Biotech Daily

Friday February 19, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 15%; ONCOSIL DOWN 12%**

*** DR BOREHAM'S CRUCIBLE: CSL**

*** COCHLEAR H1 REVENUE DOWN 4.5% TO $743m, PROFIT UP 50% TO $236m**

*** SDI H1 REVENUE DOWN 8% TO $37m, PROFIT UP 12% TO $3.5m**

*** ANTERIS REVENUE DOWN 59% TO $7m, LOSS UP 147% TO $15m**

*** REDHILL DOSES 1st RHB-107 COVID-19 PATIENT; COSMO DEAL**

*** PRO MEDICUS CO-FOUNDERS SELL 2m SHARES**

*** SIMAVITA BIDS ASX ADIEU**

*** MGC: SWISS PHARMACAN ARTEMIC FOR COVID-19 DISTRIBUTOR**

*** PAINCHEK PLEADS SCHULTZ TO ASX 29% PRICE QUERY**

*** ALTOR TAKES 6% OF HERAMED**

*** RACE LOSES 5-MONTH CMO PROF BORJE ANDERSSON**

MARKET REPORT

The Australian stock market fell 1.34 percent on Friday February 19, 2021, with the ASX200 down 92.1 points to 6,793.8 points. Five of the Biotech Daily Top 40 stocks were up, 22 fell and 13 traded unchanged.

Optiscan was the best of the few, up 2.5 cents or 15.15 percent to 19 cents, with 601,644 shares traded. Cochlear climbed 8.4 percent; Kazia and Next Science improved more than four percent; Pro Medicus rose 2.2 percent; with Avita and Resmed up by more than one percent.

Oncosil led the falls, down 1.5 cents or 12 percent to 11 cents, with 9.95 million shares traded. Impedimed lost 10 percent; Actinogen, Prescient and Uscom were down eight percent or more; Antisense fell 7.5 percent; CSL and Proteomics fell five percent or more; Genetic Signatures and Orthocell were down more than three percent; Avita, Clinuvel and Compumedics shed more than two percent; Dimerix, Medical Developments, Nanosonics, Opthea, Paradigm, Starpharma and Universal Biosensors were down more than one percent; with Cyclopharm, Cynata and Neuren down by less than one percent.

DR BOREHAM’S CRUCIBLE: CSL

By TIM BOREHAM

ASX code: CSL

Share price: $274.43; **Market cap:** $124.9 billion; **Shares on issue:** 454,997,506

Chief executive officer: Paul Perreault

Board*: Dr Brian McNamee (chairman), Paul Perreault, Dr Andrew Cuthbertson (CSO), Bruce Brook, Dr Megan Clark, Shah Abbas Hussain, Marie McDonald, Carolyn Hewson

***** Astrazeneca CEO Pascal Soriot resigned from the board, effective February 1, 2021. Christine O’Reilly retired from the board in October 2020

Financials (December half): revenue $US5.7 billion (up 16%), net profit $US1.8 billion (up 45%), earnings per share $US3.98 (up 44%), dividend $US1.04 (up 9%), cash of $US2.4 billion (up 100%)

Identifiable major shareholders: Blackrock 6.02%, Vanguard Group 4.9%, Australian Foundation Investments 0.44%, Argo Investments 0.25%.

While CSL has been in the news because of its role in the coronavirus vaccine rollout, yesterday’s half-year results highlight the real life-blood of the company: plasma.

Industry wide, things are getting interesting in terms of collection of the yellow-colored liquid component of our claret, from which CSL derives so many therapies.

In essence, the pandemic has dented plasma collections in CSL’s key US market, posing the risk of a shortage of key drugs such as immunoglobulin (IG) products.

CSL chief executive Paul Perreault says “collecting plasma is one of the hardest things we do at CSL” - a weighty observation given the scope of the company’s activities across its core Behring (plasma) business and its vaccine/biotherapies arm Seqirus.

Speaking of which, the pandemic had the overall effect of “crimping” the Behring side of the business and generating a bonanza profit for Seqirus.

But - hey - they both did more than okay: CSL’s reported net profit soared 44 percent to $US1.81billion ($AUD2.35 billion), exceeding investor expectations.

