Biotech Daily

Friday November 10, 2023

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: AVITA UP 17%; KAZIA DOWN 16%**

*** DR BOREHAM'S CRUCIBLE: NANOSONICS**

*** AVITA 9-MONTH REVENUE UP 44% TO $57m; LOSS UP 33% TO $45m**

*** MEDLAB'S DR SEAN HALL TO BUY SUBSIDIARY; RESTRUCTURE**

*** IMUGENE DOSES 1ST PHASE I 'AZER-CEL' LYMPHOMA PATIENT**

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*** ARTRYA TO RELEASE 15.6m ASX ESCROW SHARES**

*** NOVA EYE REQUESTS 'US REIMBURSEMENT' TRADING HALT**

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*** RESMED LOSES COO ROBERT DOUGLAS; MANAGEMENT CHANGES**

MARKET REPORT

The Australian stock market fell 0.55 percent on Friday November 10, 2023, with the ASX200 down 38.4 points to 6,976.5 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and four were untraded. All three Big Caps fell.

Avita was the best, up 53 cents or 16.7 percent to $3.71, with 635,605 shares traded. Neuren improved 10 percent; Genetic Signatures climbed 6.6 percent; Prescient rose 5.45 percent; Emvision was up 3.5 percent; Alcidion, Orthocell and Volpara rose more than two percent; 4D Medical, Amplia, Antisense and Opthea were up more than one percent; with Nanosonics and Polynovo up by less than one percent.

Kazia led the falls, down 1.4 cents or 16.1 percent to 7.3 cents, with 2.4 million shares traded. Next Science lost 13.2 percent; Actinogen was down 10 percent; Imugene and Proteomics fell more than four percent; Clinuvel and Immutep were down more than three percent; Micro-X and Resmed shed two percent or more; Medical Developments, Resonance, SDI and Telix were down more than one percent; with Cochlear, CSL and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: NANOSONICS

By TIM BOREHAM

ASX Code: NAN

Share price: $4.15; **Shares on issue:** 302,607,616; **Market cap:** $1.255 billion

CEO: Michael Kavanagh

Board: Steve Sargent (chairman), Mr Kavanagh, Dr David Fisher, Marie McDonald, Geoff Wilson, Dr Lisa McIntyre, Dr Larry Marshall, Dr Tracey Batten

Financials (year to June 30, 2023): revenue $166 million (up 38%), net profit $19.9 million (up 431%), earnings before interest, tax depreciation and amortisation $26.7 (up 270%), cash of $112.2 million (up 19%)

Major identifiable shareholders: Maurie Stang 6.3%, Selector Funds Management 6.2%, Yarra Capital Management 5.6%, Bernard Stang 5.4%.

Reflecting on his 10 years as CEO of the medical device play - a milestone achieved last month - Michael Kavanagh says the numbers tell the story.

A decade ago, Nanosonics turned over $14.8 million, two years after its Trophon probe sterilization device was approved in the US. The company also lost $5.8 million. Fast forward to 2022-'23 and the company posted $166 million of revenue and made a net profit of just under $20 million.

Mr Kavanagh adds the numbers tell only part of the story: "The part I'm most proud of is the amazing capabilities we have built into the business."

"We are one of a handful of labs in the world today expert in biofilm on medical devices, especially in very small lumens of less than one millimetre in diameter. We have had to build capabilities in biosciences, microbiology and chemistry."

Having Trophon-ized hospitals around the world - especially in the US - Nanosonics is poised to commercialise its second instrument, called Coris (see below).

Tackling hospital infections

Based in Sydney, Nanosonics was founded in 2001 by microbiologist Dr Ron Weinberger and engineer Stuart Hodgetts, who were inspired by the need for hospitals to reduce infections caused by poorly-cleaned medical devices.

The first device iteration was the Trophon EPR - as in Enhanced Protection and Reprocessing - which uses hydrogen peroxide vapor to disinfect ultrasound probes much more thoroughly than the old manual methods.

Nanosonics claims the Trophons protect 98,000 patients daily from ultrasound probe cross contamination - or 25 million a year.

Nanosonics listed in May 2007, raising $27 million at 50 cents apiece. The company launched the Trophon EPRs in 2009, which the US Food and Drug Administration (FDA) approved in 2011, with the pimped-up Trophon 2s launched in 2018.

