



Biotech Daily

Friday February 15, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: MEDICAL DEV UP 7%; ANTISENSE DOWN 5%**
- * **DR BOREHAM'S CRUCIBLE: CSL**
- * **FEDERAL \$39m FOR 23 RARE CANCERS, DISEASES**
- * **VICTORIA BACKS MASTER OF CANCER SCIENCES**
- * **PHARMAXIS H1 REVENUE DOWN 91% TO \$3m, PROFIT TO \$13m LOSS**
- * **BIONOMICS H1 REVENUE UP 3% TO \$2.4m, LOSS UP 19% TO \$10.6m**
- * **BARD1 5-PEPTIDE GOOD FOR MESOTHELIOMA, NOT OTHERS, IN MICE**
- * **NEUROTECH, ANCHOVY PARTNER TO DELIVER MENTE AUTISM**

MARKET REPORT

The Australian stock market edged up 0.11 percent on Friday February 15, 2019, with the ASX200 up 6.7 points to 6,066.1 points.

Just six of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and five were untraded.

Medical Developments was the best, up 27 cents or 7.4 percent to \$3.91 with 137,924 shares traded.

Benitec improved four percent; Reva was up three percent; Airxpanders rose 2.6 percent; Cynata was up 1.3 percent; with Cochlear and Ellex up by less than one percent.

Antisense led the falls, down 0.2 cents or 5.3 percent to 3.6 cents, with 119,376 shares traded, followed by Optiscan down five percent to 5.7 cents with 10,000 shares traded.

Immutep, Nanosonics, Orthocell and Proteomics lost more than three percent; Impedimed, Prana and Prescient shed more than two percent; Actinogen, Compumedics, CSL, Neuren, Opthea, Paradigm, Pharmaxis and Starpharma were down more than one percent; with Genetic Signatures, Mesoblast, Pro Medicus, Resmed and Volpara down by less than one percent.

[DR BOREHAM'S CRUCIBLE: CSL](#)

By Tim Boreham

ASX code: CSL

Share price: \$185.00

Market cap: \$83.8 billion

Shares on issue: 452,964,551

Chief executive officer: Paul Perreault

Board: Dr Brian McNamee* (chairman), Dr Andrew Cuthbertson (CSO), Bruce Brook, Dr Megan Clark, Shah Abbas Hussain, Marie McDonald, Christine O'Reilly, Dr Tadataka 'Tachi' Yamada

* Dr McNamee replaced Prof John Shine after last year's AGM

Financials (December half): revenue \$US4.505 billion (up 9%), net profit \$US1.16 billion (up 7%), earnings per share \$US2.56 (up 10%), dividend 85 US cents (up 8%), cash of \$US645 million (down 23%).

Identifiable major shareholders: Vanguard Group 5%, Australian Foundation Investments 0.39%, AMP Life 0.34%, Argo Investments 0.25%, Netwealth Investments 0.2%

What can slow the progress of our most supersized biotech stock which, truth be said, is well past the stage of idly dabbling with test tubes and scrounging for a few more scraps of working capital?

The plasma and influenza vaccines behemoth reported a \$US1.16 billion interim net profit, up 6.85 percent, with management honing full-year profit guidance to the upper end of the previously stated range of \$US1.88 billion to \$US1.95 billion (up 10 to 14 percent).

Product wise, CSL is a machine of many working parts and investors sharply sold down the stock on selective areas of weakness, mainly in albumin and plasma-derived haemophilia product sales (the recombinant product Indelvion is going gangbusters).

Global demand for CSL's suite of core immunoglobulin products remains rock solid, as does sales of its specialist therapies to treat a raft of exotic-sounding diseases.

If anything can slow the pace of CSL's growth it's the availability of the core ingredient plasma, the substance that transports red and white blood cells through our bodies and obtained mainly from US collection centres.

At the 2017-'18 full year results CSL pointed to a tighter supply because, if anything, the company is a victim of the economic resurgence in the US.

Why? There are fewer jobless people willing to donate their sauce.

CSL has responded with an unprecedented round of donor branch openings - 30 to 35 this year - and this looks to be easing the squeeze.