Some pundits now reckon the company is playing it safe with its (reaffirmed) full-year profit guidance.

But nothing is ever simple with CSL, which has more moving parts than a Meccano set.

The problem with plasma

CSL runs 280 plasma collection centres, mainly in the US where, unlike here, donors are paid.

As an essential service along with bottle shops, these centres remained open but the various mobility restrictions meant donor traffic still declined, with donors harboring concerns about safety and hygiene.

Management revealed that donations declined 20 percent in December, while the per-litre cost of collection increased by a similar amount. The company is tackling the issue with measures such as easier device-based registration for existing donors, to reduce waiting times.

Lapsed donors are being contacted again, while 17 new US collection centres were opened during the six months (with an expected 12 more in the second half-year).

While collections are improving month-on-month, Mr Perreault says "plasma collections have been challenging and will continue to be challenging".

Presumably the higher unemployment created by the pandemic would have boded well for collections, given the imperative for people to make a quick buck. But donor frequency also falls when government stimulus cheques (or tax returns) land in the mail - as they are now.

IG therapies led the way

The raw material issue aside, Behring did well with the product - an overall 11 percent sales boost to $US4.3 billion. The division's underlying earnings grew 24 percent, to $US1.7 billion. Demand was led by the core immunoglobulin portfolio, up seven percent to $US2.2 billion.

Immunoglobulins are antibodies (proteins) produced by the plasma cells and most notably are used to treat primary immune deficiency (PID) and chronic inflammatory demyelinating polyneuropathy (CIDP).

CSL's IG sales were led by the subcutaneous therapy Hizentra, which allows PID and CIDP patients to self-administer at home.

"This has allowed patients to better control their disease during the current lockdown measures," Mr Perreault says.

Albumin sales grew by a "seemingly amazing" 93 percent, but this result was skewed by the company's move to an own-distribution model in China, which had adversely affected results last time around. Albumin is the protein that makes up 60 percent of plasma, used in critical care including fluid resuscitation.

Fewer doctor consultations during the pandemic meant that demand for haemophilia products was a tad anaemic, up one percent.

Among the specialty products, Haegarda starred with a 17 percent sales increment. Launched in 2019, Haegarda treats patients with hereditary angioedema (severe swelling of the face and throat).

Demand for CSL's coagulation product Kcentra should have been impacted by reduced hospital procedures and fewer accidents, but sales rose six percent. Kcentra reverses effects of blood thinning drugs, in effect to stop patients from bleeding to death.

Toilet paper rationing one day, drugs the next?

The industry-wide dip in plasma collections poses the risk of drug shortages, especially in the IG sector which accounts for half of Behring's sales.

Mr Perreault says the company is managing the situation tightly to avoid disruptions, including not signing on new customers and ensuring "fair and equitable" supply to existing ones. "IG supply was tight even before the pandemic," he says.

Or do we C-IDP a competitive IG threat?

In early February, Dutch biotech Argenx said it would push on with enrolling 130 patients in a late-stage trial evaluating subcutaneous efgartigimod, to treat chronic inflammatory demyelinating polyneuropathy (CIDP).

The compound has also been successful with myasthenia gravis (MG) and immune thrombocytopenic purpura (ITP).

Broker Goldman Sachs reckons these ailments account for 10 to 15 percent of IG demand. A $US13 billion market, CIDP accounts for 25 to 35 percent of demand and "plays an important role in industry economics".

Efgartigimod is in a new class of drug called an FcRn inhibitor - and no we're not being rude.

A shot in the arm for 'flu vaccine sales

While social distancing reduced the incidence of influenza, Seqirus still benefited from record dose volumes (more than 100 million) as governments sought to protect vulnerable citizens from the "twindemic" of the coranavirus and the traditional winter lurgy.

Seqirus's revenue grew 38 percent to $1.4 billion, while underlying earnings more than doubled to $US693 million.

The US and Europe accounted for 80 percent of Seqirus sales. The division's revenue is also 80 percent skewed to the six months to December 31, while expenses are spread through the year, which means the current (second half) will be loss making.

