



# Biotech Daily

Tuesday August 24, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: NANOSONICS UP 22%; DIMERIX DOWN 12%**
- \* **NANOSONICS REVENUE UP 3% TO \$103m, PROFIT DOWN 15% TO \$8.6m**
- \* **SOMNOMED REVENUE UP 9% TO \$63m, LOSS UP 147% to \$1.2m**
- \* **ALCIDION REVENUE UP 39% TO \$26m, LOSS DOWN 27% TO \$2m**
- \* **IMPEDIMED RECEIVES \$1.8m FEDERAL R&D TAX INCENTIVE**
- \* **ADALTA, CARINA WORK ON I-BODY, CAR-T-CELL FOR CANCER**
- \* **SUDA: 'STADA ZOLPIMIST LICENCE FOR INSOMNIA IN AUSTRALIA'**
- \* **INVION EGM FOR CHO DEAL, 138m THIAN CHEW OPTIONS**
- \* **IMUGENE PLEADS SCHULTZ TO ASX LISTING RULE 15.7 LEAK QUERY**
- \* **PERENNIAL TAKES 8% OF 4D MEDICAL**
- \* **HEALTH MANAGEMENT SELLS MEDADVISOR SHARES TO COTIVITI**
- \* **CHINA PATENT FOR HEXIMA PEZADEFTIDE (HXP124) FOR TOE FUNGUS**
- \* **ANTISENSE DR GIL PRICE JOINS US DUCHENNE ADVOCACY BOARD**
- \* **NEUROSCIENTIFIC: DR PETER HNIK, DR FRANK BONNER ADVISORS**

## MARKET REPORT

The Australian stock market was up 0.17 percent on Tuesday August 24, 2021, with the ASX200 up 13.1 points to 7,503.0 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 11 fell and six traded unchanged.

Nanosonics was the best, up \$1.29 or 21.9 percent to \$7.18, with 7.3 million shares traded. Actinogen climbed 17.95 percent; Osprey was up 9.1 percent; Opthea improved 7.3 percent; Antisense, Immutep and Patrys were up more than five percent; Avita, Impedimed, Orthocell and Resonance were up more than four percent; Alterity and Medical Developments climbed more than three percent; Mesoblast rose 2.1 percent; Cyclopharm, Cynata, Imugene, Kazia, Next Science, Proteomics and Volpara climbed one percent or more; with Clinuvel, CSL and Neuren up by less than one percent.

Yesterday's 11.5 percent best, Dimerix, led the falls, down four cents or 11.8 percent to 30 cents, with 5.5 million shares traded. Amplia lost 7.7 percent; Pharmaxis fell 4.55 percent; Oncosil, Pro Medicus and Resmed were down three percent or more; Cochlear, Optiscan, Polynovo, Starpharma and Telix shed two percent or more; Universal Biosensors was down 1.3 percent; with Paradigm down by 0.5 percent.

## NANOSONICS

Nanosonics says revenue for the year to June 30, 2021 was up 3.0 percent to \$103,079,000 with net profit after tax down 15.4 percent to \$8,578,000.

Nanosonics said sales of its Trophon ultrasound probe cleaning systems in North America were down one percent to \$89,200,000, up 38 percent to \$7,200,000 in Europe and the Middle East, and up 42 percent to \$6,700,000 in the Asia Pacific.

The company said research and development spending was up 10.5 percent to \$17,194,000, or 16.7 percent of revenue.

Nanosonics chief executive officer Michael Kavanagh said the year had two distinct periods with the first half “when the impact of Covid-19 was the greatest ... market restrictions impacted ultrasound procedure volumes, hospital access and consequently new installed base growth”.

“Then a significant recovery in the second half as market conditions improved with total revenue growing 39 percent over first half, including an 84 percent growth in capital revenue and a 27 percent growth in consumables and service revenue and importantly, a 20 percent growth in new installed base,” Mr Kavanagh said.

Nanosonics said net tangible asset backing per share was up 11.6 percent to 41.61 cents, with diluted earnings per share down 15.6 percent to 2.81 cents, and it had cash and cash equivalents of \$96,027,000 at June 30, 2021, compared to \$91,781,000 at June 30, 2020. Nanosonics was up \$1.29 or 21.9 percent to \$7.18 with 7.3 million shares traded.

## SOMNOMED

Somnomed says revenue for the year to June 30, 2021 was up 9.4 percent to \$62,706,352 with net loss after tax up 147.1 percent to \$1,193,008.