Or should that be squeezing some more?

Where CSL is winning

The results show that sales of the core immunoglobulin drugs Privigen and Hizentra grew at 17 percent and 14 percent respectively, driven partly by approval for a new neurological indication called chronic inflammatory demyelinating polyneuropathy (CIDP).

Immunoglobulin therapies are used to treat ailments including immune deficiencies, Guillain-Barre syndrome, Kawasaki disease, AIDS/HIV and measles.

Overall immunoglobulin sales grew at a more sedate 12 percent because of the phased effect of an older therapy Carimune being taken off the market.

Immunoglobulin sales account for about half of the sales of CSL's core CSL Behring plasma arm - \$US3.468 billion in all.

"We are the global leader in immunoglobulin and continue to hold this position despite intense competition in the market place," CEO Paul Perreault says.

Still, specialty products didn't let the side down either, with sales growing by 13 percent to \$US803 million.

Last year CSL launched Haegarda, for patients with hereditary angioedema (severe swelling of the face and throat).

Given Haegarda sales tripled during the half, there was no Hagar the Horrible in that performance.

Kcentra was no blushing violet either, with sales up 19 percent. Kcentra is a prothrombin complex concentrate used to reverse urgently the effect of blood thinning drugs such as Warfarin.

"In the last 24 months we have issued five major products which is really unprecedented in the industry and in my career," Mr Perreault says.

... and where it's not

Not everything is going CSL's way, a key blot being a four percent decline in albumin sales (albumin is the protein that makes up 60 percent of plasma, used in critical care including fluid resuscitation).

Management insists the reasons for the slump are transitory, including temporary Chinese import restrictions and a lull as the company awaits regulatory approval for its new facility in Kankakee, Illinois.

CSL also saw an uptick in raw material costs, partly reflecting the increased plasma collection expenses. This contributed to payments to suppliers and employees increasing 15 percent to \$US3.28 billion.

Chief financial officer David Lamont notes: “we are clearly collecting more plasma at a higher cost but the majority is volume”. In other words, the company is building its raw inventories which, indeed, rose 30 percent to \$US938 million during the half year.

Seqirus earnings nothing to sneeze at

Coming back to highlights, CSL's 'flu drug arm Seqirus (formerly CSL Biotherapies) clocked a \$US300 million underlying profit on \$US949 million of revenue, up 21 percent.

In the first half of 2017-'18 the division made \$US185 million and three years ago it was losing \$US200 million a year.

A decent Northern Hemisphere 'flu season has helped. But the numbers also reflect a product shift to new quadrivalent doses that, as the name suggests, treats four different strains of the drug.

In particular, Seqirus also reports early runs with the quadrivalent product Fluad, the only recommended dose for those aged 65 or more in the UK and here.

Because of seasonality, Seqirus does 80 percent of its business in the first half and as a result it's expected to be a loss-maker in the second half. The likely size of this deficit is the subject of much speculation and trepidation, given it will shape the company's ability to achieve its full year guidance.

In the lab

CSL expended a chunky \$US391 million on research and development during the half, up 14 percent on the previous first half year and 8.7 percent of total revenue, overseen by research and development director and chief scientist Prof Andrew Cuthbertson.

At its December research and development strategy day, management cited a focus on five key areas: immunology and neurology, haemophilia and thrombosis, transplants, respiratory, and cardiovascular and metabolic.

While broad in scope, these conditions don't fall far from CSL's tree of expertise while most of them - notably combating transplant rejection - have huge unmet needs.

Most of the research and development cash is being spent on phase III trialling of CSL112, a novel protein infusion therapy aimed at reducing recurrent cardiovascular events following a heart attack.

The trial is humungous: 17,400 patients across 40 countries, with the first patient enrolled in March 2018 and 1,000 participating to date.

Finances and performance

As usual, it's hard to pinpoint the exact source of the investor angst that sent CSL shares down four percent on the day it reported (February 13).

Fundamentally, the overall result may have fallen slightly short of lofty expectations, while the market's full-year expectations were at the top of the upgraded full-year earnings range anyway.