Then there's the whole Covid-19 vaccine saga which involved Seqirus hastily changing tack from being a vaccine developer to a "fill and finish" manufacturer of the Oxford-Astrazeneca prophylactic.

CSL was in cahoots with the University of Queensland to develop a vaccine, with a phase I trial of 216 participants eliciting a "robust response" with a strong safety profile.

The trouble is the jabs had the potential to elicit "false positive" HIV responses in later trials and that was enough to kybosh development.

CSL is now contracted to make (or, technically, fill and finish) 50 million doses of the Astrazeneca Oxford vaccine on behalf of the Australian government.

The terminated vaccine program delivered a one-off revenue benefit of $US80 million for Seqirus. However, there was also a hefty "opportunity cost" with 400 people re-deployed or recruited and more than 11 million doses produced. Presumably these will go down the drain.

Meanwhile, the Astrazeneca vaccine is on track to be available by late March.

CSL is also preparing to trial a plasma-based experimental Covid-19 therapy to treat severe respiratory complications. Known as CSL760, the drug candidate has been developed using donations of plasma from people who have recovered from the virus.

"If successful this will become one of the earliest treatment options for hospitalized Covid-19 patients," Mr Perreault says.

Pollie takes a jab at CSL no-show

Being a former government enterprise, CSL is usually quite adept at handling politicians and we all saw the photo-opportunity yarns when the Broadmeadows vaccine facility cranked up.

But management copped a rare broadside in late January, when independent senator Rex Patrick accused the company of disrespecting the Parliamentary Covid-19 inquiry by not sending a body to the first hearing.

CSL said everyone was simply too busy gearing up to manufacture the 30 million doses and no one could be spared – not even the mail room boy.

Finances and performance

While the result was well received - CSL stock rose by as much as five percent after Thursday's announcement - the outlook is somewhat clouded by the plasma availability issue and the costs of procuring the donations.

The products manufactured now are based on plasma donated last year, at a higher per-litre cost. And the cost of plasma now will shape CSL's fortunes next financial year.

One unintended benefit of the decline in donations was an 87 percent improvement in cash flow, to $US2.3 billion. In some investing circles, cash is king.

Management has re-affirmed guidance of $US2.17 billion to $US2.26 billion for the full year to June 2021, up three percent to eight percent on the previous year.

Given the $US1.81 billion first-half profit, this implies a subdued second half even allowing for an expected seasonal loss for Seqirus.

Unlike most other biotech stocks, CSL's have not been coronavirus heroes. They've traded around the $270 to $280 level and are yet to re-test their all-time peak of $331, on February 14 last year.

In case anyone needs reminding, the then Australian Government-owned CSL listed at $2.30 in 1994. Given CSL also underwent a three-for-one share split in 2007, today's shares would be worth about $878 each - or a 380-bagger.

Dr Boreham's diagnosis:

The pandemic-era share decline means that CSL has lost its mantle of the biggest ASX-listed company, with the Commonwealth Bank of Australia restoring its status at the top of the pile.

But fundamental demand for CSL's life-saving therapies looks to continue unabated, because they're - well - life saving therapies.

However, there are enough swirling doubts about costs and plasma supply to put a lid on things for the time being.

Perhaps the most uplifting aspect of the results is the bold showing of Seqirus, which looked like a dog when it was delineated as a separate division five years ago.

By any measure it's a howling success. Despite the emphasis on Covid-19 vaccine production, don't expect the vaccines to be a big money spinner, with no expected earnings impact for the current year.

As always, CSL trades on a seemingly toppish earnings multiple of more than 40 times expected current earnings. But the company has always justified such a premium with steady earnings increases, aided and abetted by share buy-backs that increase earnings per share.

Ultimately, valuations are in the eye of the beholder, with CSL's $130 billion market cap not looking at all lavish, compared to market hero Afterpay, the unprofitable buy-now-pay later stock valued at $43 billion, or Facebook's $US767 billion or Apple's $US2.3 trillion.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He would never snub a parliamentary committee in the unlikely event of being invited to one.

