Biotech Daily

Friday March 10, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VOLPARA UP 9%; ACTINOGEN DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: SDI**

*** LABOR, GREENS ADVANCE $15b RECONSTRUCTION FUND CORP BILL**

*** VOLPARA: US FDA REQUIRES DENSE BREAST INFORMATION**

*** ANATARA REVISES 'GARP' IBS TRIAL; MUCPHARM LICENCE**

*** AUSCANN TO DIVEST 52% OF CANNPAL**

*** INCANNEX REQUESTS 'PSYCHEDELIC PROGRAM' TRADING HALT**

*** NEXT SCIENCE FOUNDER, CTO DR MATTHEW MYNTTI BELOW 5%**

MARKET REPORT

The Australian stock market fell 2.28 percent on Friday March 10, 2023, with the ASX200 down 166.4 points to 7,144.7 points. Ten of the Biotech Daily Top 40 stocks were up, 21 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Volpara was the best, up six cents or 8.8 percent to 74 cents, with 482,745 shares traded; followed by Pharmaxis up 8.3 percent to 5.2 cents with 190,333 shares traded. Both Cynata and Nova Eye climbed 5.3 percent; Paradigm and Starpharma rose more than two percent; Opthea was up 1.75 percent; with Emvision, Genetic Signatures and Neuren up by less than one percent.

Actinogen led the falls, down 0.5 cents or 6.9 percent to 6.7 cents, with one million shares traded; followed by Next Science down 6.4 percent to 65.5 cents, with 66,278 shares traded.

Avita, Polynovo and Universal Biosensors lost more than five percent; Dimerix, Mesoblast and Telix fell more than four percent; Alcidion, Clinuvel, Immutep, Imugene and Patrys were down three percent or more; Antisense, Nanosonics and Resonance shed more than two percent; CSL, Impedimed, Medical Developments, Orthocell, Pro Medicus and Proteomics were down more than one percent; with Cochlear and Resmed down by less than one percent.

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

By TIM BOREHAM

ASX code: SDI

Share price: 85.5 cents

Shares on issue: 118,865,530

Market cap: $101.6 million

Financials (first half to December 2022): revenue $50.5 million (up 9%), earnings before interest tax depreciation and amortization $6.1 million (up 16%), net profit $2.71 million (up 0.9%), earnings per share 2.28 cents (up 0.9%), dividends per share 1.5 cents (steady), cash balance $6 million (down 7.7%), net debt $20.8 million (no debt previously).

Chief executive officer: Samantha Cheetham

Board: Jeffery Cheetham (chair), Ms Cheetham, Cameron Allen, John Slaverio, Gerald Bullon, Dr Geoffrey Knight, Gerard Kennedy

Identifiable major shareholders: Cheetham family interests 45.8%, Garrett Smythe Ltd 3.2%, Nicholas and Annette Debenham 4.37%, Dr Geoffrey and Anneli Knight 1%.

For dental patients with a gob full of suction tubes and probing and whirring instruments of torture, the providence of material such as fillings and applicators is usually far from their minds.

Pinned down in the chair, the victim - er - patient might perceive the process of filling teeth doesn't seem to have changed for decades. In reality, advances in material technology are making the visit to the dentist quicker and more comfortable - with more aesthetically appealing results.

In a corporate sense there's nothing new about the ASX-listed SDI - formerly Southern Dental Industries - which has been making and exporting dental supplies for more than 50 years.

The Melbourne-based SDI is a model in longevity in a sector with high regulatory barriers and commoditized products.

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

But SDI is seeking to change the face (or mouth?) of dentistry with new techniques and materials.

About SDI

SDI was founded in 1972 by Jeffery James Cheetham - now the company chair - with pretty much the same remit of developing and manufacturing specialist dental materials.

The company listed on the ASX in 1985.

Around this time, the business nearly imploded after deciding to invest in heavy dental equipment, including chairs. As with the patients in the said chairs, this proved a painful experience and Mr Cheetham vowed the company would stick to what it knew best.

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 is based in the outer Eastern Melbourne suburb of Bayswater, where it exports to more than 100 countries. The company also has offices and warehouses in the US, Brazil and Germany.

With the exception of some electronic componentry, all of SDI's products are made at Bayswater which, by the way, is nowhere near the sea.

Last August, the company announced the $17.8 million purchase of a larger, six-acre site in nearby Montrose, with a 4,000 square metre warehouse. The company will shift its warehousing there later this year and eventually relocate its HQ and sell its current digs.

Lasty year, SDI was bestowed two gongs from Victoria's Governor Linda Dessau: Victorian Exporter of the Year and the International Health Award.

What a lovely smile

The basic technique of applying fillings hasn't changed much over time, but the desire for a perfect smile has intensified.

