



Biotech Daily

Friday July 12, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: SYNTARA UP 26%; CURVEBEAM DOWN 4%**
- * **DR BOREHAM'S CRUCIBLE: SDI**
- * **IMMUTEP: 11 of 31 RESPOND TO EFTI FOR HEAD, NECK CANCER**
- * **COMPUMEDICS RAISES \$1.85m**
- * **LA TROBE OPENS \$8m VICTORIA-BACKED BIO INNOVATION HUB**
- * **MEDICAL DEVELOPMENTS WRITES DOWN \$31m ASSETS**
- * **CAMBIUM COMPLETES 100-TO-1 CONSOLIDATION**
- * **ARGENT REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ARGENICA 500k CHAIR DIANNE ANGUS OPTIONS EGM**
- * **GREGORY GEORGE, G TO THE FOURTH TAKE 16% OF MESOBLAST**

MARKET REPORT

The Australian stock market was up 0.88 percent on Friday July 12, 2024, with the ASX200 up 69.7 points to 7,959.3 points. Twenty-two of the Biotech Daily Top 40 were up, 10 were down, seven traded unchanged and one was untraded. All three Big Caps rose.

Syntara was the best for the second day in a row, up 0.9 cents or 25.7 percent to 4.4 cents, with 6.4 million shares traded; followed by Immutep, up six cents or 20.3 percent to 35.5 cents, with 23.8 million shares traded. Medadvisor climbed 15.8 percent; Paradigm was up 12.7 percent; Clarity rose 10.05 percent; Imugene improved 9.3 percent; Dimerix was up 8.9 percent; Mesoblast increased 7.7 percent; Avita and Next Science climbed more than six percent; Prescient was up five percent; Resmed rose 4.4 percent; Alcidion, Amplia, Clinuvel, Neuren and Nova Eye were up more than three percent; Nanosonics and Telix rose more than two percent; Compumedics, CSL and Opthea were up more than one percent; with Cochlear, Medical Developments and SDI up by less than one percent.

Curvebeam led the falls, down one cent or 4.08 percent to 23.5 cents, with 5,220 shares traded; followed by Actinogen, down 0.3 cents or 4.05 percent to 7.1 cents, with 19.8 million shares traded. Universal Biosensors lost 3.3 percent; Emvision shed 2.9 percent; Orthocell, Percheron, Pro Medicus and Proteomics were down more than one percent; with 4D Medical and Cyclopharm down by less than one percent.

[DR BOREHAM'S CRUCIBLE: SDI \(FORMERLY SOUTHERN DENTAL INDUSTRIES\)](#)

By **TIM BOREHAM**

ASX code: SDI

Share price: 88.5 cents; **Shares on issue:** 118,865,530; **Market cap:** \$105.2 million

CEO: Samantha Cheetham

Financials (first half to December 2023): revenue \$52.2 million (up 3.5%), earnings before interest tax depreciation and amortization \$9 million (up 49%), net profit \$3.7 million (up 37%), dividends per share 1.5 cents (steady), cash balance \$7.1 million (down 18%), net debt \$17.9 million (down 1.1%).

Board: Jeffery Cheetham (chair), Ms Cheetham, Cameron Allen, John Slaviero (CFO/COO), Gerald Bullon, Dr Geoffrey Knight, Gerard Kennedy

Identifiable major shareholders: Cheetham family interests 45.8%, Garrett Smythe Ltd 3.2%, Nicholas and Annette Debenham 3%, Nicholas Debenham 1.5%.

In 1987, then Prime Minister Bob Hawke said no child would live in poverty by 1990 – an utterance that proved an aspirational statement rather than a core promise.

Over at the United Nations, promises are more like hard targets - at least when it comes to phasing out the use of mercury.

Specifically, signatory nations to the UN's Minamata Convention on Mercury have pledged to abolish dental amalgams - a common filling used for the last 175 years - by 2030.

About half of the amalgam material consists of mercury, which is known for its manifold health risks. The remainder consists of easily recyclable silver, tin and copper.

It's estimated that 3,000 to 5,000 tonnes of mercury are in our gobs and up to 40 percent enters water or solid waste streams. In the case of cremations, it ends up in the atmosphere along with Uncle Bertie's soul.