COCHLEAR

Cochlear says that revenue for the six months to December 31, 2020 was down 4.5 percent to $742,800,000 with net profit after tax up 49.8 percent to $236,200,000.
Cochlear said research and development expenditure was down 5.9 percent to $88,400,000 or 11.9 percent of total revenue.
The company said that a fully franked interim dividend of $1.15 a share for shareholders on the record date of March 25 would be paid on April 20, 2021, compared to $1.60 a share in dividends for the six months to December 31, 2019.
Cochlear said diluted earnings per share rose 31.7 percent to $3.594 with net tangible assets per share up 187.4 percent to $18.772 compared to the previous corresponding period, and it had cash and cash equivalents of $587,700,000 at December 31, 2020 compared to $89,400,000 at December 31, 2019.
The company said its cochlear implants sales were down 3.2 percent to $454.7 million, and service sales, including sound processor upgrades fell 4.9 percent to $214.9 million, with the acoustics division including bone conduction and acoustic implants down 10.95 percent to $73.2 million.
Cochlear said that sales revenue in the Americas fell 1.6 percent to $375.7 million, in Europe, Middle East and Africa sales were down 9.45 percent to $237.6 million, with the Asia Pacific down 2.85 percent to $129.5 million.
The company said it had received $24.6 million in Covid-19 related government assistance, primarily from the Federal Government's Jobkeeper program, which it would repay "as trading conditions have improved".
Cochlear said that for the 12 months to June 30, 2021, it expected underlying net profit of $225 million to $245 million, a 46 percent to 59 percent increase on underlying net profit for the year to June 30, 2020.
The company said it was "increasingly confident of the resilience of the hearing implant business … [with] consistent improvements in surgery rates across most markets since May as hospitals adapted to managing cochlear implant surgeries during Covid-19".
"Momentum since November has slowed across a few countries as a result of the current surge in … infection rates [but] the deployment of … vaccines, and the rapid return to surgeries that followed the March/April shutdowns, gives Cochlear some confidence that any further surgery deferrals could also recover quickly," the company said.
Cochlear was up $17.18 or 8.4 percent to $221.68 with 407,560 shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the six months to December 31, 2020 fell 8.0 percent to $36,762,000 with net profit after tax up 30.9 percent to $4,578,000.
SDI said that the revenue came from its dental products, with whitening products revenue up by 19.3 percent, equipment sales up 12.6 percent.
The company said that amalgam sales fell 32.1 percent and aesthetics products revenue was down 7.3 percent.
SDI said that an interim fully-franked dividend of 1.5 cents a share for holders at the record date of April 9 would be paid on April 23, 2021, compared to the dividend of 1.35 cents a share in the previous corresponding period.
SDI said diluted earnings per share were up 30.95 percent to 3.85 cents with net tangible asset backing up 5.1 percent to 43.69 cents.
The company said it had cash and cash equivalents of $11,059,000 at December 31, 2020 compared to $6,058,000 at December 31, 2019.
SDI was up two cents or 2.6 percent to 80 cents.

ANTERIS (FORMERLY ADMEDUS)

Anteris says revenue for the year to December 31, 2020 fell 58.5 percent to $7,078,783 with net loss after tax up 147.1 percent to $15,274,534.
In 2019, BTC Health said it had acquired the then Admedus hospital infusion business, the sale of which generated $6.3 million in revenue for the year to December 31, 2019 for Admedus (BD: May 31, Aug 26, 2019; Mar 2, 2020).
Today, Anteris said revenue came from manufacturing Cardiocel and Vascucel patches for heart tissue repair under its agreement with the Burlington, Massachusetts-based Lemaitre Vascular Inc (BD: Oct 14, 15, 2019).
Anteris said basic loss per share was up 160.6 percent to $2.58 a share with net tangible asset backing per share down from 2.1 cents to negative one cent.
The company said it had cash and cash equivalents of $4,354,355 at December 31, 200 compared to $8,968,389 at December 31, 2019.
Anteris was up 20 cents or four percent to $5.20.

