Biotech Daily

Friday April 5, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ORTHOCELL UP 9%; PARADIGM DOWN 4.35%**

*** DR BOREHAM'S CRUCIBLE: RACE ONCOLOGY**

*** ATMO TO RAISE $15m**

*** REGENEUS COMPLETES CAMBIUM MERGER; RAISES $3.5m**

*** BIOTRON: 'BIT225 COMBO BEATS STANDARD-OF-CARE FOR HIV'**

*** ONCOSIL TREATS 1st AUSTRIAN PANCREATIC CANCER PATIENTS**

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*** HERAMED TAKES 'RESTRUCTURE, SHORTFALL' HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 0.56 percent on Friday April 5, 2024, with the ASX200 down 44.0 points to 7,773.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 were down, seven traded unchanged and one was untraded. All three Big Caps fell.

Orthocell was the best, up 3.5 cents or 9.2 percent to 41.5 cents, with 213,746 shares traded. Percheron climbed 6.4 percent; Syntara was up 5.3 percent; Proteomics was up 4.9 percent; Immutep improved 3.85 percent; Resonance, Telix and Universal Biosensors rose more than two percent; Compumedics, Impedimed, Nanosonics, Opthea and Polynovo were up more than one percent; with Pro Medicus and Volpara up by less than one percent.

Paradigm led the falls, down 1.5 cents or 4.35 percent to 33 cents, with one million shares traded, followed by Micro-X down 4.2 percent to 11.5 cents, with 61,341 shares traded. 4D Medical, Actinogen, Dimerix and Mesoblast lost more than three percent; Alcidion, Amplia, Cochlear, Cynata and Next Science shed more than two percent; Avita, Clarity, Medical Developments and Prescient were down more than one percent; with Clinuvel, CSL, Cyclopharm, Neuren and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: RACE ONCOLOGY

By TIM BOREHAM

ASX code: RAC

Share price: $1.63; **Shares on issue:** 165,172,030; **Market cap:** $269.2 million

Financials (December half 2023): revenue nil, loss of $5.66 million ($4.41 million deficit previously), cash of $13.7 million (down 48%). During the period the company received a $4 million research and development tax incentives and $461,428 in interest

CEO: Dr Daniel Tillett

Board: Mary Harney (chairman), Dr Pete Smith, Phillip Lynch (Dr John Cullity resigned in August 2023)

Major identifiable shareholders: Dr Daniel Tillett 9.9%, Dr John Cullity 4.1%, Phillip Richard Perry 3.7%, Mark Juan 3.5%, Merchant Opportunities Fund 2.7%

The home of the repurposed cancer drug bisantrene, Race Oncology has been settling down after doing some 'repurposing' of its own - management-wise.

In August last year new CEO Damian Clarke-Bruce described the company's quest for a new "North Star": pursuing an oncology program based on its lead indication metastasized breast cancer (MBC).

For the navigationally challenged, a North Star symbolizes direction, guidance, stability and purpose - due to its fixed position relative to other stars.

Two weeks later Mr Clarke-Bruce – appointed only in February of that year - was gone and the company was consulting its compass again.

The befuddling strategy revamp saw the return of Dr Daniel Tillett, the company's biggest shareholder and former chief scientific officer, as CEO. Dr Tillet in effect runs the company with Dr Peter Smith, who has changed from non-executive to executive director.

Amid the upheaval, the new – or perhaps that old – guard maintains that the Race story essentially remains the same: developing bisantrene as a cardio-protective tool to enhance the efficacy of existing cancer drugs.

A key change is that the intended metastasized breast cancer trial has changed from an envisaged US program to a local study of broader solid cancers.

Race is also pursuing a treatment for acute myeloid leukaemia (AML).

"[The strategy] is evolution, not revolution," Dr Tillett says.

Pimping up an old drug

Race was founded in 2013 when US physician and entrepreneur Dr William Garner reviewed medical literature about bisantrene, which was approved by French authorities for acute myeloid leukaemia (AML) in 1988. AML is an aggressive cancer, with only one-third of patients surviving beyond a year.

The drug was developed in the 1980s by French group Lederle Laboratories as an anthracycline - a chemo-therapeutic – but without the common cardio-toxicity that results in many cancer patients dying of heart failure.

Extensive clinical trials covering 1,800 patients in 46 trials confirmed both the drug's cardio-protective and anti-tumor activities.

Lederle was taken over by American Cyanamid, which had no interest in the drug and Bisantrene ended up in the hands of the Nevada-incorporated Update Pharma, owned by Dr Garner, pharmaceutical scientist Dr John Rothman and Dr Peter Molloy (see below).