Sweden, Norway and Germany have already banned amalgam, while 128 nations have signed up to the Minamata Convention. Over the last five years, fewer than six percent of posterior teeth fillings used amalgam, compared with 73 percent five years previously.

These trends are music to the ears of SDI, our home-grown supplier of filling and aesthetics material to more than 100 countries and regions including the US, Europe and Brazil.

SDI's revenues mainly were derived from amalgam, which chief executive Samantha Cheetham dubs a "great product" given there's no need for marketing spend.

But the company has bit the bullet and swung sharply to composite and glass ionomer cement materials, as well as whitening products.

“We have a really small market share in most countries, but we are growing,” she says.

SDI holds especially high hopes for its high-margin Stela, an amalgam replacement material that promises to revolutionise filling procedures by making dentist visits quicker and more efficient.

Meanwhile, management has a spring in its step after last week’s disclosure of a record performance for the financial year just ended (see below).

Long in the tooth

For more than 50 years, SDI has been developing and exporting dental supplies from its base at Bayswater, in eastern Melbourne.

Formerly known as Southern Dental Industries, SDI was founded in 1972 by Jeffery James Cheetham (now the company chair). The company listed on the ASX in 1985, but ran into trouble after expanding into selling dental chairs.

The elaborate patient repositories seemed an obvious allied activity, but in reality, it required very different skills. The company quickly retreated to selling the mouth gob and smaller equipment, such as applicators.

Mr Cheetham’s daughter, Samantha, took over as CEO in July 2016, having been sales and marketing supremo. Two of her four brothers are also involved in the business.

SDI’s brands include Stela, Pola Rapid, Riva Star Aqua, Luna 2, Aura Bulk Fill, Riva Light Cure and Rarii Expert.

A recently-launched aesthetic product called Riva Cem Auto Mix, is a self-curing, fluoride-releasing paste/resin for cementing metal and ceramic restorations.

While small by world standards, SDI competes with the likes of Dentsply, 3M, Kerr Dental and Coltene.

A Stela product

Developed by SDI with the University of New South Wales, University of Wollongong and University of Sydney, Stela has the potential to be the gold standard of filling material.

Stela is stronger than amalgam and - being tooth coloured - has pleasing aesthetics, and reduces the steps to complete a filling. The product is relevant for about half of all fillings.

With a silvery-grey hue, amalgam fillings might look ugly but they have the advantage of being incredibly strong and lasting for decades.

“With composites you have to drill the hole, etch it and put a bond on which is cured with the blue light,” Ms Cheetham says. “You then put on composite, layer upon layer.”

The material cannot be applied at once because it sets towards the light, which can result in the filling pulling away from the tooth surface.

“Because Stela is self-curing, it sets towards the tooth so it is gap-free.”

In 2022, the US Food and Drug Administration approved Stela, followed by the local Therapeutic Goods Administration and the Brazilian regulator. European assent is pending, although post Brexit regulatory shifts have slowed the process.

With the product launched in April last year, Ms Cheetham says initial Stela sales are going “really well” and she is pleased dentists are using it not just for back teeth but the more prominent molars.

“The sales are not significant yet, but dentists are re-ordering it,” she says.

“It is something super-innovative and we are getting fantastic feedback from really important dentists and good evaluation results as well. It can take four years to get traction with any product but I would say this will be quicker.”

Stela’s \$6 million development cost was supported by \$4.5 million of government and university grants.

Finances and performance

Some companies prefer to leave it to the August reporting season to lift the kimono on performance, but SDI last week was happy to pre-reveal the key numbers.

And why not? Sales for the year to June 30, 2024 will come in at an unaudited record \$111.4 million, 3.2 percent higher. Net profit is expected to be \$9.5 million to \$10 million compared with the previous \$7.1 million, or \$10.5 million to \$11 million excluding asset impairments.

SDI posted sales of \$52.4 million for the December 2023 half year, up 3.5 percent and also a record. Net profit zoomed 36 percent to \$3.7 million, reflecting abating costs (such as logistics) which were problematic in the prior period.