Somnomed said revenue was from sales of its Somnodent product range for obstructive sleep apnoea, including Europe up 20 percent to \$38.8 million, North America down nine percent to \$18.5 million, and the Asia Pacific up 17 percent to \$5.4 million.

The company said diluted loss per share was down 14.1 percent to 1.52 cents.

Somnomed said that net tangible asset backing per share was down 9.6 percent to 18.03 cents and it had cash and cash equivalents of \$21,109,841 at June 30, 2021 compared to \$30,174,240 at June 30, 2020.

Somnomed was untraded at \$2.39.

## ALCIDION GROUP

Alcidion says that revenue for the 12 months to June 30, 2020 was up 39.1 percent to \$25,882,000 with net loss after tax down 27.1 percent to \$2,244,000.

Alcidion said revenue came from sales of its hospital management and patient care software across the UK, New Zealand, and Australia.

Alcidion managing-director Kate Quirke said the company had seen “significant success in the past 12 months with the adoption of our intuitive clinical messaging platform Smartpage to improve and secure communication between clinical and services teams”.

Alcidion chair Rebecca Wilson said the company’s “most significant [agreement] was our milestone deal with South Tees Hospitals NHS Foundation Trust” to provide Miya Precision, Better Meds and Smartpage software.

The company said that diluted loss per share fell from 0.33 cents per share to 0.22 cents, with net tangible assets per share up 41.7 percent to 1.7 cents and it had cash and cash equivalents of \$25,027,000 at June 30, 2021, compared to \$15,948,000 at June 30, 2020. Alcidion was unchanged at 36.5 cents with 3.2 million shares traded.

## IMPEDIMED

Impedimed says it has received \$1.8 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Impedimed said the rebate related to expenditure for the year to June 30, 2021.

Impedimed was up half a cent or 4.2 percent to 12.5 cents with 5.1 million shares traded.

## ADALTA, CARINA BIOTECH PTY LTD

Adalta says it has a collaboration with Adelaide's Carina Biotech to develop i-body enabled chimeric antigen receptor (CAR) T-cells.

Adalta has previously said that i-bodies are proteins from the intermediate group of immunoglobulin or immunoglobulin-like domains.

Today, the company said that the combination of its i-bodies and CAR-T-cell therapy could treat "a far greater range of cancers than the small number of blood cancers that has been achieved today".

Adalta chief executive officer Dr Tim Oldham said that "by combining our i-bodies with Carina's ... CAR-T platform, we can make this important new therapeutic approach accessible to more patients and a greater range of cancers than is possible today".

"We are well past the starting line, having worked previously on the first two targets selected for our collaboration, and with Carina on one of these," Dr Oldham said.

Carina chief executive officer Dr Deborah Rathjen said that the collaboration "gives us the capability to generate bi-specific CAR molecules and then next-generation CAR-T cell products with enhanced cancer targeting and efficacy".

"The collaboration is off to a great start with Carina having already successfully inserted an Adalta i-body into a CAR-T cell with functional cancer killing capability," Dr Rathjen said.

Adalta said it would discover and optimize panels of i-bodies that bound to designated solid tumor antigen targets, from which Carina will generate bi-specific CAR-T cells and identify optimal CAR-T product candidates, with both companies jointly funding pre-clinical proof of concept studies in mouse tumor models.

The company said that the agreement covered up to five tumor antigen targets during the next two years and would continue until completion of research on the final target.

Adalta said that the first two targets had been selected, with research to begin within the next three months.

The company said its initial contribution would use its established laboratory resources and was not expected to have a material impact on the current cash runway.

Adalta said that the companies would jointly own the products developed through the collaboration, and on a product-by-product basis the companies might elect to continue to co-develop any product, out-licence any product to third parties, or either company might exercise an option to licence the other party's share of the collaboration assets.

Dr Oldham said that part of Adalta's strategy was "to enter collaborations with partners where we can further the use of our i-bodies to address disease targets previously thought undruggable".

"The i-body-directed CAR-T cells will be the second example of this, complementing our collaboration with GE Healthcare where i-bodies are being used to deliver a [positron emission tomography] imaging agent," Dr Oldham said.

"The Carina collaboration contributes multiple potential products to our pipeline expansion goals," Dr Oldham said.

Carina is a private company.

Adalta was up 1.2 cents or 14.5 percent to 9.5 cents with 1.6 million shares traded.

## SUDA PHARMACEUTICALS

Suda says it has licenced Zolpimist for insomnia in Australia to Stada Pharmaceuticals Australia Pty Ltd, part of the Frankfurt, Germany-based Stada Arzneimittel AG Group. Yesterday, Suda said that Mitsubishi Tanabe Pharma Korea indicated its intention not to proceed with the licence and supply agreement for Zolpimist, which followed Mitsubishi Tanabe Pharma Singapore intending “not to proceed” (BD: Jan 27, Aug 23, 2021).

