Biotech Daily

Friday February 14, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMPEDIMED UP 17%; AMPLIA DOWN 11%**

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

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MARKET REPORT

The Australian stock market was up 0.38 percent on Friday February 14, 2020, with the ASX200 up 27.0 points to 7,130.2 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 15 fell, two traded unchanged and one was untraded. All three Big Caps rose.

Impedimed was the best, up 1.7 cents or 17.35 percent to 11.5 cents with 2.1 million shares traded. Proteomics climbed 15.5 percent; Alterity and LBT were up more than 11 percent; Antisense was up 9.4 percent; Prescient improved 8.2 percent; Pharmaxis, Telix and Uscom climbed more than six percent; Resonance was up 5.1 percent; Medical Developments was up 4.9 percent; Avita and Starpharma were up three percent or more; Cochlear, Compumedics, Cyclopharm, Nanosonics and Opthea rose more than two percent; Genetic Signatures, Immutep, Paradigm and Resmed were up by more than one percent; with Clinuvel, CSL and Cynata up by less than one percent.

Amplia led the falls, down 1.2 cents or 11.4 percent to 9.3 cents with 761,910 shares traded. Actinogen lost 6.25 percent; Imugene, Neuren, Osprey and Pro Medicus fell more than five percent; Ellex and Next Science were down more than three percent; Oncosil, Polynovo and Universal Biosensors shed more than two percent; Mesoblast, Orthocell and Volpara were down more than one percent; with Kazia down 0.8 percent.

DR BOREHAM'S CRUCIBLE: CSL

By Tim BOREHAM

ASX code: CSL; **US (over the counter):** CSLLY

Share price: $331.19; **Market cap:** $150.3 billion; **Shares on issue:** 453,882,387

Financials (first half to December 2019): revenue $US4,910.6 million ($A7,297.7 million, up 9%), net profit $US1,248.0 million ($A1,854.7 million, up 7.5%), earnings per share $US2.74 (up 6.9%), interim dividend 95 US cents (up 12%), cash and cash equivalents $US659.7million (up 2.3%)

Chief executive officer: Paul Perreault

Board: Dr Brian McNamee (chairman), Mr Perreault, Prof Andrew Cuthbertson; Bruce Brook, Dr Megan Clark; Abbas Hussein, Marie McDonald, Christine O'Reilly, Carolyn Hewson*****
***** Ms Hewson replaced Dr Tadataka Yamada who stepped down in October

Identifiable major shareholders: Blackrock Group 5.02%, Vanguard Group 5.1%.

With the blood products group vying with the Commonwealth Bank of Australia to be Australia's biggest company - listed or otherwise - CSL chief Paul Perreault could be excused for displaying a coronavirus-sized outbreak of hubris.

After revealing a 7.5 per cent profit surge for the half year and upgrading full year guidance this week, he was keeping the proverbial lid on it - but only just.

"We expect strong demand for our therapies to continue and we expect to outpace the market as far as plasma collection is concerned," he said.

Justifiably or not, investors are ascribing a supersized valuation to CSL relative to the so-called Big Four banks that have long cluttered the ASX top-10 rankings.

On the same day CSL bared all, the Commonwealth Bank of Australia disclosed a $4.5 billion interim cash profit compared with CSL's $1.85 billion.

Yet, with a circa $150 billion market capitalization CSL is not far off the $156 billion ascribed to CBA, Australia's biggest listed company.

This means that CBA shares are trading on a price-earnings multiple of 17 times - high for a bank historically - while CSL is on 48 times.

But with CSL shares trading at record levels, investors clearly believe the banks are going nowhere and nothing can stop the growth trajectory of our global wonder stock.

For the record, CSL is the world's fifth biggest biotech and its plasma arm CSL Behring is the biggest in the $30 billion a year plasma industry.

What's the fuss about?

CSL makes an array of products but the core of its business is simple: the company collects blood plasma - notably from centres in the US where donors are paid for their claret - and slices and dices it into specialist therapeutics.