Previous to his decade-long Nanosonics gig, Mr Kavanagh was marketing head honcho at Cochlear.

Another key contributor is Maurie Stang, who chaired the company from 2007 until July last year.

On October 3 this year, long-time chief financial officer McGregor Grant stepped down, in favor of former local GE Healthcare CEO Jason Burriss. Mr Grant has since won a board seat on, and is chair of, device play Impedimed.

A notable recent Nanosonics board addition is Dr Larry Marshall, the sometimes-controversial scientist and entrepreneur who headed CSIRO for more than eight years.

Germs gone with Trophon

About the size of a microwave, Trophons sanitise probes to certified high level disinfectant (HLD) standards. The units protect against nasty bugs including drug-resistant bacteria, fungi, blood-borne viruses, venereal diseases and - if anyone still cares - Sars-Cov-2.

The Trophon process takes seven minutes and produces harmless water and oxygen as a byproduct of the disinfectant hydrogen peroxide.

Pre-Trophon, sterilization standards have ranged from a quick ‘once-over’ with a cloth to a procedure involving an isolating room with dangerous chemicals.

As well as selling (or leasing) the units, Nanosonics also makes money from servicing and consumables. The latter consists mainly of the hydrogen peroxide canisters that are used in the procedure (rather like a dishwasher powder tablet). In the US, the Trophons were distributed exclusively by GE Healthcare. But this arrangement was revised and the company now mainly sells directly.

Hospitals are doing it hard

Nanosonics continues to grow its base of Trophons - albeit at a slower run rate than pre-pandemic.

“Our customers [hospitals] are experiencing one of the most difficult operating environments for a very long time,” Mr Sargent told last week’s AGM.

“Costs are rising at a faster rate than revenue and governments have increasing budgetary pressures.”

By June 2023, Nanosonics had an installed base of 32,450 Trophons, up nine percent for the year and 55 percent higher than five years ago. Of these, 28,390 are in the US (up nine percent). Europe and the Middle East account for a further 2,100 (up 10 percent) and Asia Pacific (mainly Australia) another 2,050 (up eight percent).

The full-year accounts show 2,600 newly installed Trophons, down 16 percent year-on-year. But there were 1,800 upgrades from Trophon to the bells-and-whistles Trophon 2. These units include enhanced audit features to enable hospitals to keep up with ever-stricter compliance requirements.

Coris takes a flexible approach

A new product, Coris, is intended for flexible probes commonly used in procedures such as colonoscopies, gastroscopies, enteroscopies, endoscopic ultrasounds and bronchoscopies.

They have more fiddly bits than rigid endoscopes and are harder to clean, a process requiring scrubbing and long hours of standing.

As a guide, up to 200 manual actions are required (such as brushing and flushing) to clean the instruments. Because the channels can be one millimetre in diameter, “extensive biofilms” - that is, gunk - remain after cleaning.

Cleaning the probes costs $US11 to $US37 each - more than mere lunch money.

Coris delivers a “novel sonicated mist” that penetrates probe surfaces including the body handle and all crevices, thus reducing the risk of pathogens. As with the Trophons, the Corises emit harmless oxygen and water.

The company says 60 million endoscopies are done each year in the US, Europe, and Australia, with gastroscopies (especially colonoscopies) accounting for 45 million.

Mr Kavanagh expects Coris to have “at least the same” financial impact as Trophon, although the revenue from equipment sales are likely to be lower, and that’s because Corises are placed centrally, rather than at the point of care (as with the Trophons). But the units are likely to be used more, resulting in higher consumables income.

“With Coris we clearly understand the problem and have been able to innovate in a very complex area,” Mr Kavanagh says.

Star spangled spanner in the works

Not for the first time, the FDA recently showed “it’s my way or the highway” by demanding that testing of Nanosonics’ key new product, Coris, be carried out on its shores and not here.

An FDA submission under the agency’s de novo (novel device) route is now expected in the March quarter of 2024.

Mr Kavanagh says the FDA wanted to see more work in relation to “human factors” - that is, ensuring the instrument can be easily used and not misused.

He says the FDA’s demands were a blessing in disguise: “It’s lot better to know [the requirements] before you submit for approval, rather than to have to go back and re-do them.”

Nanosonics is part of the FDA’s Safer Technologies Program (Step), a ‘concierge’ style process to improve communication with the agency and streamline the route to approval.