Last year, the company said that the Australian Therapeutic Goods Administration had approved Zolpimist (BD: Jul 29, 2020).

Today, Suda said Stada would pay \$170,000 upfront plus a \$40,000 milestone payment, pending approval of the enhanced child-resistant lock, and a 10 percent royalty on sales, for a perpetual, exclusive licence for Zolpimist for Australia, with the option to distribute in New Zealand.

The company said it would manufacture and supply the product at agreed supply prices and Stada would be responsible for commercialization in Australia.

Suda said it would submit a further application to the TGA for a modification to the spray unit, incorporating a more economical, elegant, and user-friendly child resistant lock.

Suda executive director and head of business development David Phillips said the licence was expected “to lead to Suda’s first revenue stream from the commercialization of a product from our portfolio”.

The company said that Stada expected commercial sales to begin by October 2022.

Suda was up 0.1 cents or 2.1 percent to 4.8 cents with 4.2 million shares traded.

## INVION

Invion says shareholders will vote to issue executive chair Thian Chew 138,488,557 options and approve the June licence with the RMW Cho Group.

Invion said that the independent expert concluded that the issue of shares to Mr Chew under the resolution was “not fair but reasonable to non-associated shareholders”.

The company said it proposed to issue Mr Chew 138,488,557 options valued at \$1,310,102 and exercisable at 1.7 cents each by September 23, 2025, vesting in four tranches from the date of the grant and then on November 1, 2021, 2022 and 2023.

Invion said that in addition to his \$90,000 fee as chair, Mr Chew’s remuneration for his duties as chief executive officer amounted to \$309,000 with an annual short-term incentive of up to 50 percent of the remuneration.

Invion said that the issue of options, valued at \$54,740, to Mr Bennallack was in lieu of a cash payment for his directors’ fees, with the options having a deemed price based on the 14-day volume-weighted average price at the date of the meeting.

The company said the meeting would also vote to approve 321,428,571 placement shares to RMW Cho Health Technology and licence the rights to the NGPDT from the RMW Cho Group.

In June, Invion said it had co-development and exclusive distribution and licence agreements with RMW Cho Group to co-develop next generation photo dynamic therapy technology, including the existing Photosoft product, for the treatment of atherosclerosis and infectious diseases including viral, bacterial, fungal and parasitic (BD: Jun 2, 2021).

The company said at that time that that it would gain exclusive distribution rights to the technology in Asia Pacific for these indications, and it had a placement agreement with RMW Cho Health Technology to provide \$4.5 million for shares at 1.4 cents a share.

The meeting will be held at Level 4, 96-100 Albert Road, South Melbourne and by teleconference on September 23, 2021 at 12pm (AEST)

Invion was unchanged at 1.3 cents with 2.3 million shares traded.

## IMUGENE

Imugene has told the ASX is not aware how information about its \$90 million capital raise appeared in a news article.

The ASX said that Imugene requested a trading halt on July 27 “pending an announcement in relation to a capital raising” at 8.44am (AEST) and an article titled ‘Paul Hopper’s biotech Imugene hunts \$85m’ was published by the Australian Financial Review at 10:15am (AEST) on July 27, which contained details of the capital raising.

The ASX said Imugene announced the \$90 million placement and \$5 million share plan on July 29, 2021 and asked how the information in the announcement appeared in the article and what arrangements it had to ensure compliance with Listing Rule 15.7, prohibiting the provision of information to any party prior to the ASX.

In its reply, Imugene told the ASX that the detail of the article was “scarce on pricing and inaccurate on the amount raised”.

“The article appears to be speculative street talk” based on the trading halt, Imugene said. Imugene told the ASX that the company, or officers of the company, were not consulted and did not have contact with the journalist in relation to the article.

“The company through its lead manager arranged for wall-crossing presentations to sophisticated and professional investors after the company was placed in a trading halt and a deal term sheet may have been shared as part of the wall-crossing process,” Imugene said.

Biotech Daily understands that “wall-crossing” is the practice of providing certain investors confidential information after a trading halt.

Imugene told the ASX that it had a disclosure policy to assist ensuring compliance with Listing Rule 15.7, with reminders “distributed throughout the company at least quarterly to assist ensure [sic] the importance of controlling the distribution of insider information is known and understood”.

Last week, Dimerix told the ASX it had nothing to do with a leak of information to the Australian Financial Review about its \$20 million placement (BD: Aug 16, 19, 2021).