Race listed in July 2016 via a resources shell, raising $4.3 million at 20 cents apiece.

So who's in charge here?

Best known as head of the ASX-listed influenza drug developer Biota, Dr Molloy resigned from Race to devote his attention to anti-infectives house Firebrick Pharma (which listed on the ASX in January 2022). Race was then run by executive chair Dr John Cullity and Dr Tillett, before the latter resigned in March 2023 after a disagreement on strategy.

A former executive at Johnson & Johnson's consumer division, Phillip Lynch took over as CEO in May 2020, to be replaced by Mr Clarke-Bruce in February 2023.

Dr Smith was appointed to the board in June, replacing Daniel Sharp. In April, Mary Harney was appointed chair, replacing Dr Cullity who resigned from the board in August.

With three decades' experience in drug development, Dr Smith was the former CEO of the ASX-listed Alchemia and Amrad.

Earlier, Dr Garner was a director and Race's biggest shareholder. He quit the board in October 2020 and sold down his shareholding in the latter part of 2021.

Great for cancer, not for the heart.

Derived from bacteria, anthracyclines are widely used to treat many types of solid and blood cancers.

They work okay, but the trouble is that after six years, about half of the metastatic breast cancer patients on these drugs will develop cardiac problems such as arrythmias, left ventricular disfunction and full heart failure.

“Literally millions of patients around the world are damaged by these drugs every year,” Dr Smith says. “There aren’t alternatives and probably won’t be for a long time.”

A classic case of the cure being worse than the disease?

The company is in the throes of reformulating bisantrene as RC220, enabling a more convenient delivery via infusion through veins in the arm, rather than a main artery.

Last month, Race said that its contract manufacturer, Ardena NV had produced 2,600 vials of RC220 to the “exacting standards” of local, European and US regulators. The key significance here is that the drug is now ready for use in trials.

Where’s the proof?

Race’s acute myeloid leukaemia (AML) program is focused on an estimated 16,000 patients classed as unfit for current treatments (relapsed or refractory) and awaiting a bone marrow transplant. The company also targets extra-medullary AML, when tumors escape from the bone marrow, enter the surrounding tissue and behave like solid tumors.

Currently, the AML program is focused on an ongoing investigator-led, phase II, open label trial at Israel’s Chaim Sheba Medical Centre.

In December last year, Race reported results from the first 15 evaluable relapsed or refractory AML patients treated with bisantrene in combination with the standard-of-care fludarabine and clofarabine. Six patients (40%) responded, with five complete responses and one partial response. The complete responders were able to be bridged to a stem cell transplant within three months of treatment.

“To see such meaningful clinical responses in a group that would typically be receiving palliative care is striking,” Dr Smith said. “It is also encouraging that the safety profile was manageable, even for this advanced patient population.”

On the back of the “stunning” results, Dr Smith says Race has been approached by an “experienced haematologist” who wants to do an investigator-sponsored phase I/II trial in Australia. Costed at up to $4 million, the trial would target up to 60 patients and would kick off in late 2024 or early 2025.

Meanwhile, Race last month announced that bisantrene showed “potent anti-cancer activity” in diverse cell and animal models for acute myeloid leukaemia, in combination with the chemotherapy drug decitabine. While pre-clinical in nature, the announcement appeared to spark a strong share surge (or at least coincided with one).

We’ll take all comers

The company had intended to do a metastatic breast cancer trial in the US, comparing bisantrene with the standard-of-care doxorubicin, but the phase Ia/Ib trial would have been costly and would not have met the company’s honed strategy of achieving things with existing resources.

The trial will now be carried out in Australia, enrolling 25 to 50 patients at 10 sites. The cost is expected to be $11 million, about one quarter to one third less than a US trial (and that's before the Federal Research and Development Tax Incentives).

The trouble is, not enough breast cancer patients can be recruited here because doxorubicin is not so much used because of the cardio-toxicity issues.

The solution? Open the trial to patients with other relevant solid cancers where doxorubicin is used, such as sarcomas and ovarian cancers.

Dr Smith says Race's original approach is "completely intact", because bisantrene historically has been effective against a range of solid cancers.

"It's just a question of where we do it and how it is funded."

The trial is expected to start later this year. Pending the results, the company plans a $32 million follow-on trial of up-to 120 patients, focusing on cardio protection.

Finances and performance

Race held cash of $13.7 million at the end of December 2023, the remnants of a $30 million raising in a share purchase program in November 2021. While the company recorded no revenue it pocketed a research and development tax incentive of $4 million and $461,428 in bank interest.

