.9 percent to \$3,676,431.

The company said diluted loss per share was up 300 percent to 0.72 cents, with net tangible asset backing per share up 350 percent to nine cents, and it had cash and cash equivalents of \$46,846,946 at June 30, 2023 compared to \$6,102,192 at June 30, 2022.

Polynovo fell eight cents or 5.1 percent to \$1.475 with 4.4 million shares traded.

BTC HEALTH

BTC says its subsidiaries' sales for the year to June 30, 2023 was about the same at \$9.46 million, with net loss before tax up 1665.0 percent to \$10,167,862.

Last year, BTC said that it was an "investment entity and therefore does not consolidate the operating results of its investment ... [but] with a view to providing shareholders with a greater insight into the operating results of [its] underlying investments, a pro-forma consolidated, unaudited, financial view of BTC and its wholly owned subsidiaries is provided" (BD: Aug 17, 2023).

Today, the company said the audited results for the ASX-listed investment vehicle showed revenue for the 12 months to June 30, 2023 down 86.0 percent from \$95,004 last year to \$13,260 for the year to June 30, 2023.

In the shareholder update, BTC said that sales to hospitals from its distributor BTC Speciality Health totaled \$8.3 million up 1.2 percent for the year, while specialty pharmaceuticals including Pharmaxis' Bronchitol and Aridol decreased by about 8.7 percent to \$1.16 million.

The company said that its underlying business, BTC Speciality Health, had been devalued but that sales "continued to perform well", despite the loss of its Avanos supply contract in April, and that it had negotiated extended product supply terms through to the end of December 2023 and had sourced alternative infusion pumps.

BTC said it had also reduced overhead expenditure by \$1.1 million.

BTC said its net tangible assets per security was down 78.3 percent to 0.99 cents.

The company said that it had cash and equivalents of \$1,736,899 compared to \$2,170,473 the previous year.

BTC was untraded at 2.1 cents.

CURVEBEAM AI

Curvebeam says its revenue for the year to June 30, 2023 was \$8,055,193, with net loss after tax up 509.1 percent to \$52,048,595.

Curvebeam listed on the ASX today (see above).

Curvebeam managing-director Greg Brown told Biotech Daily that "pro forma revenue for [2022-'23] was \$11.45 million ... [up 55%] with only two or three reps in the US".

Mr Brown said the \$8 million sales were those recoded following the merger of Strax Corp and Curvebeam to become Curvebeam AI, which was completed in September 2022.

"Around 80 percent of sales are going to be coming from the US market, the rest is mainly through Europe," Mr Brown said.

He said the Stryker US foot and ankle division agreement gave access to 500 Stryker sales representatives and 40 regional specialists.

Earlier this month, Curvebeam said its computed tomography (CT) scanners would "support medical practitioners in the clinical assessment and management of musculo-skeletal health conditions" and combined with artificial intelligence would automate the analysis of images "assessing, for example, a patient's bone mineral density to assist in the clinical assessment of fracture risk" (BD: Aug 1, 2023).

Curvebeam said the flagship product was the Hirise CT scanner, which had the ability to perform weight bearing CT scans, with the patient standing in a normal, weight bearing pose, as well as more traditional non-weight bearing CT scans.

The company said the weight bearing CT scans were "quicker and easier" than traditional computed tomography or magnetic resonance imaging (MRI) devices.

Curvebeam said that 170 devices had been placed worldwide to date, including at US medical institutions such as Mayo Clinic and at the University of California, Los Angeles.

ARGENICA THERAPEUTICS

Argenica says the US Food and Drug Administration has said its protocols are “acceptable” for its proposed phase II trial of ARG-007 for acute ischaemic stroke. Argenica said the pre-investigational new drug application meeting was to obtain feedback and guidance from the FDA on the appropriateness of the chemistry, manufacturing and controls for ARG-007, as well as feedback and guidance on the completed pre-clinical studies and proposed phase II trial protocol.

The company said the FDA indicated the studies conducted to date were appropriate for the stage of development, and the proposed phase II clinical trial protocol was acceptable in regard to assessing the preliminary efficacy and safety of ARG-007 in acute ischaemic stroke patients.

Argenica managing director Dr Liz Dallimore said the feedback “received from the FDA is extremely encouraging and provides the company with great confidence as we progress ARG-007 into a phase II clinical trial in acute ischaemic stroke patients at the end of this calendar year”.

“The feedback provides the company with a confirmed path for clinical development of ARG-007,” Dr Dallimore said.

Argenica was up five cents or 13.2 percent to 43 cents.

CORRECTIONS: CANN GROUP, CLEO DIAGNOSTICS

Last night’s edition incorrectly reported that Cann Group had been suspended for failing to pay its annual listing fees.

Cann Group was not suspended by the ASX, it was the similarly named but completely different Cann Global that was suspended for not paying its annual listing fees.

Separately, the edition said that the Cleo US patent for CXCL10, announced on the day the company listed, would provide intellectual property protection until 2022, which of course should have been 2024.

We apologize unreservedly to both companies.

The Tuesday sub-editor has moved to a new vocation and shall henceforth be the reserve goal umpire at the Adelaide Oval.