In response to a similar ASX query, Dimerix said that neither it, nor any of its officers, had contact with the Financial Review and it was not aware of how the information in the announcement was sourced and appeared in the article, which “was published without the knowledge of the company”.

Dimerix said that Canaccord Genuity (Australia) was the lead manager to the raising and began a process of “wall-crossing”, providing certain institutional and sophisticated investors confidential information after the trading halt “in line with industry standards”.

“It may be that the information which appeared in the article, was initially disclosed by such person with whom the deal term sheet was shared in the wall-crossing process,” Dimerix said.

In July, Imugene said its placement was led by Bell Potter Securities.

Imugene was up half a cent or 1.6 percent to 31.5 cents with 32.4 million shares traded.

## 4D MEDICAL

Perennial Value Management says they have increased their substantial holding in 4D Medical from 16,128,334 shares (5.35%) to 19,894,267 shares (6.76%).

The Sydney-based Perennial said that it bought and sold shares between March 31 and August 19, 2021 with the largest acquisition 776,430 shares for \$1,050,487 or \$1.353 a share.

4D was up eight cents or 5.6 percent to \$1.50.

## MEDADVISOR

Health Management Services says it has ceased its substantial holding in Medadvisor selling with 43,999,999 shares for \$US11,305,140 (\$A15,793,252) or 35.9 cents a share. The Irving, Texas-based Health Management Services said it conducted an off-market transfer of all shares held in Medadvisor to Cotiviti Services LLC.

Yesterday, the South Jordan, Utah-based Cotiviti said it had become substantial in Medadvisor with 43,999,999 shares or 11.66 percent (BD: Aug 23, 2021).

Medadvisor was unchanged at 35.5 cents.

## HEXIMA

Hexima says it has been granted a Chinese patent for pezadeftide, formerly known as HXP124, as a potential topical treatment for onychomycosis or toe fungus.

Hexima said that the patent, titled 'A Method of Treatment' provided protection covering the therapeutic use of pezadeftide, as well as topical formulations containing pezadeftide, for the treatment of onychomycosis, until at least 2035 in mainland China.

The company said that it had similar granted patents in the US, Japan, Europe, Singapore, Mexico and Australia, along with further patent filings in these and other jurisdictions.

Hexima chief executive officer Michael Aldridge said that "China's continued growth and development as an important pharmaceutical market underscores the potential value of this granted China patent".

Mr Aldridge said that joining the Access China Biotech Forum would help the company assess the level of interest in China for pezadeftide as a potential treatment for onychomycosis.

Hexima was up 1.5 cents or 5.8 percent to 27.5 cents.

## ANTISENSE THERAPEUTICS

Antisense says that medical-director Dr Gil Price has been appointed as an advisor to a US advocacy group for Duchenne muscular dystrophy.

Antisense said that the Florida-based Dr Price would join the pharmaceutical advisory board for the new Duchenne guidance for Parent Project Muscular Dystrophy.

The company said that pharmaceutical advisory board worked with the steering committee and working group chairs, representing the patient advocate, caregiver, clinician, researcher, academic, and pharmaceutical industry to ensure perspectives from companies with an interest Duchenne community were represented throughout the guidance.

Antisense said that Parent Project Muscular Dystrophy (PPMD) developed the first patient group-initiated draft guidance for companies developing treatments for Duchenne in June 2014.

The company said the work had become a landmark in the Duchenne community and across rare disease communities "exemplifying the value patients and caregivers can bring to drug development".

Antisense said that PPMD had begun modernizing the 2014 document to ensure it reflected advancements in knowledge, understanding, care, clinical trials and approvals over the recent years.

The company said that PPMD lobbied in Washington, DC and had secured hundreds of millions of dollars in funding.

Antisense was up one cent or 5.9 percent to 18 cents.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed ophthalmologist Dr Peter Hnik and toxicologist Dr Frank Bonner to its scientific advisory board.

Neuroscientific said that Dr Hnik held a Doctor of Medicine from Prague's Charles University and of Prague in 1981 and performed surgery and consultation in glaucoma and neuro-ophthalmology at the Eye Clinic of the Charles University Hospital.

The company said that Dr Hnik was part of the Vancouver's University of British Columbia glaucoma research group and held a Master of Health Sciences from the University of British Columbia.

Neuroscientific said that Dr Bonner had more than 35 years' experience in toxicology and non-clinical drug development, including as Sanofi SA's head of non-clinical safety.

Neuroscientific was up one cent or 3.3 percent to 31 cents.