Plasma is the substance that carries red and white blood cells through the body so it's kind of, like, important.

The therapies are relevant for disorders such as haemophilia, primary immune deficiencies, hereditary angioedema and inherited respiratory disease.

In the immunoglobin bracket, leading products are the intravenously-delivered Privigen and the subcutaneous Hizentra

Coagulation products include Idelvion, an albumin fusion protein cited as the new standard of care for haemophilia B.

CSL's albumin range includes Alburx and Albuminar, used for purposed such as replacing blood loss after trauma and surgery. Albumin is a protein derived from blood (and also found in egg whites).

Specialty products include Haegarda, an esterase inhibitor for hereditary angioedema (severe swelling of the face and throat) and Kcentra for urgent warfarin reversal (that is, when a patient on the blood thinning medication is bleeding to death).

This week, the US Food & Drug Administration approved Privigen for the investigational treatment of the autoimmune disease systemic sclerosis.

The 'flu vaccine arm was formerly known as Bio-CSL but was re-named Seqirus after CSL bought pharma giant Novartis's influenza vaccine business in 2015.

Seqirus is Latin for 'made up name because all the sensible ones were taken'.

Seqirus sells season vaccines such as the quadrivalent Flucelvax that is effective against four strains and the adjuvanted (supercharged) Fluad for high risk populations.

The company cites a seasonal vaccine market of $US4 billion, or 500 to 600 million doses (150 million in the US).

Just popping down to the (blood) bank

CSL is perceived as a no-brainer business because a growing population will ensure a market of sick people in need of the therapeutics.

As Dracula would attest, efficient plasma collection is the key and there's a dark art in terms of centre location. CSL claims to be the best in the business and who are we to argue?

Currently CSL has 235 collection centres, mainly in the US, but also in Germany, Hungary and China.

The company opened 30 new US centres in 2018-'19 and a further 20 in the December half, bang on target for 40 openings for the full year.

According to broker Citi, the four plasma collectors opened 67 US outlets in the December half, with CSL accounting for 28 of them.

Dissecting the results

CSL's half-year profit bounce was underpinned by the 10 percent sales surge for the core Behring division.

In particular, sales of immunoglobin products rose by 26 percent, with Privigen turnover up 28 percent and Hizentra sales soaring 37 percent.

Demand for primary immune deficiencies remains robust, but the company also benefited from Privigen and Hizentra being approved in the US for chronic inflammatory demyelinating polyneuropathy (CIDP), a rare neurological disorder.

The key weakness was a 33 percent decline in albumin-based products, owing to a change in distribution arrangements in China. This disruption had been well-flagged and should already have been accounted for in analysts' spreadsheets.

"Sales are expected to return to more normalized levels in 2021," Mr Perreault says.

CSL's fortunes are also being bolstered by the fortunes of the Seqirus division, with revenue up nine percent to $US1.018 billion.

In particular, both quadrivalent and adjuvanted doses both rose by 21 percent, bearing in mind the seasonal nature of the division.

And seeing you asked, the company is not affected by the coronavirus – now formally named Covad-19 – in either positive or negative ways.

"We have been closely watching development and have been supporting our long-standing partner, the University of Queensland, in their vaccine program," Mr Perreault says.

The company also has a facility in the virus epicentre province of Wuhan, but this does not appear to be causing supply problems. Chinese collection centres are also closed for the time being and management is waiting for Beijing's nod to re-open them.

Ahead of the results, management guided to net earnings of $US2.05 billion to $US2.11 billion for the full year to June 2020.

Despite the albumin issue and supply constraints in some specialty lines, management has cheerfully upped guidance to $US2.11 billion to $US2.17 billion (up 10 to 13 percent on the previous year).

Sizing up the rivals

It's sometimes easy to forget that CSL does have competitors, notably Takeda, Grifols, Octapharma and Baxter.

But Mr Perreault says CSL isn't striving for world domination because it can't service all the demand. He notes that when you become entrenched in a market, patients are loath to change if you have showed reliability of supply.