"Everyone looks at themselves - far more especially in these Zoom times," Ms Cheetham says - a reference to staff wanting to look their best on video calls.

In the days of yore, most of SDI's revenues derived from the old amalgam filling material, which has an unappealing silvery-grey look.

Your columnist wonders why this gob bog is still used widely, given visible cavities are filled with white material based on powdered glass.

"Amalgam is much stronger and lasts 10 to 20 years," Ms Cheetham says. "They are also easy to place with fewer steps involved".

"It's been a tried and proven filing material. It's like steel in your mouth but it's ugly and we recognize that everyone wants to have a much more beautiful smile."

Hoping for a Stela performance

Last year the US Food and Drug Administration approved Stela, a tooth-colored filling that is stronger than amalgam and “able to withstand high mastication forces”.

The Australian Therapeutic Goods Administration and Brazilian regulator has also approved the product, with European assent expected this year.

While amalgam remains an important revenue source for the company, it’s becoming less important in the sales mix in favor of tooth whitening and white filling products.

Stela is as close as it gets to a “blockbuster” release, although management is coy on the likely revenue it will generate.

Stela is a replacement not just for an amalgam, but for all posterior (back) fillings that account for about half of all fillings.

The Stela kits contain a metal tip which directly exudes the substance into the cavity and a special curing light is not required.

Another key advantage is the dentist can fill the cavity at once, rather than building the filler layer-by-layer so that it dries properly (any handyperson who has worked with Polyfilla will understand this).

“It’s super strong and won’t cause sensitivity because it is gap-free,” Ms Cheetham says.

Stela was developed in cahoots with the University of New South Wales, University of Wollongong and University of Sydney.

The first US orders are expected this year, while the company will use this month’s International Dental Show in Cologne to launch in countries that don’t require formal approvals.

“We are excited by Stela and the opportunity it creates, not only as an amalgam replacement product but its aesthetic character, given its strength and natural tooth color,” Ms Cheetham says.

Stela cost SDI a modest $1.5 million of the total $6 million development cost, with the remainder borne by the universities and government grants.

Filling in the product gaps

SDI is also poised to launch another aesthetic product called Riva Cem Auto Mix, a self-curing, fluoride-releasing paste/resin for cementing metal and ceramic restorations.

SDI has a long-standing target of releasing one to two new products each year, if only tweaks on the company’s current offerings. A past example is Reva Star Aqua, a non-smelly fluoride product that is dispensed to kids more easily.

Ms Cheetham’s says SDI’s in-house scientists focus on manufacturing readiness and advancing ideas from university collaborations or the company’s own staff.

“We operate in a highly regulated industry and our investments in research and development are key to maintaining our relevance and market advantages,” she says.

SDI also has another composite product in the offing, as well as a mixing machine for the capsules, a new applicator for glass ionomer capsules and a new glass ionomer cement.

“We are starting to be recognized by the Americans as an innovative company.,” Ms Cheetham says.

Finances and performance

SDI posted record sales of $50.5 million for the December 2022 (first) half year, up nine percent year-on-year. However, stubbornly high costs limited the net profit increase to $2.7 million, up 0.9 percent.

The increased sales were spurred by both the new-world aesthetic and old-school amalgam products: the former gained eight percent to $47.4 million, while the latter increased 17.8 percent to $17.4 million.

The amalgam performance was helped by two dental giants exiting this market segment. Whitening products declined 18.7 percent to $28.9 million, largely because of sales in inflation-ravaged France being not so magnifique.

UK demand was especially strong - which goes to show that Brits value pearly whites as well as stiff upper lips, in tough times. Europe accounted for 34 percent of revenue and North America 23 percent, with South America - mainly the beauty conscious Brazilians - contributing six percent.

SDI’s previously ‘lazy’ balance sheet has gone to the gym: the property purchase means SDI has net debt of $20.8 million, compared with nil previously.

But the gearing didn’t deter management from proclaiming a 1.5 cents per share dividend, steady on the previous period. Debt will be reduced by $5 million to $6 million from proceeds of selling two existing premises.

Bayswater HQ - which has a book value of $15 million and a market value well beyond that - eventually will be sold as well.

Investors were underwhelmed by the results, ending SDI shares down eight cents, or 8.4 percent, to 87 cents.

Over the last year SDI shares have swung between 73 cents (mid-June last year) and 94 cents (early February 2023). Over time SDI shares have moved between seven cents (early 1999) and $2.38 (January 2004).

This might hurt a bit

Management reports that inflation and cost pressures are starting to moderate - a key message of the Australian profit reporting season generally.

But chief finance officer John Slaviero said the company was still being impacted by high input costs, notably for specialized refrigerated shipping containers.