REDHILL BIOPHARMA

Redhill says it has dosed the first patient in its phase II/III trial of RHB-107 for Covid-19 and it has signed a manufacturing agreement with Cosmo Pharmaceuticals.
Last year, Redhill said the US Food and Drug Administration had cleared the randomized, parallel-group, double-blind study of RBH-107, or upamostat, for patients with symptomatic Covid-19 not requiring hospitalization, but did not disclose the number of patients.
Today, the company said RHB-107 was an inhibitor of several serine proteases and had demonstrated anti-viral and potential tissue-protective effects including inhibition of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).
Redhill medical director Dr Terry Plasse said that the “dosing of the first patient in the phase II/III study of RHB-107 in patients with symptoms but not needing hospital care, the largest Covid-19 patient group, is a key step forward in Redhill’s efforts to help combat the widespread effects of this pandemic”.
“Together with opaganib, we now have two novel, orally-administered compounds, with unique mechanisms of action, in advanced development for treating patients at different stages of COVID-19 disease,” Dr Plasse said.
Last year, Redhill said that data from 40 hospitalized Covid-19 patients in its 270-patient phase II study of opaganib showed it assisted recovery and was safe (BD: Jan 17, 2021).
Separately, the company said that it had an agreement with the Dublin-Ireland based Cosmo Pharmaceuticals to manufacture its Movantik for opioid-induced constipation as well as its RHB-204 for pulmonary nontuberculous mycobacteria disease currently in a phase III trial (BD: Nov 23, 2020).
Last year, Redhill said it had licencing and manufacturing agreement with Cosmo for multiple products and would pay Cosmo EUR5.5 million ($A9.1 million), plus milestones and royalties, for the technology transfer, formulation and development of Movantik and RHB-204 (BD: Aug 14, 2020).
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
On the Nasdaq, Redhill fell 54 US cents or 4.98 percent to $US10.30 ($A13.27) with 513,775 shares traded.

PRO MEDICUS

Pro Medicus says its co-founders, Dr Sam Hupert and Anthony Hall have each sold 1,000,000 shares at yesterday's closing price of $45.97 a share.
Pro Medicus said the shares represented less than four percent of their respective holdings, and their combined holdings remained more than 52 percent of the company.
The company said that Dr Hupert and Mr Hall did not intend to sell more shares for "the foreseeable future".
Pro Medicus chair Mr Peter Kempen said that in February 2018 "the board had encouraged the founders to consider selling up to three million shares each, in order to improve the liquidity in the company's shares".
"This latest transaction completes that process," Mr Kempen said.
Pro Medicus was up $1.03 or 2.2 percent to $47.00 with 980,223 shares traded.

SIMAVITA

The ASX says that Simavita's shares were suspended from trading on the ASX from the close of business last night.
Simavita has been commercializing incontinence systems for the aged care market.
Executive chair Michael Spooner told Biotech Daily that Simavita would continue as a public unlisted company, and eventually become a private company.
In 2013, Melbourne's Genetic Technologies said that 75.82 percent subsidiary Gtech International Resources would acquire the incontinence diagnostic company Simavita Holdings, raising $14 million in an initial public offer to list on Toronto Stock Exchange Ventures, with Philippa Lewis as chief executive officer (BD: July 30, Dec 3, 2013).
In 2014, Simavita listed on the ASX, claimed US sales of its 'smart incontinence management', reporting revenue for the six months to December 31, 2014 of $458,082, but later losing inaugural chair Peter Cook and then chief financial officer and company secretary Tom Howitt (BD: Feb 20, 2014; Jan 18, 2015; Jan 25, 2016).
In early 2016, the company announced a belt-tightening exercise and lost directors Ari Bergman and Damien Haakman, saying Mr Bergman had been a director for 15 years and was the son of the late Dr Fred Bergman, whose original concept led to the precursor to Simavita (BD: Feb 16, 2016).
In 2017, Simavita said that Michael Spooner and Dr Gary Pace would replace chair Michael Brown and Ms Lewis, later delisting from the Toronto exchange and changing its business model (BD: Apr 27, 2016; May 27, 2017).
Following a series of small capital raises and loans against the expected Federal Research and Development Tax Incentive, Simavita said it had Conformité Européenne (CE) mark for its Smartz wearable and disposable nappy technology for adults and infants and climbed 2.4 cents or 480 percent to 2.9 cents (BD: Nov 25, 2019).
Last year, the ASX suspended Simavita for failing to lodge accounts and a week later the company said that revenue for the year to June 30, 2020 fell 76.45 percent to $43,469, with net loss after tax up 3.4 percent to $4,066,679 (BD: Oct 1, 8, 2020).
The company announced plans to delist citing Covid-19 as a factor (BD: Oct 30, 2020).
Simavita chair Michael Spooner told Biotech Daily today that there had been confidential discussion with a number of organizations.
"The company is delisting because the shareholders support the future of the technology, which has a significant opportunity in the $US65 billion incontinence market and fundamentally hasn't changed in 25 years," Mr Spooner said.
"We believe we have a game-changing technology," Mr Spooner said.
Last night Simavita closed at 1.7 cents.