"We launched the first subcutaneous [immunoglobin] product in the US in 2005," he says. It's taken us from then until now to grow the primary immunodeficiency to half the [patient] population."

"We think we are clearly the market leader in subcutaneous. We have a great product for patients but it has to be the right patient and it has to be able to be administered at home."

What's cooking?

CSL's post profit pow-wows these days follow a different script to a couple of years ago, when analysts and reporters would grill management on where it would find tomorrow's profits.

Management would respond by unveiling yet another share buyback to reduce shares on issue and thus boost earnings per share.

Now, the company has turned to the lab: in the six months to December 31 it spent $US446 million on research and development, having expended $US832 million in the full 2018-'19 year.

So, there's plenty of stuff bubbling away on the Bunsen burners at CSL's Bio21 research hub at company HQ in Melbourne's leafy Parkville.

For a start, CSL is halfway through a massive $800 million clinical trial of its experimental heart drug trial known prosaically as CSL112 (a plasma-derived infusion therapy).

The phase III trial has enrolled 7,000 patients across 90 hospitals in 46 countries. In all 17,000 patients are expected to enrol and as far as clinical trials go it doesn't get much more expansive and costlier than this.

Aimed at 10 percent or so of heart attack victims who have second attack within 90 days of the first - often fatally - the trial is seen as binary. It will work or it won't. Expect the results of a "futility analysis" at CSL's August full-year results.

If CSL112 were to be brought to market it would be worth billions.

CSL also has a phase I trial of an asthma therapy - let's call it CSL311 because that's what it's named - aimed at zapping the agents that inflame the airways. This one targets 235 million asthma sufferers, notably children.

CSL is also developing Privigen and Hizentra as a treatment for scleroderma and Hizentra for dermatomyositis.

As for new therapies, the non-exhaustive list of targets includes sickle cell anaemia, contact-mediated thrombosis, diabetic nephropathy, neutrophilic dermatoses, systemic lupus and erythematosus.

My there are a lot of ailments in the world, aren't there?

Dr Boreham's diagnosis:

CSL shares have had a monster 12 months and are now trading at a record $331 a share, compared with $188 in February 2019. Five years ago, they traded at a "mere" $88 or so.

CSL's naysayers point out that the company was gifted to private investors when the then Keating government privatised it in 1994 at $2.30.

To say the Government left some money on the table is a gross understatement: allowing for a three for one share split in 2007, the original shares are now worth close to $1,000 apiece.

Indeed, the company quietly made multimillionaires of former staff availing of the employee share scheme, in what turned out to be the ultimate 'get rich slowly' scheme.

On balance though, are CSL shares now overvalued? Given the lofty earnings multiple the stock trades on, the obvious answer is: "Yes". But we thought the same when the stock was trading at $30 … and then $100 … and then $200.

Beyond commercialization of the heart drug, it's hard to see a transformational 'big bang' event for CSL, such as a mega acquisition.

As with fellow home-grown hero Resmed, it's all about developing extension products and some new ones as well. If a fraction of the stuff at Bio21 works out, CSL could well lay claim to the mantle of Australia's biggest company.

In the longer term, gene therapies may well supplant some plasma-based therapies- but that's a bit like saying air travel will be replaced by transmat beams or the like.

"I wouldn't be opening more plasma centres if I didn't think growth in demand wasn't going to continue," Mr Perreault says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he does own a modest wad of CSL shares, acquired at somewhat north of $2.30 a share.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the six months to December 31, 2019 was up 7.7 percent to $39,963,000 with net profit up 11.9 percent to $3,497,000.
SDI said that the revenue “was driven by strong growth in [dental] whitening sales and continued strong growth in aesthetics sales, including glass ionomers and composites, offset by the ongoing decline in amalgam sales”.
The company said that an interim fully-franked dividend of 1.35 cents a share for holders at the record date of April 3, 2020 would be paid on April 17.
The company said net tangible asset backing was up 1.9 percent to 41.58 cents and diluted earnings per share was up 11.8 percent to 2.94 cents.
SDI said it had cash and cash equivalents of $6,058,000 at December 31, 2019 compared to $6,068,000 at December 31, 2018.
SDI was up eight cents or 9.2 percent to 95 cents.