“There’s a lot of moving parts in the results, including currency movements, product and geographic mix and logistics costs,” chief finance officer John Slaviero says.

Post-pandemic, elevated supply chain costs have reduced but and are unlikely to come down further.

While most of SDI’s raw materials (including silver) are locally sourced, some chemicals are imported, while Switzerland is the main supplier of mercury.

In line with the 10-year trend, aesthetics products led the way with revenue of \$26.3 million for the half year, up five percent. Management attributes this to “market share gains and new product”.

Conversely, amalgam product sales crumbled 17 percent to \$7.7 million. This fall was partly attributed to stronger sales in the previous period, the result of two big rivals withdrawing from the market.

(While the use of amalgam has diminished, it's still widely used in the US - especially in lower socio-economic markets).

Whitening product sales were 0.6 percent off the pace, although European sales held up. The company doesn't service the do-it-yourself whitening market, for fear of annoying dentists.

Geographically, Europe and Australia each account for around 35 percent of sales, followed by North America on 22 percent and Brazil on 7.0 percent.

A curious aspect of the record first-half year turnover was that sales declined everywhere except for Europe, where they increased by 16 percent. This more than compensated for the falls elsewhere.

Brazil lost its cha cha cha, with sales down 13 percent, the result of major distributor Henry Schein reducing inventory. This was expected to “normalise” in the June half year.

Ms Cheetham says Brazil's 200 million people are well serviced by 350,000 dentists.

“They are the most beautiful looking, made-up people, including the men,” she says of this populace. “They are very conscious of the way they look.”

Australian sales declined 2.5 percent, the result of “inconsistent ordering patterns affected by customer import licences, payment terms and credit limits.”

A property purchase (see below) resulted in the company taking on debt in 2023, having had none previously.

Investors were bestowed with a 1.5 cent a share interim dividend, steady on previously.

Over the last year, SDI shares have gnashed between 72 cents (mid-February 2024) and 88 cents (mid-March this year). The stock peaked at \$2.38 in January 2004.

On the move

Having outgrown its current premises, SDI is on the move - but only down the road to nearby Montrose.

In 2022, the company confirmed the \$19 million purchase of a 24,500 square metre site, which includes an 11,200 square metre warehouse (to be refurbished to a manufacturing facility in a staged process.) The company hopes to move in in the 2026-'27 year.

In total, the company expects to spend \$60 million on the Montrose site - \$45 million on land and buildings and \$15 million on machinery - for an expected return on investment of more than 20 percent.

SDI's current net debt stands at \$17.9 million. Mr Slaviero says gearing will peak at \$38 million, falling to \$22 million after the sale of the 16,200 square metre Bayswater site.

The new facility is expected to support annual sales of \$200 million - twice the current run rate.

Dr Boreham's diagnosis:

Ms Cheetham notes that tooth decay is the world's number-one non-communicable disease - at a time when people are becoming more conscious of their dental health.

While the principle of applying fillings hasn't changed much over the ages, the techniques certainly have. These days, all or most of the pain felt by patients is in the anticipation of the visit - and perhaps the wallet afterwards.

SDI is a minnow in a sea of giants, with a sub one percent share of the US composites market and a circa five percent share here.

But over the ages, the company has proved nimble enough to compete with the titans of teeth.

With products like Stela, it is well-placed to address the 'body beautiful' market for which ugly silvery-grey fillings are simply not Instaworthy.

SDI has a solid record of earnings and dividends, although some observers reckon the company could do more in terms of expanding its global reach.

"In our category, there is so much we can do but you may as well stick to your knitting. We know what we can develop," Ms Cheetham says.

Having seen more than a few up-and-coming corporates subsumed by their hubris, your columnist doesn't mind the humble approach.

A year ago, SDI management said investors should see the benefit of increased sales "flowing through in the next year or so".

Given the Stela revenue boost is yet to be seen in earnest, this utterance was more an aspirational statement more than anything.

But unlike Hawkie's infamous promise, at least it has some semblance of being achieved.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is often told to shut his gob - and not just because of the ugly grey fillings

IMMUTEP

Immutep says 11 of 31 (35.5%) evaluable patients in cohort B of its phase IIb trial of efti with Keytruda for head and neck tumors had an objective response.

