Biotech Daily

Tuesday August 27, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: NANOSONICS UP 23%; CYNATA DOWN 7%**

*** WEHI HOPES '66TEN' WILL INVEST $66m OVER 10 YEARS**

*** RDTI IS NOT REVENUE - EDITORIAL**

*** NANOSONICS REVENUE UP 2% TO $170m, PROFIT DOWN 35% TO $13m**

*** SDI REVENUE UP 3% TO RECORD $111m; PROFIT UP 26% TO $10m**

*** NEUREN H1 REVENUE DOWN 50% TO $32m; PROFIT DOWN 76% TO $11.5m**

*** CYCLOPHARM H1 REVENUE DOWN 19% TO $13m, LOSS UP 159% TO $7.5m**

*** LUMOS REVENUE UP 6% TO $16m; LOSS DOWN 9% TO $13m**

*** VISIONEERING H1 REVENUE DOWN 1% TO $6.8m, LOSS UP 1% TO $2.7m**

*** MEDICAL DEVELOPMENTS RETAIL RIGHTS RAISE $3.1m; TOTAL $10m**

*** ACRUX: FDA APPROVES GENERIC ACZONE GEL FOR ACNE**

*** ISLAND OPENS US ARMY PHASE II ISLA-101 DENGUE FEVER TRIAL**

*** ARCHER TESTS BIOCHIP TO DETECT POTASSIUM FOR KIDNEY DISEASE**

*** CORRECTION: COCHLEAR**

*** RADIOPHARM CHAIR PAUL HOPPER DILUTED BELOW 5%**

*** GEOFF COCKERILL REPLACES VITURA CEO TOM HOWITT, ON $450k PA**

*** TELIX PROMOTES RICHARD VALEIX, KEVIN RICHARDSON, RAPHAEL ORTIZ**

MARKET REPORT

The Australian stock market fell 0.16 percent on Tuesday August 27, 2024, with the ASX200 down 13.3 points to 8,071.2 points. Seventeen of the Biotech Daily Top 40 companies were up, 17 fell, five traded unchanged and one was untraded.

Nanosonics was the best, up 61 cents or 22.6 percent to $3.31, with 4.4 million shares traded. Paradigm climbed 8.5 percent; Atomo, Medadvisor and Medical Developments improved more than four percent; Imugene was up 3.85 percent; 4D Medical, Clinuvel, Emvision, Genetic Signatures and Prescient rose more than two percent; Immutep, Neuren, Orthocell and Resmed were up more than one percent; with Avita, Opthea and Telix up by less than one percent.

Cynata led the falls, down 1.5 cents or 7.1 percent to 19.5 cents, with 246,609 shares traded. Actinogen, Micro-X and Universal Biosensors lost more than six percent; Nova Eye fell 4.3 percent; Aroa, Curvebeam and Cyclopharm shed more than two percent; Alcidion, Clarity, Dimerix, Mesoblast, Polynovo, Proteomics and Resonance were down more than one percent; with Cochlear, CSL, Pro Medicus and SDI down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it hopes to invest $66 million over 10 years in medical innovations through its '66ten' investment fund.
The Institute said that 66ten was "the largest internal pre-seed and seed fund created by an Australian medical research institute".
WEHI did not say how much had been invested since it began operations in July 2023, nor the amount currently held.
The Institute said that 66ten was managed by WEHI Ventures to bridge "the gap between scientific discoveries and commercial viability" to ensure positive outcomes for patients and healthcare systems as well as financial returns for investors.
WEHI said that 66ten had invested in diverse medical innovation projects including one focused on Prader-Willi syndrome, a rare disease with very high unmet medical need.
The Institute said that 66ten was managed by a commercialization team and scientists with commercial research and development experience.
WEHI business development head and WEHI Ventures chief executive officer Dr Anne-Laure Puaux said that the Institute had "an established record of outstanding scientific discoveries".
"66ten was established to transform groundbreaking discoveries into innovative commercial programs that can deliver outcomes for patients and financial returns to investors," Dr Puaux said.
"66ten is designed to deliver commercial success for WEHI and its stakeholders, with the aim of shortening the timeframe to patients benefitting from WEHI discoveries," Dr Puaux said. "Any financial returns generated via portfolio activities will support WEHI research, discoveries and technologies, to continue WEHI's fulfilment of its research mission and contribute to the institute's financial sustainability."
WEHI acting deputy director Prof Marnie Blewitt said that "66ten is not just financial support for WEHI scientists to realize their vision; it also offers the expertise, guidance, discipline and network to fast track discoveries, which eventually will result in the delivery of life-changing therapeutics and technologies for patients and healthcare systems".