USCOM

Uscom says China’s Hubei province has recommended haemodynamic monitoring for the diagnosis and treatment of coronavirus infected children.
Uscom said that haemodynamic monitoring was recommended during ani-shock treatment of severe cases.
The company said that its ultrasonic cardiac output moniter, the Uscom 1A, was widely used in China and elsewhere to optimize circulation management in neonates and children and it was working with its distributors to implement national and regional recommendations, protocols and guidelines, including those published by the Pediatric Branch of Hubei Medical Association, the Pediatric Branch of Wuhan Medical Association and the Pediatric Medical Quality Control Centre of Hubei.
Uscom executive chairman Prof Rob Phillips said Uscom had been in China for more than 15 years and would continue to provide equipment and care “in this difficult time”.
Uscom was up 2.5 cents or 6.8 percent to 39.5 cents with 7.8 million shares traded.

INVION

Invion has released further pre-clinical data of a mouse model, supporting its Photosoft light technology for ovarian cancer.
In November, Invion said that an ovarian cancer mouse study, undertaken by Melbourne’s Hudson Institute of Medical Research, found that its Photosoft technology reduced tumor size to less than half its original size (BD: Nov 27, 2019).
Today, the company said that when exposed to light at 652 nano-metres, Photosoft was immediately activated and efficiently produced singlet oxygen, which killed cancer cells.
Invion said Photosoft was cleared rapidly from cells, which minimized photo-toxicity side effects and unlike other sensitizers tested, and had no observable ‘dark toxicity’ due to the absence of light activation.
The company said Photosoft localized rapidly to tumor tissue following injection into the mouse ovarian cancer model and was retained in tumor tissues for at least 48 hours.
Invion said Photosoft activation resulted in substantial inflammation and necrosis of tumor tissue after two days, showed an increase in immune cells after three weeks and a reduced tumor burden by more than 50 percent after three weeks.
The company said the results were presented at the Lorne Cancer Conference, on Victoria’s south-west coast held between February 13 and 15, 2020.
Invion was up 0.1 cents or 10 percent to 1.1 cents with 8.4 million shares traded.

RECCE PHARMACEUTICALS

Recce says Recce 327 antibiotic has demonstrated positive efficacy against Gram negative Escherichia coli in kidney and urinary tract or bladder infections in rats.
Recce said the rat study aimed “to determine whether Recce 327 has the potential to form part of a broader anti-infective treatment model by tackling a leading initial cause of sepsis” namely kidney and urinary tract or bladder infections, while in its pre-sepsis early stage, localized form.
The company said it administered a single 24-hour intravenous infusion of Recce 327 at both 50 milligrams/kilogram and 500mg/kg.
Recce said it found a dependent anti-bacterial effect in kidneys at both 50mg/kg and 500mg/kg and at 500mg/kg, found significant activity compared to control ($p < 0.050$).
The company said it found a significant dose dependent antibacterial effect in the bladder at both 50mg/kg and 500mg/kg compared to a vehicle control ($p < 0.50$) and rats remained apparently normal when observed for adverse clinical signs.
Recce said the data showed the potential of Recce 327 to form a broader anti-infective treatment model in pre-sepsis and it had filed a provisional patent family submission.
Recce chairman Dr John Prendergast said “the data support the use of Recce-327 across the full therapeutic road map for pre-sepsis and sepsis conditions, now including the treatment of primary infection by E coli in kidney and UTIs”.
“This further justifies the … potential of Recce 327 as a new class of antibiotics as we continue to gather new data ahead of our first-in-human … studies,” Dr Prendergast said.
Recce was up nine cents or 20.45 percent to 53 cents with 1.95 million shares traded.