In some cases, goods have been held up in a container at the docks for up to six months, which meant the company had to use air freight to fill orders.

The company is managing to pass on some - but not all – of the cost rises to customers.

Dr Boreham's diagnosis:

While SDI has been quietly ambling along for decades, Stela promises to move the dial in a way no other product has done to date.

One non-company estimate doing the rounds is for potential short-term sales of $75 million and as much as $600 million in the longer term.

Not one for rash prognostications, Ms Cheetham says SDI would be happy with one to two percent of the market and "it will take us a few years to build traction".

In the meantime, SDI continues as an unusual Australian manufacturing success story.

"We are lucky enough to have good margins," Ms Cheetham says.

"Our key competitors are based in the US, Japan and Germany, Switzerland and Liechtenstein, so they have large cost bases as well."

One nagging question is why SDI's earnings per share have remained stubbornly unchanged over the last decade.

CFO John Slaviero says investors should see the benefit of higher sales flowing through "in the next year or so" and we'll take that as a core promise.

Meanwhile, a new generation of narcissists almost guarantees growth in SDI's targeted aesthetics and whitening sectors.

The pandemic Zoom Boom might have abated, but folk are still demanding the perfect smile.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Thanks to a childhood addiction to Fruit Tingles, he has so many cavities that his dentist is re-filling his old fillings.

FEDERAL GOVERNMENT, THE GREENS

The Federal Government says the National Reconstruction Fund (NRF) Corporation Bill passed the House of Representatives, and the Greens say with its amendments.

A media release from the Federal Minister for Industry Ed Husic and the Minister for Finance Senator Katy Gallagher said the Bill would “deliver one of the largest peacetime investments in Australian industry”.

The Government said that the National Reconstruction Fund would invest $15 billion across priority areas of the economy including renewables and low emissions technologies, medical science, transport, value-adding in resources, value-adding in agriculture, forestry and fisheries, defence capability and enabling technologies.

The media release said the National Reconstruction Fund would “also help address the inflation challenge in the economy by reducing our dependence on broken supply chains”.

Mr Husic said the Fund would “rebuild Australia’s industrial capability and support long-term sustainable economic growth”.

The media release said that the Fund would be “administered at arm’s length to Government by an independent board making independent investment decisions”.

More detail is at: https://www.industry.gov.au/news/national-reconstruction-fund.

“After a decade of neglect from the former Liberal-National Government, the Albanese Government is revitalizing Australian manufacturing,” Mr Husic said.

“We are now one step closer to delivering one of the largest peacetime investments in manufacturing this country has ever seen,” Mr Husic said.

“The National Reconstruction Fund is a nation-building, transformational investment to help deliver a better future,” Mr Husic said.

Senator Gallagher said the Federal Government “wants to see more things made here in Australia which also means more jobs for Australians and that’s what the National Reconstruction Fund will deliver”.

Australian Greens Leader Adam Bandt and Greens spokesperson on Industry, Transition and Regional Development Senator Penny Allman-Payne said they had secured agreement from the government on amendments to the National Reconstruction Fund Bill that will prevent future governments using the fund to invest in coal and gas projects or log native forests.

The Greens said their amendments imposed a class of ‘prohibited investments’ that banned the National Reconstruction Fund Corporation from financing the extraction of coal and gas, the construction of gas pipelines and the logging of native forests.

The Greens said the Party would “support the passage of the bill through the House of Representatives with the government agreeing to support the Greens amendments on coal and gas”.

“The Greens will also support the bill in the Senate subject to consideration of government and other amendments,” the media release said.

“We thank the government for the constructive approach they have taken in the negotiations and hope this can continue in the Safeguard and Housing Bill discussions in the coming period.”

“The Greens took a policy for a manufacturing fund to the election and we strongly support public investment in rebuilding manufacturing in Australia,” Senator Allman-Payne said.

“The amendments the Greens have secured will ensure that the National Reconstruction Fund will be focused on creating high-quality jobs across a diverse economy, particularly in regional Australia,” Senator Allman-Payne said.

“The Greens have made sure that this fund will only be invested in building the future of Australian manufacturing, not propping up coal and gas corporations,” Senator Allman-Payne said.