Bizarrely for a biotech, post-raising Race launched a share buyback of up to four million shares. In the early days of his short reign, Mr Clarke-Bruce called it off in favor of investing in the advertised clinical programs - which sounds reasonable.

In an unusual 'buy now, pay later' fund raising, in November 2023, Race announced two tranches of bonus options, aimed at raising up to $36.7 million.

The one-for-20 options are exercisable at 75 cents each, up to June 2024. For each option exercised, punters get three 'piggyback' options exercisable at $1.25 by May 2026.

Dr Smith says management structured the raising partly as cost-of-living relief, in that investors didn't have to shell out in the cash-sapping pre-Christmas period.

In any case, the company doesn't need the money until the trials start.

With Race shares climbing from their 12-month low of 67 cents on February 6 this year to $1.69 on March 18, all these options are in-the-money and a trickle of them have been exercised already.

Race shares peaked at $3.70 (March 2021) and traded as low as 5.0 cents, in mid-2019.

Meanwhile, Dr Tillett says he is "already overweight" - financially, not metabolically speaking - but nonetheless will take half of his salary as well out-of-the-money options (at a strike price of $4.25).

No offence, Fatso

Speaking of weight, Race also has an interest in the fat mass and obesity associated protein (FTO), which is overexpressed in a diverse range of cancers, including melanomas and clear-cell carcinomas.

Naturally, it's known as Fatso.

Because it regulates cancer stem cells, Fatso plays a critical role in cancer development and progression.

Research at Los Angeles' City of Hope hospital identified two small molecules that appeared to suppress tumor growth in multiple cancers, when other treatments failed.

No prizes for guessing that one of them was bisantrene.

In July 2023, Race and the City of Hope struck an exclusive licencing deal pertaining to the hospital's Fatso intellectual property.

Dr Boreham's diagnosis:

The Race story is a familiar one in Australian biotech: a solid scientific story lacking a commercial vision, resulting in management resets, confusing strategic U-turns and a sagging share price.

But these companies plug away and eventually investors will take another look - as last month's 150 percent share spurt attests.

As with other drug repurposers such as Paradigm Biopharmaceuticals and Pharmaust, and a previous incarnation on Invion, Race has the benefit of the big dollars the former owners sunk into the drug candidate.

"Our strategic plan now provides a clear regulatory pathway," Dr Smith says.

As Dr Tillett notes, the drug was approved in the 1980s for acute myeloid leukaemia and there's little doubt it works.

"It's finding the right way to bring it forward commercially and get the best returns for shareholders."

Ah! That's always the tricky but, but at least the compass bezel at Race HQ looks to be aligned with true North.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Forever navigationally challenged, his new North Star is Google Maps and Siri.

ATMO BIOSCIENCES

Ord Minnett says that Melbourne's Atmo hopes to raise $15 million at $1.65 a share, for its gas-sensing gut capsule, with $10.5 million committed by existing investors.

Stock-brokers Ord Minnett said the funds will be used to "complete product development and develop its US market opportunity … [for] the world's first ingestible gas-sensing capsule, to provide unique insights into gut health and the microbiome function".

Last year, Atmo said it raised $8 million to study the gas-sensing capsule for assessing gastro-intestinal motility such as gastro-paresis and constipation (BD: Mar 30, 2023).

In December, Atmo said it had recruited more than 200 patients in its pivotal trial of its gas sensing capsule with results to be used for a US Food and Drug Administration 510(k) application (BD: Aug 10, Dec 14, 2023).

Today, Ord Minnett said the raise had the support from existing investors, including Japan's Otsuka Pharmaceutical Co and Breakthrough Victoria.

The company said that a US launch was planned this year, pending FDA 510(k) approval.

Atmo chief executive officer Malcolm Hebblewhite told Biotech Daily that "the pre-money valuation is $54.7m on a fully diluted basis".

"We recently successfully completed a pivotal clinical trial and we are drafting a 510(k) submission to the FDA which will be submitted this quarter," Mr Hebblewhite said. "Funds will be used to obtain a clearance, launch the product in the USA for an initial indication this calendar year, and generate first revenues in an under-penetrated market."

"The predicate device used in the pivotal trial has been discontinued, leaving an opportunity to fill a clear unmet clinical need for gastroenterologists by providing them with a reimbursable diagnostic tool to diagnose and manage common and debilitating gut motility disorders," Mr Hebblewhite said.

Ord Minnett said it was the lead manager to the raise.