NOXOPHARM

Noxopharm says interim data from 32 of 56 planned patients, in its phase I/II clinical trial of Veyonda with radiation therapy, shows a survival benefit for prostate cancer.
Noxopharm said the single-arm, open label, four cohort study, conducted by Sydney’s St Vincent’s Hospital, evaluated Veyonda, formerly NOX66, in combination with radiopharmaceutical therapy using lutetium prostate specific membrane antigen 617 (Lu-PSMA-617), for late-stage metastatic castration-resistant prostate cancer.
The company said the study evaluated patients with progressive end-stage prostate cancer in up to six weekly interval doses, in order to assess a safety and dose response.
Noxopharm said that all patients had received and failed two prior lines of therapy, including chemotherapy and androgen-signaling inhibitors, and 29 of 32 patients had failed an additional line of chemotherapy prior to the trial.
The company said the interim data was from eight men who received 400mg of Veyonda and 24 who received 800mg, with a further 24 men to receive 1,200mg.
Noxopharm said that 17 of 32 patients or 53 percent were not well enough to receive all six cycles of therapy and the median overall survival rate was 17.1 months.
The company said that 28 of 32 patients (87.5%) had a fall in prostate specific antigen (PSA) levels and 20 of 32 patients (62.5%) had a PSA response over 50 percent.
Noxopharm said that 12 of 24 patients with severe pain at the beginning of the study showed a significant reduction in pain due to secondary tumors.
The company said that half of the patients experienced mild adverse events, including 17 of 32 with dry mouth, 15 with fatigue and 14 with anemia, and minimal higher-grade side effects were reported but were manageable.
Noxopharm said the 24 men in cohort four were currently receiving 1,200mg of Veyonda and it expected a final read-out in mid-2021.
Noxopharm was up 1.5 cents or 6.7 percent to 24 cents with 1.7 million shares traded.

EXOPHARM

Exopharm says its exosomes might be used for erectile dysfunction by stimulating regenerative capacities to reverse post-operative tissue damage.
Exopharm said it had developed therapeutic exosome products as an alternative to stem-cell therapies, which had shown the potential to reverse damage to the cavernous nerve, a side effect of prostate or colorectal surgery, to protect smooth muscle cells from apoptosis and prevent fibrosis, to promote repair to damaged nerves and to treat non-surgical causes of erectile dysfunction such as diabetes-related erectile dysfunction.
Exopharm chief executive officer Dr Ian Dixon said that Viagra and other competitor drugs addressed erectile dysfunction but were usually ineffective on damaged tissue.
Exopharm fell 1.5 cents or 4.5 percent to 32 cents.

OVENTUS MEDICAL

Oventus says its O2vent Optima for sleep apnoea has been approved for reimbursement in the US.
Oventus said the mouthguard-style devices would be available to all patients, including those covered by the Centres for Medicare and Medicaid.
The company said dentists would be able to bill and be reimbursed for the delivery of the O2vent Optima by Medicare and other commercial payers.
Oventus chief executive officer Dr Chris Hart said it was “a very significant development”.
Oventus was up 10 cents or 21.7 percent to 56 cents with 4.8 million shares traded.

MEDIBIO

Medibio said it is planning both US and European regulatory pathways for “depressive burden” associated with five stages of the sleep cycle.
Medibio said it planned a de-novo submission and 510(k) application to the US Food and Drug Administration and for Conformité Européene (CE) mark approval of its depressive burden sleep software medical device.
Last April, Medibio said it had withdrawn its de-novo submission for its heart rhythm test for mental illnesses filed to the FDA in 2018 (BD: Apr 30, 2019).
Today, Medibio said it was working on development of a software medical device to identify depressive burden in primary and secondary sleep disorder patients, including those with hypersomnia, insomnia and obstructive sleep apnoea.
The company said the MEB-001 platform had a sleep staging algorithm, an overlaying resting heart rate and heart rate variability algorithm and a depressive burden analysis.
Medibio said it had begun a study to support a de-novo submission to the FDA, following approval of its sleep analysis of depressive burden study.
The company said it would perform data analysis for every 50 patients and conduct a full statistical analysis once it reached sufficient statistical power.
Medibio said the results would be used for an FDA pre-submission meeting and to prepare for a final 300-patient multi-centre pivotal study for a de-novo submission.
The company said the MEB-001 platform included an algorithm called Stager, which used artificial intelligence and neural network methodology to identify the five sleep stages.
Medibio said it had completed development of Stager, which was expected to be completed in June 2020 for an FDA 510(k) submission.
The company said it had scheduled a May 2020 meeting with the German regulatory body DQS to file a potential CE mark application for Stager.
Medibio was unchanged at 0.8 cents with 11.9 million shares traded.