Cann Group was up half a cent or four percent to 13 cents.

Cann Global was in a suspension and last traded at 2.1 cents.

Cleo fell one cent or 4.8 percent to 20 cents with 1.2 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has paid its \$4 million Mitchell Asset Management loan, with interest, and taken a further \$2.85 million loan with Australia Oracles Holding.

In 2021, Epsilon said it had extended its \$4 million loan with Mitchell Asset Management (BD: Oct 27, 2021).

Today, the company said the Australia Oracles loan would be due on November 19, 2023 and be under substantially the same terms as the loan from Mitchell Asset Management.

Epsilon said the \$500,000 of the loan funds would be used as working capital, and to expand Epsilon Pharma and Epsilon Clinics and invest in the subsidiary entities.

Epsilon was up 0.3 cents or 14.3 percent to 2.4 cents.

AVECHO BIOTECHNOLOGY

Avecho has requested a trading halt pending an announcement “regarding a capital raising”.

Trading will resume on August 25, 2023, or on an earlier announcement.

Avecho last traded at 0.9 cents.

INVEX THERAPEUTICS

Invex says the US Patent and Trademark Office has granted a patent relating to its Presendin (sustained release exenatide) for neurological conditions.

Invex said that the patent, titled ‘Elevated Intracranial Pressure Treatment’ would provide intellectual property protection “until at least August 2035”.

On Monday, the company said that it had closed its phase III trial of Presendin for idiopathic intracranial hypertension (IIH) due to limited market opportunity and operating costs (BD: Aug 21, 2023).

Today, Invex said the patent covered “the use of exenatide in disorders associated with raised intracranial pressure (ICP), with additional new claims in brain injury and brain trauma”.

Invex executive director Dr Tom Duthy said the second US patent for Exenatide was “particularly important in providing additional intellectual property protection in traumatic brain injury”.

“When overlaid with our recently secured orphan drug designation in Europe for [traumatic brain injury] which provides 10 years’ market exclusivity for Invex, we have once again harnessed both patent and regulatory mechanisms via the orphan drug designation route to enhance the value of our core drug product,” Dr Duthy said.

Invex fell half a cent or 2.9 percent to 17 cents.

ALTERITY THERAPEUTICS

Alterity says the European Patent Office has granted a composition of matter patent for a new class of iron chaperone drug candidates for major neuro-degenerative diseases.

Alterity said that the patent, titled ‘Compounds for and Methods of Treating Diseases’ covered “more than 150 novel pharmaceutical compositions ... designed to redistribute the excess iron implicated in neuro-degenerative diseases”.

The company said the patent would confer 20 years of exclusivity over the compounds, but did not include the filing date.

The European Patent Office website said that the patent had a priority date of March 15, 2019, implying intellectual property coverage until 2039.

Alterity said that iron in the brain was implicated in the pathology of many neuro-degenerative diseases, including Alzheimer’s and Parkinson’s diseases.

Alterity chief executive officer Dr David Stamler said the patent was “an important component of our strategy to become a leader in the development of drugs that target critical neuro-degenerative diseases”.

“Through restoration of normal iron balance in the brain, we have the potential to slow disease progression of diseases including Parkinson’s and Alzheimer’s,” Dr Stamler said.

Alterity was unchanged at 0.7 cents.

[NEXT SCIENCE](#)

Next Science says director Aileen Stockburger will replace retiring chair Mark Compton, and has appointed Grant Hummel as a director, effective from today.

Next Science said Mr Compton's retirement followed "two recent close family bereavements and his need to take some personal time".

The company said Ms Stockburger had been a Next Science non-executive director since 2018, and previously was for Johnson & Johnson's DePuy Synthes Group business development head, and was currently a director at Microbot Medical, Orchid Orthopaedic Solutions and Materna Medical.

Next Science said Ms Stockburger held a Bachelor of Science and Master of Business Administration from the University of Pennsylvania.

The company said Mr Hummel was part of the company's initial public offering and ASX listing deal team in 2019 and was a non-executive director of GLG Corp.

Next Science said Mr Hummel held a Bachelor Science and a Bachelor of Laws from the University of Tasmania.

Ms Stockburger said "the board has been saddened to learn of Mark's personal circumstances which have necessitated his retirement as chair".

"We were privileged to have Mark as our chair and colleague and he leaves the board with our sincere gratitude for his valued contribution and our thoughts during a difficult time,"

Ms Stockburger said.

Next Science was up four cents or 6.9 percent to 62 cents.

[ANTEOTECH](#)

Anteotech says it has appointed Andrew Cook as its chief financial officer and company secretary, replacing the Tom Milicevic, effective from August 28, 2023.

Anteotech said Mr Cook had more than 20 years' experience in financial roles, including as Entyr chief financial officer, Origin Energy division manager and SAB Miller Plc's finance development director for Latin America.

The company said Mr Cook held a Bachelor of Commerce, but did not name the granting institution.

Anteotech said that Mr Milicevic had been acting chief financial officer and company secretary and would remain available to facilitate an orderly transition.

Anteotech fell 0.2 cents or 6.7 percent to 2.8 cents with 4.6 million shares traded.