RDTI IS NOT REVENUE - BIOTECH DAILY EDITORIAL

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, companies know it is deceitful to claim $5 million in revenue when there is no product on the market.

Government grants and the Federal Government Research and Development Tax Incentive are not income – unless what one is trying to say 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.

We are pleased that most companies have stopped claiming the RDTI as revenue, which deliberately misleads the industry and investors.

David Langsam
Editor

NANOSONICS

Nanosonics says revenue for the year to June 30, 2024 was up 2.4 percent to $170,012,000, with net profit after tax down 34.8 percent to $12,972,000.

Nanosonics said revenue was from sales of its Trophon ultrasound probe cleaning systems, with installations of its systems down 10 percent “due to a range of market conditions including hospital capital budget constraints”.

The company said revenue from Trophon installations and upgrades in North America were up 2.6 percent to $154.2 million, up 23.6 percent to $10.1 million in Europe and the Middle East, and down 22.6 percent to $5.8 million in the Asia Pacific.

Nanosonics chief executive officer Michael Kavanagh said the opportunity remained “significant given the growing pipeline and … emphasis on infection prevention”.

Mr Kavanagh said that despite challenges faced by hospitals “a significant turnaround in the second half was experienced, with a considerable upswing in unit sales”.

“This not only reversed the negative revenue growth in the first half but steered the company back to a trajectory of revenue growth for the full year, creating a solid platform for future growth and expansion,” Mr Kavanagh said.

The company said research and development spending on Trophon products and its Coris endoscope cleaning device was up 11.2 percent to $32,809,000, or 19.3 percent of revenue, compared to the previous corresponding period.

In May, Nanosonics said it had submitted a de novo application to the US Food and Drug Administration for the Coris device (BD: May 1, 2024).

The company said that diluted earnings per share fell 35.3 percent to 4.20 cents, net tangible asset backing per share was down 10.4 percent to 54.68 cents, with cash and equivalents of $129,552,000 at June 30, 2024, compared to $112,159,000 at June 30, 2023.

Nanosonics was up 61 cents or 22.6 percent to $3.31 with 4.4 million shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the year to June 30, 2024 was up 3.1 percent to a record $111,206,000, with net profit after tax up 26.4 percent to $10,099,000.

SDI said revenue was from sales of its dental equipment and dental aesthetics, amalgam and whitening products.

SDI chief executive officer Samantha Cheetham said that “continued sales growth along with improved product margins and well managed operating expenses have resulted in a record profit for the year”.

“Product margins have been driven by operational efficiencies plus favorable product mix with the growth in our higher margin aesthetic products,” Ms Cheetham said.

“Amalgam sales declined as expected, and we expect whitening sales to improve with our planned rebranding in the first half of 2025,” Ms Cheetham said.

The company said Asia Pacific sales climbed 7.1 percent, North America rose 3.5 percent, South America 7.7 percent and Europe increased 7.8 percent, with Middle East and Africa sales down 8.9 percent.

SDI said the final fully-franked dividend was up 8.6 percent to 1.9 cents, for shareholders on the record date of September 6, to paid on September 20, 2024.

The company said that diluted earnings per share was up 47.6 percent to 8.77 cents, net tangible asset backing per share was up 4.65 percent to 53.35 cents, with cash and equivalents of $6,275,000 at June 30, 2024, compared to $6,022,000 at June 30, 2023.

SDI fell half a cent or 0.5 percent to 92.5 cents.