Higher collection costs and the albumin performance appear to be factors as well. Overall, the market ignored Mr Perreault's pleas to take into account the fact that the results compared to a previous buoyant period in the first half of 2017-'18.

This time around, the spreadsheet boffins didn't ask the perennial question about CSL's generous cash balance of \$US645 million, bearing in mind the company has interest-bearing liabilities of \$US4.64 billion.

Until recently, share buy-backs soaked up the excess cash. Now, upgraded research and development expenditure and other maintenance and growth capital commitments will account for plenty of the folding stuff in the next 12 months.

Still, if CSL finds some more suitable businesses to buy, it will hardly be constrained from doing so financially.

While recent purchases have fallen short of being transformational, CSL has opened the cheque book in recent times.

In August 2017 the company acquired gene therapy company Calimmune Inc for \$US82 million.

It then paid \$US352 million for 80 percent of Ruide, which makes plasma-derived products for the Chinese market. In June last year CSL spent \$US102 million to acquire the remaining 20 percent.

In 2015 CSL outlaid \$US275 million for the influenza vaccine business of global giant Novartis - a big shot in the arm for the Seqirus business.

'No' to share split

CSL shares over the last 12 months have wavered between a record high of \$232 in early September and \$149 in March 2018.

Having sharply retracted late last year, the stock trades on a price-to-earnings multiple of around 30 times. Whether CSL is overpriced or a bargain - and it depends on to whom you talk - the stock is trading in line with its historic norm.

In case anyone needs reminding, the then Australian Government-owned CSL listed at \$2.30 in 1994. Given the company undertook a three for one share split in 2007, one original share is worth a cool \$561 today - a 27,800 percent increase.

Given the lofty share price, management has been besieged by shareholder queries about another share split, but the answer is a firm 'Nyet'.

At last year's AGM chairman Prof John Shine pointed out that as CSL's shareholder base had grown from 100,000 to 150,000 over the last four to five years, investors weren't exactly being deterred by the 'expensive' shares.

Dr Boreham's diagnosis:

CSL remains one of those rare stocks with an almost assured growth in demand for its product - come rain, hail or recession.

In a slide presented at the R&D day, management estimated the 'targeted protein therapeutic market' - in other words, the company's core business - at \$US30.5 billion. This compares with CSL's annual revenue (ex-Seqirus) of a tad over \$US7 billion.

This implies ample room for growth with CSL's existing activities.

At the periphery, CSL's growth will be influenced by the pipeline of new products and the progress in China. But in essence if CSL can keep doing what it's doing - and executing well - that should justify the \$84 billion market valuation.

We know, it sounds like a lot of noughts. But Apple until recently was valued at more than \$US1 trillion and what do we need more, iPhones or plasma?

(Millennials may well opt for the former).

In the board room, meanwhile, the long-serving Dr Shine has just stepped down in favor of Dr Brian McNamee.

Now that name rings a bell - and not just because his brother Paul was a tennis player. Dr McNamee of course ran CSL for 23 years, until he 'retired' in 2013.

The corporate governance textbooks frown on the CEO-returning-as-chair syndrome. But by all accounts, Dr McNamee and Mr Perreault get along famously and we're sure the chair will keep his butt out of the day-to-day stuff.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He owns a modest wad of CSL shares but not acquired at \$2.30, sadly.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$38.6 million for 23 research projects in rare cancers and rare diseases.

A media release from the Federal Minister for Health Greg Hunt said the projects would be funded through the Medical Research Future Fund as part of the 'Rare Cancers, Rare Diseases and Unmet Needs Clinical Trials Program'.

Last year, the Government said it would provide \$26 million for 19 research projects in rare cancers and rare diseases with a further \$33 million in the 2018-'19 financial year (BD: Jan 24, 2018).

Today, a spokesperson for Mr Hunt told Biotech Daily that this round was new money. The Government said the program included a trial of different chemotherapy treatments for glioblastoma brain cancer, a trial of precision medicine for relapsed high-grade glioma, trials of children and adolescents with medulloblastoma, and trials for other brain tumors. The media release said that the clinical trials aimed to enhance clinical trial activity, treatments, cures and to extend and improve quality of life for Australians with rare cancers and diseases.