Last year, Immutep said it had enrolled the 171-patient, phase IIb trial of eftilagimod alpha, or efti, with the anti-programmed cell death-1 therapy pembrolizumab, marketed as Keytruda, for head and neck squamous cell carcinoma (BD: Nov 9, 2023).

At that time, the company said the study's cohort A enrolled 138 patients with tumors expressing programmed-cell death-ligand 1 (PD-L1) with a combined positive score of more than one, with cohort B enrolling 33 patients with PD-L1 expressing tumors with a combined positive score of less than one.

Last month, Immutep said the trial showed efti with Keytruda led to "overall response rates that exceed Keytruda monotherapy" including 26 evaluable non-programmed-cell death-ligand-1 (PD-L1)-expressing patients in cohort B (BD: Jun 27, 2024).

At that time, the company said patients in cohort B had shown a "substantially improved" overall response rate compared to the 26.9 percent in preliminary results reported in April, but that final topline results would be delivered in an oral presentation on July 11, 2024.

Today, Immutep said efti with Keytruda achieved a disease control rate of 58.1 percent in cohort B patients compared to Keytruda alone which led to a previous response rate of 5.4 percent and a disease control rate of 32.4 percent.

The company said cohort B had "a high complete response rate of 9.7 percent, with three patients showing a disappearance of cancer lesions post-treatment ... [compared] to a historical control of zero percent from anti-PD-1 monotherapy".

Immutep said one patient with early progressive disease was a "confirmed partial responder" and remained on therapy after 14 months.

The company said it would discuss the path forward with regulatory agencies.

Immutep said efti in combination with Keytruda continued "to have a favorable safety profile with no new safety signals observed".

The company said the additional results from cohort B were presented by the Manchester, England-based Christie National Health Services Foundation Trust's Dr Robert Metcalf at the European Society for Medical Oncology's virtual plenary sessions on July 11, 2024.

Dr Metcalf said the high response rate from the combination treatment was "well above other treatment approaches without chemotherapy".

"It matches historical response rates from chemotherapy-based treatments but without the associated toxicities," Dr Metcalf said. "This is really significant for patients with head and neck squamous cell carcinomas who have a [combined positive score] less than one and for whom chemotherapy is the current first-line treatment."

"Achieving complete responses in this group bodes well for this immunotherapy combination's future potential, especially given the positive trend in response durability," Dr Metcalf said. "The clinically meaningful response rate and high unmet medical need warrant further investigation of eftilagimod plus pembrolizumab in this patient population." Immutep was up six cents or 20.3 percent to 35.5 cents with 23.8 million shares traded.

COMPUMEDICS

Compumedics says it has issued 6,607,143 placement shares at 28.0 cents a share, worth \$1,850,000, to Australian institutional investors.

Last week, Compumedics said it had raised \$1.9 million at 28.0 cents a share, a 10 percent discount to the 15-day volume weighted average price, in a placement to fund the US rollout of its Somfit home sleep test (BD: Jul 4, 2024).

Compumedics was up half a cent or 1.7 percent to 29.5 cents.

LA TROBE UNIVERSITY, VICTORIA GOVERNMENT

La Trobe University says it has opened its \$8 million Bio Innovation Hub to support biotechnology businesses, with funding from the Victorian Government.

La Trobe University said the facility was opened today at its Bundoora facility by the Victoria Minister for Precincts Colin Brooks on behalf of the Minister for Training and Skills and Regional Development Gayle Tierney.

The University said the Bio Innovation Hub included “‘wet’ laboratories, joining just a handful of the sought-after labs in the state, and world-class equipment to help businesses commercialize their research discoveries”.

La Trobe said start-ups, small to medium-sized biotechnology and agricultural-technology businesses would be able to be tenants at the hub in its research and innovation precinct. The University said its spin-out Allesense, Aeterna Health and Vivazome Therapeutics Pty Ltd were the first occupants of the Hub.

Vivazome managing-director Xenia Sango said the company was developing extra-cellular vesicles targeting treatments for neuro-degenerative diseases.