NEUREN PHARMACEUTICALS

Neuren says revenue for the six months to June 30, 2024 was down 50.15 percent to $32,106,000, with net profit after tax down 75.9 percent to $11,529,000.
Neuren said revenue was from royalties on sales of its trofenitide for Rett syndrome, marketed by Acadia Pharmaceuticals as Daybue in the US (BD: Mar 13, Jun 7, 2023).
The company said royalty income increased to $24.3 million from $3.5 million in the prior corresponding period, offset by a one-off $59.4 million milestone payment from Acadia in the six months to June 30, 2023, “earned on the first commercial sale of Daybue”.
Neuren chief executive officer Jon Pilcher said the company expected “full-year revenue from Daybue of $132 million to $138 million and we now have highly encouraging results from phase II trials of NNZ-2591 across three syndromes”.
“With cash and short-term investments of $213 million, Neuren is in the ideal position to optimize the potential of NNZ-2591 in multiple indications,” Mr Pilcher said.
The company said research and development costs increased by $6.1 million, or 52.4 percent, to $17.9 million “due to higher expenditure for the half- year ended June, 30 2024 for the NNZ-2591 phase II clinical trials and the foundational work to prepare for phase III development of NNZ-2591 across multiple indications”.
Neuren said corporate and administrative costs were down 22.0 percent to $2.4 million and income tax expenses for the six months rose 111.1 percent to $3.8 million, compared to the previous corresponding period.
The company said that diluted earnings per share were down 83.3 percent to 6.13 cents, with net tangible assets per share up 135.35 percent to 168.44 cents.
Neuren said it had cash and cash equivalents of $2,571,000 at June 30, 2024, compared to $38,389,000 at June 30, 2023.
Neuren was up 16 cents or one percent to $15.75 with 382,744 shares traded.

CYCLOPHARM

Cyclopharm says revenue for the six months to June 30, 2024 was down 19.2 percent to $13,319,379, with net loss after tax up 159.4 percent to $7,509,594.
Cyclopharm said revenue was from sales of its Technegas lung imaging device for pulmonary embolism, third party products and servicing.
The company said revenue in Europe rose 10.2 percent to $8,138,260, Asia Pacific sales fell 58.7 percent to $2,464,058, Canada decreased 15.0 percent, sales in other territories rose 216.7 percent to $130,659 and it received first revenue from the US of $249,557.
Cyclopharm said the increased loss “was mainly due to … expanding US operations” with the previous period’s results “positively impacted by a third-party capital equipment and installation sale, a one-off legal recovery benefit and foreign exchange gains”.
Cyclopharm managing-director James McBrayer said the company confirmed “its guidance of 300 Technegas generators in place by December 2025 and generating revenues”.
“Cyclopharm is confident Technegas transitional pass-through status in the US, which allows for a full reimbursement for each procedure over the next three-year period, will allow for a rapid acceleration of sales in the US,” Mr McBrayer said.
The company said it would not pay an interim dividend following the 0.5 cents unfranked interim dividend it paid in the prior period.
Cyclopharm said that diluted loss per share was up 148.6 percent to 7.83 cents, with net tangible assets per security up 22.6 percent to 38 cents, and it had cash and cash equivalents of $27,562,359 at June 30, 2024 compared to $18,077,806 at June 30, 2023.
Cyclopharm fell 3.5 cents or 2.5 percent to $1.38.

LUMOS DIAGNOSTICS

Lumos says revenue for the year to June 30, 2024 was up 5.7 percent to $US11,131,000 ($A16,407,000) with net loss after tax down 9.0 percent to $US8,594,000 ($A12,668,000).
Lumos said revenue came primarily from its development and manufacturing services, down 2.9 percent to $US9.9 million, with sales of its Viradx influenza and Covid-19 test as well as Febridx viral and bacterial infections test up 289 percent to $US1.2 million.
The company said its costs were “well controlled, coming in at $US11,100,000, a reduction of $US800,000 and six percent from $US1,900,000 in the prior year”.
Lumos said diluted loss per share fell 51.6 percent to 1.85 US cents, with negative net tangible assets per share up 27.6 percent to negative 0.37 US cents, and it had cash and equivalents of $US6,479,000 at June 30, 2024 compared to $US3,015,000 the prior year.
Lumos was up 0.1 cents or 2.5 percent to 4.1 cents.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the six months to June 30, 2024 fell 0.7 percent to $US4,640,000 ($A6,845,000) with net loss after tax up 1.3 percent to $US1,819,000.
Visioneering said revenue was from sales of its Naturalvue multifocal contact lenses for myopia and presbyopia, with revenue down 7.5 percent in North America to $US4,030,000 and up 93.0 percent in Europe, Asia and the Pacific to $US610,000.
The company said sales and marketing costs fell 14.8 percent to $US1,696,000, with clinical and manufacturing costs up 4.4 percent to $US1,086,000 and general and administrative costs up 24.5 percent to $US1,710,000.
Visioneering said diluted loss per share fell 50.0 percent to 3.0 US cents, with net tangible asset backing per share down 46.15 percent to 7.0 US cents, and it had cash and cash equivalents of $1,825,000 at June 30, 2024 compared to $US3,267,000 at June 30, 2023.
Visioneering was up half a cent or five percent to 10.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has raised $3.1 million at 38.0 cents a share in its fully-underwritten, one-for-7.35, retail rights offer, taking the total raised to $10 million.
Last month, Medical Developments said that it had raised $6.9 million at 38.0 cents a share in an institutional placement and rights offer, with a $3.1 million retail rights offer to follow (BD: Jul 30, 2024).
Today, the company said $1.5 million of the retail entitlement offer was raised from eligible retail shareholders, with the shortfall to be taken up by Bell Potter Securities.
Medical Developments was up two cents or 4.4 percent to 47 cents.