MGC PHARMACEUTICALS

MGC says it has a three-year distribution agreement with Swiss Pharmacan AG for its proposed Covid-19 treatment Artemic as a food supplement.
MGC said the agreement followed the 50-patients, phase II, double-blind, placebo-controlled trial of Artemic for Covid-19 in Israel and India "that met all its primary and secondary endpoints".
Last year, MGC said the trial "successfully met the primary and secondary endpoints", with the primary endpoint "clinical improvement" defined by the UK national early warning score 2 (News2), over 24 hours compared to routine treatment (BD: Dec 15, 2020).
The company said at that time that News2 measured a patient's degree of illness to prompt critical care intervention and all 33 patients in the Artemic group met the primary endpoint with News2 scores of less than 2.0 when discharged from hospital.
The company said that "the average News score of patients in the placebo group was 2.25; statistically significantly higher than in the treatment group" ($p < 0.04$).
MGC said that all patients in the Artemic group achieved the secondary endpoints, with one of the 17 placebo patients experiencing life-threating condition.
The company said that no adverse events related to the study drug were reported.
In April, MGC said that its anti-inflammatory Artemic comprised of artemisinin, vitamin C, curcumin and boswellia serrata, or Indian frankincense (BD: Apr 17, 2020).
This week, MGC said the agreement included a minimum wholesale order of 40,000 units of Artemic Rescue per quarter, and the initial wholesale order of 10,000 units had a retail market value of US$850,000 for Swiss Pharmacan AG.
The company said that it would produce a "daily dosage immune support supplement" called Artemic Support which Swiss Pharmacan would distribute "with specific focus on countries currently reporting high numbers of Covid-19".
MGC said that Swiss Pharmacan had agreements with Relay Medical Corp, Glow Lifetech and Onasis Holdings Corp for distribution.
MGC was up three cents or 31.6 percent to 12.5 cents with 218.7 million traded.

PAINCHEK

Painchek has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the share price rose 28.6 percent from a low of 7.0 cents to a high of 9.0 cents on February 18, and noted a "significant increase" in the trading volume between February 17 and 19, 2021.
Painchek fell 0.7 cents or 7.9 percent to 8.2 cents with 10 million shares traded.

HERAMED

Altor Capital Management Pty Ltd says it has become a substantial shareholder in Heramed with 10,853,467 shares or 6.16 percent of the company.
The Brisbane-based Altor said that on February 10, 2021 it bought 2,233,334 shares for $319,000 or 14.3 cents a share.
Heramed was unchanged at 10.5 cents.

RACE ONCOLOGY

Race says Prof Borje Andersson has resigned as chief medical officer after five months in the role but will remain chair of the clinical advisory board.

In January 2020, Race said it had appointed Prof Andersson as a director and in October he was appointed chief medical officer, before resigning from the board to focus on his other roles within the company (BD: Jan 28, Oct 2, Dec 10, 2020).

Today, the company said the 1,600,000 options issued to Prof Andersson on his appointment as chief medical officer would lapse upon his resignation, following a three-month transitional period.

Race said it had started the recruitment process for a chief medical officer.

Race fell seven cents or 2.3 percent to $2.93 with 602,927 shares traded.