“By delivering these therapeutic [extra-cellular vesicles] directly to the injured brain, we aim to repair damaged cells and potentially restore lost functions, offering improved quality of life for patients with [traumatic brain injury],” Ms Sango said.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it expects to recognize “write-downs to the carrying value of assets of approximately \$31 million” in its full-year financial reports.

Medical Developments said the write-downs were expected to have an “after-tax earnings impact of approximately \$26 million”, the non-cash asset write-downs were subject to audit and expected to include \$16 million in US registration and development costs, which would trigger an “after-tax impairment charge of \$12 million”.

Medical Developments said the write-down followed its decision to pause investment in its US expansion plans and that it did “not meet the criteria under the relevant accounting standard to maintain balance sheet recognition”.

The company said the impairment charge did “not reflect the inherent value of the work completed to date, and it may be reversed when development is re-commenced”.

Medical Developments said the write-downs included redundant fixed assets of \$1 million and “deferred tax assets of \$14 million relating to the de-recognition of tax losses carried forward from prior financial years, giving rise to a tax expense of \$14 million”.

The company said it would “not recognize deferred tax assets or tax benefits in respect of losses” for the year to June 30, 2024, and it expected underlying earnings before interest and taxation, excluding impairment charges, to be “strongly improved” compared to the previous corresponding period.

Medical Developments chief executive officer Brent MacGregor said the company “reported in April that we have paused investment in the US” and told Biotech Daily the company had been required by the ASX to file quarterly reports under “Listing Rule 4.7B regarding our cash position” (BD: Apr 29, 2024).

Mr MacGregor said the company’s priority was “driving further momentum in our existing markets for Pentrox”.

“The US commercial opportunity for Pentrox remains open to us, and we will re-commence market entry activity at the appropriate time,” Mr MacGregor said.

“The significant work we have completed, over several years, remains valuable and relevant to future plans,” Mr MacGregor said.

Medical Developments was up 0.25 cents or 0.5 percent to 47.75 cents.

[CAMBIUM BIO \(FORMERLY REGENEUS\)](#)

Cambium says it has completed its 100-to-one stock consolidation and has 11,931,006 post-consolidation shares on issue.

Earlier this year, Cambium said its extraordinary general meeting would vote on a 100-to-one stock consolidation; and last month, the company said 96.64 percent of the meeting approved the consolidation (BD: May 23, 2024).

Cambium was unchanged at a post-consolidation 40 cents with 418 shares traded.

[ARGENT BIOPHARMA \(FORMERLY MGC PHARMACEUTICALS\)](#)

Argent has requested a trading halt pending the “release of an announcement regarding a capital raising”.

Trading will resume on July 16, 2024, or on an earlier announcement.

Argent last traded at a post-1000-to-one-consolidation 30.5 cents.

[ARGENICA THERAPEUTICS](#)

Argenica says its extraordinary general meeting will vote to issue 500,000 options to chair Dianne Angus, exercisable at 93 cents each by May 31, 2027.

Argenica said half of Ms Angus’ options would vest on November 30, 2024 and the remainder vesting on November 30, 2025.

The company said Ms Angus’ current yearly remuneration was \$95,000 and she had not previously been issued equity under the employee incentive plan.

Last year, the company said Ms Angus would replace Geoff Pocock as non-executive chair, effective from December 1, 2023 (BD: Nov 30, 2023).

Argenica said investors would vote to ratify the issue of 23,076,923 placement shares.

The meeting will be held at Unit 3, 117 Broadway, Nedlands, Perth on August 14, 2024 at 9am (AWST).

Argenica fell three cents or 3.2 percent to 90 cents.

[MESOBLAST](#)

Gregory George and G to the Fourth Investments say they have increased their Mesoblast holding from 166,849,364 shares (14.67%) to 179,847,742 shares (15.81%).

The Tampa, Florida-based Mr George said the shareholders included James George, Grant George, Citicorp and JP Morgan and that they acquired the securities between April 30 and July 9, 2024, with the single largest purchase 1,752,230 shares on July 9 for \$US1,286,531, or 73.4 US cents (\$A1.085) a share.

Mesoblast was up 8.5 cents or 7.7 percent to \$1.19 with 12.6 million shares traded.