ACRUX

Acrux says the US Food and Drug Administration has approved its generic version of topical Aczone gel, dapsone gel, 7.5 percent for acne vulgaris.
Last year, Acrux said it had US Food and Drug Administration approval to manufacture and market its generic version of Aczone gel, or dapsone, 5.0 percent as a topical treatment for acne vulgaris (BD: Jun 7, 2023).
Today, the company said dapsone gel was indicated for the topical treatment of acne vulgaris in patients nine years of age and older, and the approval was its fifth topical abbreviated new drug application to be approved by the FDA.
Acrux was up 0.6 cents or 10 percent to 6.6 cents with 6.1 million shares traded.

ISLAND PHARMACEUTICALS

Island says the US Army has approved screening and enrolling for its 14-patient, phase IIa/b trial of ISLA-101 as a prophylactic and therapeutic for dengue fever.

Last year, Island said it was awarded $US1.3 million ($A1.95 million) from the US Department of Defense's Congressionally Directed Medical Research Program for a phase IIa trial of ISLA-101 for dengue fever; and later, said it had re-allocated $US625,000 ($A962,000) of the grant for the trial (BD: Jul 7, 2023, May 8, 2024).

Earlier this year, Island said its 24-subject, single-ascending dose study showed that ISLA-101 achieved the required levels of blood concentration; computer models had confirmed a "predicted ideal single dose" for a phase II clinical study; and the US Food and Drug Administration had approved a change to its dengue fever phase IIa/b trial to include a therapeutic and prophylactic arm (BD: Apr 16, Jun 3, Aug 7, 2024).

Today, Island said it required ethics approval from the US Army because "the attenuated strain of the dengue challenge virus has been manufactured by the US Army".

The company said that it was required to wait until the end of the mosquito season to ensure the public was "protected from unwanted transmission of the virus".

Island said the first cohort would be the prophylactic arm, and that it would pre-treat the subjects with ISLA-101 in "late September and then infect them with the attenuated challenge virus on, or after, October 1".

The company said it expected to provide a full readout of the phase IIa cohort "well before the end of this calendar year", with the phase IIb therapeutic cohort expected to begin dosing "in January 2025".

Island managing-director Dr David Foster said the approval from the US Army "was the final requirement in the ethics approval process and we are now working closely with [the Syracuse-based State University of New York] to rapidly progress the screening and enrolling of our subjects for the phase IIa prophylactic arm of the trial".

Dr Foster said the company would "begin dosing subjects in the coming weeks".

Island was up 0.3 cents or 4.55 percent to 6.9 cents.

ARCHER MATERIALS

Archer says it has begun experiments to detect and monitor chronic kidney disease by detecting potassium on its Biochip graphene field effect transistor sensors.

Earlier this year, Archer Materials, formerly Archer Exploration, said it had developed a computer chip to detect the electronic signals from genetic sequence reactions, enabling the potential detection of multiple diseases (BD: Jan 23, 2024).

At that time, the company told Biotech Daily the micro-chip technology was a 10cm (four inch) silicon wafer able to hold 40-to-45 microchips and was expected to be able to detect multiple unnamed diseases from a single liquid sample on a micro-chip in a mobile device.

Today, Archer said through its foundry partners it had verified a process that directly grew graphene surfaces to "produce superior devices, rather than transferring the graphene to a device from a wafer, as previously done".

The company said it had tested the devices and found "no significant degradation in performance".

Archer said it would prepare the graphene surfaces with molecules that were would selectively bind to potassium, an important chemical in monitoring chronic kidney disease patients, and use the experiments "to produce first demonstrator data on detection of relevant ions in liquid, the initial step to initiate development of at-home sensing and monitoring of elements like potassium for renal patients".

Archer was up 0.5 cents or two percent to 26 cents.

CORRECTION: COCHLEAR

Last night's edition reported that APG Asset Management NV had ceased its substantial holding in Cochlear, selling 637,234 shares for 195,195,034 Netherlands Guilders or ANG306.32 ($A252.17) a share on October 17, 2023.