The Government said the funding from the Medical Research Future Fund included \$10.8 million for rare cancer clinical trials, \$18.3 million for rare diseases clinical trials, \$6.6 million for unmet needs clinical trials, \$4.5 million for brain cancer clinical trials and \$2.9 million would be invested, with an addition \$1.6 million from Carrie's Beanies 4 Brain Cancer and the Mark Hughes Foundation.

VICTORIA GOVERNMENT

The Victoria Government says it is supporting a University of Melbourne Master of Cancer Sciences in partnership with the Victorian Comprehensive Cancer Centre Alliance.

A media release from the Victoria Parliamentary Secretary for Health Anthony Carbines said the Government would provide \$600,000 towards the development of the Masters degree, which would be delivered through an online suite of graduate programs in cancer research, education and care.

The Government said it was the first cancer-specific online Masters program in Australia and was just one of two in the world, for health professionals who care for cancer patients. The media release said the first intake of 41 students included 26 from Victoria, 14 from other states and one from outside Australia.

PHARMAXIS

Pharmaxis says that revenue for the six months to December 31, 2018 was down 90.6 percent to \$2,950,000, turning the previous net profit after tax to a \$12,587,000 loss.

Last year, Pharmaxis said it had received \$27.0 million from Boehringer Ingelheim as a milestone payment for the phase II trial of BI 1467335, formerly PXS4728A, for non-alcoholic fatty liver disease (BD: Feb 15, 2018).

Today, the company said the revenue included Bronchitol sales of \$600,000 compared to \$1.5 million for the six months to December 31, 2017, Aridol sales up \$600,000 to \$1.6 million and \$264,000 from sub-leasing parts of its premises.

Pharmaxis said that the previous diluted earnings per share of 0.02 cents turned to a diluted loss per share of 0.03 cents for the six months to December 31, 2018, with net tangible assets per share up 74.2 percent to 5.4 cents and cash and cash equivalents of \$42,003,000 at December 31, 2018, compared to \$25,045,000 at December 31, 2017.

Pharmaxis fell half a cent or 1.9 percent to 26 cents.

BIONOMICS

Bionomics says that revenue for the six months to December 31, 2018 was up 3.0 percent to \$2,424,127 with net loss after tax up 19.3 percent to \$10,555,094.

Last year, Bionomics included the Federal Research and Development Tax Incentive of \$6,788,454 in the total revenue of \$7,168,539.

This year's report includes actual revenue from collaboration income, royalties, sales income, rental income and interest income and said that revenue was up 3.0 percent to \$2,424,127.

The company said that diluted loss per share rose 22.2 percent to 2.2 cents for the six months to December 31, 2018 and net tangible asset backing per share fell 60.4 percent from 4.8 cents at December 31, 2017 to 1.9 cents at December 31, 2018.

Bionomics said it had cash and cash equivalents of \$27,354,787 at December 31, 2018 compared to \$32,021,177 at December 31, 2017.

Bionomics was unchanged at 12 cents.

BARD1 LIFE SCIENCES

Bard1 says its 5-peptide vaccine is effective in a mouse model of malignant mesothelioma mice, but has no effect in lung, colon or breast cancer.

Bard1 says its 5-peptide vaccine delayed tumor growth, prolonged survival and induced an immune response in the mouse model of malignant mesothelioma.

The company said the results were encouraging but it would require further research to evaluate different antigens, vaccine formulations and doses.

Bard1 said the research program was undertaken with the Perth-based University of Western Australia's Institute for Respiratory Health to examine the potential of its 5-peptide at 100µg or 200µg doses.

The company said the 5-peptide vaccine showed a significant but variable effect on malignant mesothelioma in mice, but the formulation and dose selected was "unlikely to be optimal and therefore further studies [were] required".

Bard1 fell 0.4 cents or 16.7 percent to two cents with 59.8 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it will partner with Anchovy to deliver its Mente autism product in a subscription-based go-to-market model.

The Malta-based Neurotech said the partnership would allow clinics to offer Mente to their patients.

Neurotech was unchanged at 2.7 cents.