VOLPARA HEALTH

Volpara says the US Food and Drug Administration will require mammography facilities to inform patients whether their breasts are composed of dense tissue.
Volpara said its volumetric breast density assessment software was able to make "accurate, objective assessments of breast density possible" and its Trudensity artificial intelligence image analysis algorithm was cleared by the FDA, Health Canada, the Australian Therapeutic Goods Administration and had Conformité Européenne (CE) mark.
The company said that its Thumbnail module provided two images of the patient's breasts and explained what breast density meant in "simple-to-understand terms and visuals".
Volpara said that the FDA would require all patient reports and summaries to include non-dense and dense breast notification by September 10, 2024.
The company said that dense breast tissue was common, could "dramatically impact" early detection of breast cancer, decrease the accuracy of mammography and had been linked to an increased risk for breast cancer.
Volpara managing-director Teri Thomas told Biotech Daily that the announcement was "great news for us, something we've been waiting for since 2019".
"It will have an impact within the US but I also believe it will have an impact in non-US markets," Ms Thomas said.
"For the US to take such a strong stance about density validates the importance of density as a risk factor for breast cancer," Ms Thomas said. "It will put pressure on addressing it in places like Australia, New Zealand and Europe."
In the company's media release to the ASX, Ms Thomas said: "The FDA breast density notification language is a key step in equitably empowering all women in the United States to understand their breast density so they can take informed, actionable steps to monitor their own breast health."
Volpara was up six cents or 8.8 percent to 74 cents.

ANATARA LIFE SCIENCES

Anatara says it has revised its phase I for irritable bowel syndrome study protocol and signed a licencing deal with Sydney's Mucpharm.
Anatara said it had enrolled 50 of 90 planned participants in the trial of its gastro-intestinal re-programming (Garp) pineapple stem bromelain-based complementary medicine trial.
The company said it had enrolled 50 participants, influenced by "an anticipated variable withdrawal rate" and expected to reach the 90-participant target for stage one of the trial by July 2023, "slightly later than previously indicated" with an analysis by October 2023.
Anatara said it had hired Melbourne's Propharma Group as its clinical research organization, and would focus on "new Garp trial criteria" for irritable bowel syndrome, excluding only the constipation subset, as well as address "screen failure inconsistences".
In 2021, Anatara said it had approval for a 200-patient Garp trial for irritable bowel syndrome with diarrhoea (BD: Feb 8, Aug 20, 2021).
The company said an interim safety and efficacy analysis would assess two strengths of Garp against placebo prior to stage two.
Anatara said Mucpharm had licenced technology from its portfolio for use in mucin producing cancers and biofilms and that it would receive royalties on sales and sub-licencing, but did not disclose the commercial details nor specify the licenced technology.
The company said that Mucpharm was "focused on the treatment of mucin-containing and secreting conditions" and was developing the novel use of Bromac, a combination of bromelain and acetylcysteine, in fields including cystic tumours.
Anatara was unchanged at 2.8 cents with one million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says it will "partially privatize" its animal health business, Cannpal Animal Therapeutics Pty Ltd by divesting 52 percent to Animal Health Holdings Pty Ltd.

In 2020, Auscann and Cannpal said they had a scheme of arrangement for Auscann to acquire Cannpal (BD: Nov 16, 2020).

Today, Auscann said that Animal Health Holdings was a "special purpose vehicle" which would assume responsibility for all expenses for development and commercialization of Cannpal's animal health assets.

The company said that the partial divestment would see it retain a 48 percent "free carried interest in Cannpal" and was expected to enable quicker research and development progress, reduce overheads, allow Cannpal to access alternative funding sources and remove its obligation for Cannpal related expenses.

Auscann said the partial divestment allowed it to retain "certain beneficial rights" including a pre-emptive right to supply raw marijuana materials for Cannpal products and options to re-acquire the shares in Cannpal for nominal consideration of $1 to $2 the failure of the Cannpal to reach agreed development and commercialization milestones.

The company said the first milestone was the registration of Dermacann as an approved veterinary medicine in Australia and New Zealand within 12 months of the agreement date and the second milestone was a phase II study of CPAT-01 and a payment for a research agreement with a clinical research organization within 24 months.

Auscann said it was not required to obtain shareholder approvals for the partial divestment, which it said was expected to be completed by March 31, 2023.

Auscann said that Animal Health Holdings would be controlled by its outgoing chief executive officer Layton Mills and outgoing chief scientific officer Dr Margaret Curtis.

Auscann was in a suspension at four cents.

INCANNEX HEALTHCARE

Incannex has requested a trading halt pending "the release of a material update regarding the company's psychedelic program".

Trading will resume on March 14, 2023 or on an earlier announcement.

Incannex last traded at 14.5 cents.

NEXT SCIENCE

Founder and chief technology officer Dr Matthew Myntti says he has ceased his substantial holding in Next Science.

In 2022, the Sydney-based Dr Myntti said he had reduced his holding in Next Science from 14,068,000 shares (7.11%) to 12,774,989 shares (5.95%) (BD: Nov 10, 2022).

Today, Dr Myntti said that between April 12, 2022 and March 7, 2023, he sold and transferred shares, with the single largest sale on March 7, 2023 of 1,320,000 shares for $849,420, or 64.35 cents a share.

Next Science fell 4.5 cents or 6.4 percent to 65.5 cents.