“The review does not bypass statutory requirements or make it faster, but it certainly helps the cause,” Mr Kavanagh says.

Finances and performance

Consolidating its post-pandemic recovery, Nanosonics reported revenue of $166 million, 38 percent higher, in the year to June 2023.

Net profit surged 431 percent to $19.9 million. Adjusted to exclude expenditure on growth initiatives, earnings from the existing sales grew 175 percent to $32.5 million.

At August’s full-year profit, management guided to 15 to 20 percent revenue growth in 2023-’24. At last week’s AGM, management declined to update the current-year outlook, given only four months of it had elapsed.

The 2022-’23 research and development bill amounted to $29.5 million, up 32 percent and attributable mainly to the Coris program. The R&D spend accounted for 18 percent of revenue, compared with the industry standard of 12 percent. But Mr Kavanagh says this proportion will decline as the company matures and grows its revenue.

Capital sales (that is, Trophon units) accounted for 67 percent of total revenue ($54.2 million, up 44 percent), with consumables (the cartridges) and service income accounting for the rest (112 million, up 35 percent).

Over the last 12 months, Nanosonics shares have traded between $3.28 (mid-October 2022) and $5.80 (late April this year). They peaked at a record $8 in December 2020 and have traded as low as 18 cents (November 2018).

What the brokers say

Broker Wilsons’ Nano-watcher Dr Shane Storey says the company’s full-year earnings beat expectations, but the Coris delay announcement was “clearly the biggest disappointment”.

He notes the “ongoing dismay of investors who have long awaited Nanosonics’ second product”.

The firm chalks in a modest $12.8 million of inaugural Coris revenue in the 2025-’26 year.

Dr Storey still rates Nanosonics as “overweight” – which is current stockbroker-marketing-speak for “a buy” - but has downgraded his valuation from $6 to $5.46.

RBC Capital Markets concurs the profit was okay, but lower-than-expected new Trophon sales, the Coris delay and weak guidance were all negatives.

For its two bobs’ worth, Citi rates the stock a sell, with a revised valuation from $4.20 a share to $3.90.

“It remains unclear when markets outside the US will become material,” the firm harrumphs.

Dr Boreham’s diagnosis:

Is Nanosonics undervalued?

Mr Kavanagh notes the Trophon business generated a pre-tax profit of $44 million, which means the company would be wildly profitable if it simply stopped investing in new products.

The installed Trophon base is still ticking up and with the average unit now seven years old, more users will be angling for an upgrade.

Management cites an “installed base opportunity” of 140,000 units: 60,000 in the US, 40,000 in Europe/Middle East and 40,000 in Asia Pacific.

If Crucible’s slide rule is correct, Nanosonics has a 23 percent overall market penetration. But this is skewed by a market share approaching 50 percent in the US and only five percent in Europe and the Asia Pacific (albeit with 85 percent saturation of Australia).

Not surpassing, the company is ramping up its sales efforts in the UK, Ireland, and Germany, while it’s got more than a weather eye on the germ-obsessed Japanese market.

One broker opines the company is “catalyst-less” until Coris gets to market - a claim with which Mr Kavanagh can’t agree.

“The growth prospects for the business for Trophon alone are still quite robust and the business continues to evolve,” he says.

As one market luminary - possibly Warren Buffett - once said: the share market is the transfer of wealth from the impatient to the patient.

On that note, Nanosonics’ 15 percent share slide since its financial results might present an opportunity for the true believers.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he likes to think he posits probing questions while keeping clean at the same time.

AVITA MEDICAL’

Avita says revenue for the nine months to September 30, 2023 was up 44.0 percent to $US35,948,000 ($A56,536,000), with net loss after tax up 32.9 percent to $US28,316,000 ($A44,527,000).
Avita said receipts from customers for the three months to September 30, 2023, primarily from sales of its Recell spray-on skin, were up 50.1 percent to $US13,645,000 million compared to the prior corresponding period.
The company said its increased net loss was a result of higher operating expenses for the three months to September 30, 2023, up from $US14.2 million in the prior corresponding period to $US21.1 million, due to a $5.1 million increase in sales and marketing costs.
Avita said diluted loss per share was up 31.8 percent to $US1.12.
The company said that it had cash and cash equivalents of $US50,854,000 at September 30, 2023 compared to $US23,613,000 at September 30, 2022.
Avita was up 53 cents or 16.7 percent to $3.71 with 635,605 shares traded.