Inquiries should be directed to Ord Minnett's managing-director and head of capital markets Gavan Carroll at GCarroll@ords.com.au, Atmo chief executive officer Mr Hebblewhite at mal.hebblewhite@atmobiosciences.com or Atmo chief financial officer Carl Runde at carl.runde@atmobiosciences.com.

Atmo is a public unlisted company

REGENEUS

Regeneus says it has completed its merger with Cambium Medical Technologies LLC and will change its name to 'Cambium Bio Limited' and trade under ticker code 'CMB'.

Last week, the company said investors voted 98.5 percent in favor of its merger with the Atlanta, Georgia-based Cambium Medical Technologies for its Elate Ocular for dry eye disease and to rename the company 'Cambium Bio' (BD: Mar 28, 2024).

Today, Regeneus said it raised $3.48 million in a placement at 0.6 cents a share, or a 20 percent premium to yesterday's closing price, to fund non-clinical studies of Elate Ocular and prepare for phase III trials as well as general working capital purposes.

The company said following the merger Terence Walts would become an executive director, head of US operations and remain as chief executive officer of Cambium Medical Technologies on a salary of $US300,000 ($A4567,000) a year, with Dr Edmund Waller an executive director and part-time chief scientific officer on an annual salary of $US100,000.

Regeneus said director Leo Lee had resigned, with chair Barry Sechos to remain as chair of Cambium Bio and Dr Yu Hung (Sebastian) Tseng to be appointed a director.

The company said it had lodged a notice of name change with the Australian Securities and Investment Commission, and its ASX code would change to 'CMB'.

Regeneus was up 0.8 cents or 160 percent to 1.3 cents with 33.1 million shares traded.

BIOTRON

Biotron says a 27-patient, phase II trial of BIT225 with standard-of-care shows a “more rapid reduction in plasma virus levels” compared to standard-of-care alone ($p < 0.02$).
In 2021, Biotron said it had begun a 27-patient, Thailand-based, phase II trial, for the first-time testing BIT225 in people who had been taking approved anti-retroviral drugs for an extended period, with well-controlled HIV-1 infections (BD: Nov 1, 2021).
Today, the company said the 24-week, double-blind, placebo-controlled trial showed a daily 200mg dose of BIT225 in combination with an anti-retroviral therapy of 50mg of Dolutegravir, 300mg of Tenofovir disoproxil fumarate and 200mg of Emtricitabine was “safe and generally well-tolerated”.
Biotron said preliminary analysis indicated “a more rapid viral clearance between days 14 and 56”, or the second phase of viral decay, than in patients receiving the standard-of-care therapy alone ($p < 0.02$).
The company said it observed changes in immune cell populations compared to the control group, with statistically significant differences in levels of clusters of differentiation 4 (CD4) and CD8 T-cells ($p < 0.05$), as well as CD16/56 natural killer cells, which were a “key cell type combatting viral infection”.
Biotron said adverse events from BIT225 administration in the trial were “congruent with that seen in previous trials”.
The company said two patients withdrew from the study with one withdrawal was not related to BIT225 or standard-of-care anti-retroviral therapy.
Biotron chief executive officer Dr Michelle Miller said “the positive outcomes from this trial further our understanding of BIT225”.
“The blood plasma viral load data in particular should be highlighted, as it suggests that BIT225 is having an impact on a critical phase of viral decay when latent reservoirs are established,” Dr Miller said.
“Current [anti-retroviral therapy] is efficient at rapidly and durably reducing virus levels in the blood, but this does not translate into clearance of latent reservoirs,” Dr Miller said.
“The observed changes to immune markers and cells further the results from the previous … trial and suggest the utility of targeting viroporins as a new class of antiviral drugs,” Dr Miller said.
“The results reported here are preliminary, and ongoing analysis of the … study … will be reported when complete,” Dr Miller said.
Biotron was up 0.7 cents or 9.3 percent to 8.2 cents with 78.4 million shares traded.

ONCOSIL MEDICAL

Oncosil says the first two patients in Austria have been treated with its radiation device for pancreatic cancer with chemotherapy.
Oncosil said the treatments took place yesterday at the Universitätsklinikum St Pölten (Saint Polten University Hospital).
The company said Austria was the fourth European country after Spain, Italy and Greece where commercial treatment using its device for locally advanced pancreatic cancer had been completed.
Oncosil said it expected treatment in other European countries in the coming months, with the UK, Portugal and Germany beginning “training on the usage of the … device”.
Oncosil chief executive officer Nigel Lange said “these treatments yet again demonstrate our ability to deliver tangible evidence that the Oncosil device is gaining traction as a treatment option for patients with locally advanced pancreatic cancer”.
Oncosil was unchanged at half a cent with 45.5 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says Amsterdam University has begun using its Northstar 3-dimensional mapping system for cardiac ablation, after a delay due to the Covid-19 pandemic.