Yesterday, the Amsterdam-based APG said that between June 28, 2021 and October 17, 2023 it bought and sold shares in more than 800 transactions, with the last sale 637,234 shares for a consideration of "195,195,034" but did not disclose the currency.

Biotech Daily saw that the Cochlear trading value on that date matched the Dutch Guilders conversion to Australian dollars and incorrectly assumed that was the currency.

Today, APG analyst Rik de Koning filed an amended substantial shareholder notice, adding a further three pages or about 100 trades, concluding with APG selling 637,234 shares on August 22, 2024 for 195,195,034 which translates to $306.32, the price that Cochlear shares were trading in Australian dollars on that day.

Cochlear fell 32 cents or 0.1 percent to $300.48 with 137,364 shares traded.

RADIOPHARM THERANOSTICS

Radiopharm chair Paul Hopper says his shareholding in the company was diluted below five percent following a placement on August 21, 2024.

Earlier this year, Radiopharm said it had "firm commitments" to raise about $62.5 million at 4.0 cents a share in a placement, taking the total raised with a previous placement at 5.0 cents a share to Lantheus to $70 million (BD: Jun 25, 2024).

Last month, Mr Hopper said his 94,221,428 share-holding in the company was diluted from 20.5 percent to 8.9 percent following a placement (BD: Jul 7, 2024).

According to its most recent filing, Radiopharm had 2,079,210,756 shares on offer, meaning that Mr Hopper retains about 4.5 percent of the company.

Radiopharm was unchanged at 3.4 cents.

VITURA HEALTH

Vitura says it has appointed Geoff Cockerill as its chief executive officer, replacing interim chief executive officer Tom Howitt, effective from November 25, 2024.

Earlier this year, Vitura said founding chief executive officer Rodney Cocks would resign on June 30, 2024, with chief financial officer Tom Howitt appointed interim chief executive officer (BD: Apr 22, 2024).

Today, the company said Mr Howitt had returned to his role as chief financial officer.

Vitura said that Mr Cockerill had more than 11 years' experience at Diageo, Lion, Subway, Queensland Cricket and was most recently chief executive officer of ATP Science, as well as having held "several non-executive directorships".

According to his Linkedin profile, Mr Cockerill held a Bachelor of Commerce from the Gold Coast, Queensland Griffith University.

Vitura said that Mr Cockerill would receive a base salary of $450,000 a year, plus superannuation and be eligible to up to 50 percent of his base salary in short-term incentives and up-to 70 percent of the base salary in performance rights and options as a long-term incentive.

The company said that chief commercial officer Guy Headley would transition to a non-executive director by the end of August 2024 and provide advisory services.

Vitura said that Kirsty Garrett would be replaced by Nicola Swarbrick as chief operating officer.

Vitura was up 0.45 cents or 6.5 percent to 7.35 cents with 1.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has promoted Richard Valeix, Kevin Richardson and Raphael Ortiz “as part of an internal reorganization to align its operations across four business units”.

Telix said former chief commercial officer Mr Valeix had been appointed chief executive officer of its therapeutics business, leading its therapeutic pipeline commercialization and business development.

The company said former Americas chief executive officer Mr Richardson had been appointed chief executive officer of its precision medicine business, to lead the development of its diagnostics, including marketing and commercial operations.

Telix said former chief executive officer of Europe, the Middle East, Africa and Asia Pacific Mr Ortiz had been appointed chief executive officer of its international business to oversee commercial operations outside of North America.

The company said Darren Patti remained as its chief operating officer and would be responsible for its manufacturing operations, including ARTMS, Iso Therapeutics and Optimal Tracers.

Telix managing-director Dr Christian Behrenbruch said the structure would “optimize the development and commercialization of [diagnostic and therapeutic] radio-pharmaceuticals”.

“Telix is at an inflection point: momentum in our therapeutics business is growing, with prostate, kidney and brain cancer therapeutic candidates currently in, or advancing to, pivotal clinical trials,” Dr Behrenbruch said.

“Precision medicine is our global commercialization engine, to bring personalized, [diagnostic and therapeutic products] to market and is underpinned by a growing manufacturing footprint that enables enhanced control over the supply chain,” Dr Behrenbruch said.

“Telix is evolving, and the revised business model reflects our differentiated position, harnessing the power of targeted radiation at every step of the patient journey,” Dr Behrenbruch said.

Telix was up 11 cents or 0.55 percent to $19.97 with 1.8 million shares traded.