MEDLAB CLINICAL

Medlab says executive director Dr Sean Hall will buy subsidiary Medlab Pty Ltd and it will licence its products to T2 Pharma Pty Ltd, raise capital and make board changes.
In March, Medlab said it retrenched 78 percent of its staff and Hall Chadwick had been appointed to assist a “restructure of the company’s financial affairs” (BD: Mar 7, 16, 2023).
Later that month, the company said it would either sell its intellectual property and pharmaceutical inventory, merge, court a major investor, start a joint venture or sell its corporate shell (BD: Mar 21, 2023).
In September, Medlab said it had received “several” indicative bids regarding its proposed restructure and would consider the offers (BD: Sep 13, 2023).
Today, Medlab said chief executive officer Dr Hall would acquire the Medlab Pty Ltd subsidiary in return for a 20 percent royalty on all revenue from sales of products using the Nanocelle technology as well as any fees for the grant of any licence or sub-licence for the Nanocelle technology, for four years from the settlement date.
The company said Medlab Pty Ltd held all its “intellectual property related to … [its] drug delivery technology and have the right to use this intellectual property in certain patent protected jurisdictions” and the intellectual property would transfer to Dr Hall.
Medlab said it would seek shareholder approval for the agreement with Dr Hall at a general meeting, with the notice of meeting to be released in the “coming weeks”.
Medlab said that the unrelated party T2 Pharmaceutical Pty Ltd would be granted a licence to the Nanocelle technology in countries not patent protected by Medlab, in return for a 16.5 percent royalty payment for any sales revenue or licence fees from the technology.
The company said T2 Pharma was an “innovative start-up” and an unrelated party, with 25 percent of the company owned by Nishnil Singh and 75 percent owned by Dharmit Kaushik Goradia.
The company said it was currently in discussions to hold a capital raising after completing the licencing agreement but had not yet determined the details of the raise, with the funds to be used for working capital and to explore potential opportunities and assets.
Medlab said once it had completed the sale of its subsidiary it would replace some of its directors and appoint alternative directors, but the details of the changes had not yet been determined.
Medlab was in a suspension at a post-consolidation $6.60.

IMUGENE

Imugene says it has dosed the first of 10 patients in its phase Ib trial of its ‘azer-cel’ for non-Hodgkin’s lymphoma and B-cell acute lymphocytic leukemia.
In August, Imugene said it would pay Precision Biosciences up to $US227 million ($A352 million) for its off-the-shelf ‘azer-cel’, or azercabtagene zapreleucel, CD19 chimeric antigen receptor (Car) T-cell therapy for blood cancers (BD: Aug 16, 2023).
Today, the company said the phase Ib trial followed “strong safety and efficacy signals” from 84-patients dosed with its off-the-shelf ‘azer-cel’ technology in a phase I trial.
Imugene said the first phase Ib diffuse-large B-cell lymphoma patient was dosed at Phoenix, Arizona’s Banner Health, and that after the phase Ib trial it would move to a phase II registrational trial in 2024, subject to US Food and Drug Administration approval.
Imugene said chief executive officer and managing-director Leslie Chong said it was a “great credit to our team that the phase Ib study has been initiated and the first patient dosed, in under three months since acquiring the technology”.
Imugene fell half a cent or 4.55 percent to 10.5 cents with 377.1 million shares traded.

LITTLE GREEN PHARMA

Little Green Pharma says investors will vote to approve the separation of its Reset psychedelics business, a capital reduction and an in-specie distribution of shares.
Little Green said its extraordinary general meeting would vote to approve its decision to transfer the “balance of the spin-out assets to Reset and being issued shares in Reset as consideration for the transfer” and that it would retain its medical cannabis business.
The company said that the spin-out of the 3,4 methylene-dioxy-meth-amphetamine (MDMA or ecstasy) and mushroom-based psilocybin psychedelics business was in order “to focus its efforts on its medical cannabis business”.
The company said Reset intended to make a public offering of 10,000,000 shares at 20 cents a share, to raise up to $2,000,000, with existing eligible Little Green shareholders having a priority for up-to 5,000,000 Reset shares.
Little Green said it had a partial underwriting agreement with Reset for the offer and any shares not distributed in the in-specie distribution.
The company said that the offer had a record date of November 9, would open on November 17 and close on December 1, 2023.
Little Green said shareholders would vote to approve a change of auditor.
The meeting will be held online and in person at Level 2, Suite 2, 66 Kings Park Road, Perth on December 11, 2023 at 4pm (AWST).
Little Green was unchanged at 12.5 cents.