In 2022, Imricor said that the Northstar-MR used Siemens magnetic resonance imaging (MRI) scanners and removed "the reliance on others to develop 3-D mapping systems needed for complex ablation procedure" (BD: Dec 15, 2022).

Today, Imricor said Amsterdam University Medical Centre was constructing a laboratory for magnetic resonance imaging-guided ablations, and that its existing laboratory was being used for ablation procedures in the meantime.

Earlier this year, the company said it had approval for an up-to 91-patient trial of its Vision-MR cardiac ablation catheter and irrigation pump products at three sites in the US, Switzerland and France (BD: Jan 21, Mar 8, 11, 2024).

Today, the company said the centre was "pursuing final approvals required to participate in [its] … trial with more hospitals joining the trial in the near future".

Imricor fell 3.5 cents or 5.9 percent to 55.5 cents.

MACH 7 TECHNOLOGIES

Mach 7 says the US Court of Appeals for the Federal Circuit has dismissed the Dallas, Texas-based AI Visualize Inc's patent infringement lawsuit.

In 2021, Mach 7 said it would vigorously defend itself against allegations of patent infringement brought by the Plano, Texas-based AI Visualize (BD: Nov 8, 2021).

In 2022, the company said the US District Court for the District of Delaware had granted its request to dismiss all claims made by AI Visualize; and later, said that AI Visualize had appealed the dismissal (BD: Jul 13, Aug 10, 2022).

At that time, Mach 7 said that AI Visualize alleged that Nuance Communication's Powershare Network, in combination with Mach7's Eunity diagnostic image viewing platform, infringed four US patents, which described "methods and systems for fast access to advanced visualization of medical scans and three-dimensional views using a dedicated web portal".

The company said the US Court of Appeals dismissed the claim, ruling that the patent claims were "patent ineligible because they are directed to an abstract idea and fail to transform that abstract idea into patent-eligible subject matter".

Mach 7 said it was "pleased with the affirmation of this dismissal and the closure of this legal action".

Mach 7 was up half a cent or 0.7 percent to 70.5 cents.

CHIMERIC THERAPEUTICS

Chimeric says the US Patent and Trademark Office has granted it a patent for its natural killer-cell therapies including CHM0201, CHM0301, CHM1301 and CHM2301.

Chimeric said the patent, titled 'Compositions for Expanding Natural Killer Cells', protected the technology used to manufacture its intellectual property until 2039.

Chimeric chief executive officer Jennifer Chow said the patent laid "the foundation for the intellectual property portfolio supporting our best-in-class pipeline of allogeneic NK cell assets.

Chimeric was unchanged at three cents with 3.8 million shares traded.

VITURA HEALTH

Vitura says Perth's Optima Ovest has begun manufacturing 40mg 3,4-methylene-dioxy-meth-amphetamine (MDMA) capsules for use in clinics and trials.
In 2023, Vitura said it had a 50-50 joint venture with Toronto's Pharmala Biotech, called Cortexa Pty Ltd, to produce and supply psychedelics for Australian research and clinical use, including MDMA and psilocybin (BD: May 2, 2023).
Today, the company said the deal with Ovest would "free local clinicians and researchers from the costly and time-consuming burden of importation and provides seamless access to medication".
Vitura was up half a cent or 3.0 percent to 17 cents.

EMYRIA

Emyria says a second psychiatrist has been granted Therapeutic Goods Administration authorized prescriber status for 3,4-methylene-dioxy-meth-amphetamine (MDMA).
Emyria said it believed the psychiatrist was the "first, and currently only, female authorized prescriber for MDMA-assisted therapy in Australia".
Emyria was up 0.1 cents or 1.6 percent to 6.2 cents.

SOMNOMED

Somnomed says it has requested a further extension to its voluntary suspension while it prepares an entitlement offer and finalizes a downgrade of its earnings guidance.
On Tuesday, Somnomed requested a suspension following last week's trading halt in relation to "a trading update and earnings guidance" (BD: Mar 27; Apr 2, 2024).
Today, the company said it expected to make the announcement by April 9, but requested to remain in a suspension until April 10, 2024.
Somnomed last traded at 38.5 cents.

HERAMED

Heramed has requested a suspension, following Wednesday's trading halt regarding board changes, business restructure and the rights issue shortfall" (BD: Apr 3, 2024).
Trading will resume on April 29, 2024, or on an earlier announcement.
Heramed last traded at 1.7 cents.