NOXOPHARM

Noxopharm says it hopes to raise $8.1 million through a $3.09 million equity placement at 18 cents a share and $5 million loan from an existing shareholder.
Noxopharm said the placement price was a 20 percent discount to the last close.
The company said the loan was secured by its expected 2020 Research and Development Tax Incentive forecast to exceed the maximum loan value.
Noxopharm said it intended to repay the loan on receipt of the rebate, expected in October 2020, at an interest rate of 10 percent.
The company said the funds would be used to progress current initiatives, including trials and to buy back and terminate convertible notes held by the Lind Partners and CST Investment Funds to repay $4.16 million.
Noxopharm said Baker Young Stockbrokers was the lead manager to the placement.

MMJ GROUP HOLDINGS

MMJ says it hopes to raise $5 million through a share purchase plan at 11 cents a share, a 10.9 percent discount to the five-day volume weighted average price.
MMJ said shareholders would be able to purchase up to $30,000 worth of shares without brokerage or transaction costs.
The company said the record date for the share plan was February 13 and it expected the share plan to open on February 19 and close on March 10, 2020.
The company said the funds would be used for investments in existing and new cannabis and hemp businesses, for operating expenses and general working capital.
MMJ said Canaccord Genuity Australia was the lead manager to the share plan.
MMJ fell one cent or 8.3 percent to 11 cents with 1.4 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics 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 company's share price rose 9.38 percent from a low of 32 cents to a high of 35 cents on February 14, 2020 and noted an increase in trading volumes.
Proteomics said its share price reached a day time high of 38 cents, an 18.75 percent increase.
Proteomics closed up 4.5 cents or 15.5 percent to 33.5 cents with 2.3 million shares traded.

BENITEC

Benitec says its scheme of arrangement meeting to approve the US-based Benitec Bio Pharma to become its parent company will be held next month.
Benitec said the meeting would be held at Grant Thornton, Collins Square, Tower 5, 727 Collins Street, Melbourne on March 26, 2020 at 10am (AEDT).
Benitec fell 0.1 cents or 2.6 percent to 3.7 cents with 1.4 million shares traded.

IDT AUSTRALIA

Anthony Huntley and associated entities say they have become substantial in IDT with 12,828,815 shares or 5.4 percent.
The Melbourne-based Mr Huntley said the associated companies were Adansonia Capital and Picherit's Farm Pty Ltd as trustee for the Huntley Super Fund.
Mr Huntley said he bought the shares between August 29, 2019 and February 11, 2020, with the two largest purchases adding up to 500,000 shares for $75,206 or 15 cents a share.
IDT was up one cent or 7.7 percent to 14 cents.

IMUGENE

The Sydney-based Private Portfolio Managers says it has been diluted below the five percent substantial shareholder level in Imugene.
In 2018, Private Portfolio Managers said it had become a substantial shareholder with 224,551,412 shares or 7.12 percent (BD: Jul 10, 2018).
Today, Private Portfolio Managers said it was diluted on December 6, 2019, following a $24.6 million oversubscribed placement at 3.6 cents a share (BD: Dec 2, 2019).
Imugene fell 0.2 cents or 5.9 percent to 3.2 cents with 15.9 million shares traded.

RESPIRI

Respiri says chief executive officer Marjan Mikel, was appointed last December, will receive a salary of $450,000 including compulsory superannuation (BD: Nov 25, 2019).
Respiri said that "at this stage" there were no short- or long-term incentives.
Respiri was unchanged at 8.4 cents.