ISLAND PHARMACEUTICALS

Island says it has received $386,345 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.
Island said the rebate related to research and development expenditure for the year to June 30, 2023.
The company said the refund was “a valuable and supportive source of funding for the company’s lead asset, ISLA-101, which is being repurposed for the prevention and treatment of dengue and other mosquito borne diseases”.
Island fell 0.3 cents or 3.95 percent to 7.3 cents.

TISSUE REPAIR

Tissue Repair says it will release 13,684,488 shares from ASX mandatory escrow on November 18, of which 4,656,830 shares will be in voluntary escrow until May 18, 2024.
According to its most recent filing, Tissue Repair currently has 46,780,355 shares on issue, meaning that following the release from ASX escrow the company will have 60,464,843 shares on issue, with 4,656,830 shares in voluntary escrow.
Tissue Repair was unchanged at 24.5 cents.

ARTRYA

Artrya says it will release 15,610,470 shares from ASX mandatory escrow on November 26, 2023.
According to its most recent filing, Artrya had 63,038,523 shares on issue and following the release from ASX it would have 78,648,993 shares on issue.
Artrya was up 4.5 cents or 23.7 percent to 23.5 cents with 1,914 shares traded.

NOVA EYE MEDICAL

Nova Eye says it has requested a trading halt in relation to a further “proposed change to national US Medicare reimbursement for minimally invasive glaucoma surgical products”.
Last month, Nova Eye said proposed US Medicare local coverage determination changes included limited or denied coverage for several minimally invasive glaucoma surgery procedures effective from December 24, 2023 (BD: Oct 31, 2023).
Trading will resume November 14, 2023, or on an earlier announcement.
Nova Eye last traded at 18.5 cents.

STARPHARMA HOLDINGS

Starpharma says it has appointed Cheryl Maley chief executive officer and managing-director, replacing Dr Jackie Fairley from January 8, 2024, to be paid $550,000 a year.
Starpharma said Ms Maley was currently a Clarity and had been acting chief executive officer at Biointelect as well as an executive at Novartis, Abbvie/Abbott, Servier Laboratories, Wyeth Pharmaceuticals and the Commonwealth Scientific and Industrial Research Organisation.
The company said Ms Maley would receive a total fixed yearly salary of $550,000 and would be eligible to as well as a short-term incentive of up-to $70,000 and long term incentive with a face value of up-to $330,000.
Starpharma said that from July 1, 2024 Ms Maley would be eligible for short-term incentives up to 50 percent of her base salary in cash and equity and a long-term incentive of up to 80 percent of her salary.
According to her Linkedin page, Ms Maley held a Bachelor of Science and a Master of Business Administration from the Armidale, New South Wales’ University of New England.
Starpharma chair Rob Thomas thanked Dr Fairley “for her dedicated leadership and service to Starpharma during the last 17 years”.
“Throughout her tenure, Jackie transformed the company from a start-up to a mature business with a highly valuable platform technology,” Mr Thomas said.
“Jackie’s foresight and determination led to the development of our [dendrimer-enhanced product] portfolio, which has significantly expanded the company’s commercialization opportunities for the dendrimer technology,” Mr Thomas said.
Starpharma was unchanged at 14 cents with 2.8 million shares traded.

RESMED

Resmed says chief operating officer Robert Douglas will retire and it is restructuring and changed its operating model “to accelerate long-term growth”.

Resmed said that Mr Douglas had transitioned from chief operating officer to special adviser to the chief executive officer effective immediately and would retire effective from January 1, 2024.

The company said that the head of sleep and respiratory care Lucile Blaise would become the head of strategy and business development, with the head of Asia and Latin America Justin Leong appointed chief product officer, the head of Germany Katrin Pucknat to be the chief marketing officer and the head of North America sales Mike Fliss appointed as chief revenue officer.

The company said the change “aims to increase the velocity of product development and sharpen our customer and brand focus”.

Resmed fell 59 cents or 2.6 percent to $22.39 with 3.1 million shares traded.