Biotech Daily

Friday June 5, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 17%; CYCLOPHARM DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: VOLPARA HEALTH TECHNOLOGIES**

*** CSL, UQ, CEPI COLLABORATE ON COVID-19 VACCINE CANDIDATE**

*** ATOMO: RAPID COVID-19 TEST AUSTRALASIA DISTRIBUTION RIGHTS**

*** HERAMED RAISES $2.3m; SHARE PLAN FOR $1.5m MORE**

*** PAINCHEK RECEIVES 2nd $1.25m FEDERAL PAYMENT**

*** LBT CUTS COSTS, REDUCES WORK WEEK, PAY 20%**

*** FIRB, FEDERAL APPROVAL FOR AVITA US MOVE**

*** CYCLOPHARM AGM VOTES ON 1m M-D INCENTIVE, LOAN SHARES**

*** MEDIBIO REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** SUDA TAKES 'LICENCING, CAPITAL RAISING' HALT TO SUSPENSION**

*** PROTEOMICS REQUESTS 'CLARIFICATION' TRADING HALT**

*** JM FINANCIAL, NO PLAN B INCREASE, DILUTED TO 14% OF MACH7**

MARKET REPORT

The Australian stock market was up 0.12 percent on Friday June 5, 2020, with the ASX200 up 6.9 points to 5,998.7 points. Eight of the Biotech Daily Top 40 stocks were up, 23 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Proteomics was the best, up 6.5 cents or 16.9 percent to 45 cents, with 503,405 shares traded. Oncosil climbed 11.1 percent; Alterity was up 6.25 percent; Compumedics and Pharmaxis rose more than two percent; Cynata and Opthea were up more than one percent; with Starpharma up 0.95 percent.

Cyclopharm led the falls, down 10 cents or 6.6 percent to $1.41, with 45,464 shares traded. Nanosonics and Resonance lost five percent or more; Dimerix, Impedimed, Optiscan, Pro Medicus and Universal Biosensors fell four percent or more; CSL, LBT, Mesoblast, Next Science and Uscom were down more than three percent; Cochlear, Genetic Signatures, Imugene, Kazia, Medical Developments, Polynovo, Resmed and Telix shed more than two percent; Antisense, Neuren, Paradigm and Prescient were down one percent or more; with Volpara down by 0.7 percent.

DR BOREHAM'S CRUCIBLE: VOLPARA HEALTH TECHNOLOGIES

By TIM BOREHAM

ASX code: VHT

Share price: $1.395

Shares on issue: 247,437,034

Market cap: $345.2 million

Chief executive officer (and co-founder): Dr Ralph Highnam

Board: Paul Reid (chairman), Dr Highnam, Dr Monica Saini (chief medical officer), Roger Allen, Prof John Michael Brady, John Diddams, John Pavlidis, Karin Lindgren

Financials* (full year to March 2020): revenue $NZ12.6 million (up 153%), net loss after tax $NZ20.3 million (previously an $NZ11.7 million deficit), cash of $NZ31.4 million (up 118%).

***** One $NZ1.00 equals $A0.92

Major shareholders (as of April 30): Harbour Asset Management 9.0%, Patagorang Pty Ltd (Roger Allen) 8.95%, Dr Highnam 6.75%, Prof Michael Brady 2.76%, Marcus Sarner 2.49%

As we emerge from the coronavirus era, the Wellington-based breast imaging software play clearly expects opportunities - and by that we mean more acquisitions - to supplement its big-ticket purchase of US group MRS Systems for $NZ21 million ($A19 million) a year ago.

Clearly flagging its intent, Volpara has just raised $37 million for "general working capital and further acquisitions" - which puts paid to the notion of capital being scarce in the biotech sector.

A year ago, Volpara raised $NZ55 million to fund the MRS purchase - and more - so management clearly is not scared of going to the well, if needs be.

With its coffers now swollen to $NZ69 million and with no debt, the company has amassed an impressive armory to pounce when the opportunity arises.

Put it this way: the company might be all about breasts but it's in no danger of going bust.

Volpara last month demonstrated its top-line progress by posting full-year revenue of $NZ12.6 million, 150 percent up on the previous year.

While breast screening fell off a cliff during Covid-19, the March quarter was the company's strongest fourth quarter performance to date.

The danger of density

Volpara's platform technology focuses on improving the detection and diagnosis of breast cancer, with an emphasis on measuring breast density. Dense-breasted women are at greater risk of cancer because not only are they at greater risk in the first place, the fatty tissue does not come up well on the mammogram.

"It's like spotting a polar bear against a white background," says Volpara founder and CEO Dr Highnam.

In the US, 10 percent of women are classed as extremely fatty breasted, which we - not Volpara - will dub the Dolly Parton cohort.

Eighty percent are mid-density and 10 percent are "extremely dense" - and any Australian comparison is likely to be no different.

One problem is that the dense-versus-fatty classification is somewhat subjective, despite US medical authorities devising a scale from A to D (A being 'extremely fatty' and D being 'extremely dense').

"One of our jobs at Volpara is to make it more objective and give a true physical score of breast density," Dr Highnam says.

He says mammography is effective in reducing mortality rates by 30 percent to 40 percent - but there are better ways of doing it.

"If you have fatty breasts, there's a 90 to 100 percent chance the cancer will be detected at screening, but if you have dense breasts you are down to 60 to 65 percent probability of it being detected,' he says.

"There really is a significant masking risk for women with dense breasts."

Keeping abreast of Volpara

Dr Highnam is a global expert - perhaps the global expert - on breast density. He even completed an Oxford D Phil (Doctorate of Philosophy) on the topic in the early 1990s, while his fellow scholars were sculling on The Isis or sculling yard arms in the Bear Inn (the town's oldest pub).

Dr Highnam founded Volpara in 2008. The company listed on the ASX on April 26 2016, raising $10 million at 50 cents apiece.

Since then, the company has raised a further $132 million.

Volpara started with Volpara Density, a tool to measure breast density and thus identify at-risk women for more frequent examinations. Volpara then devised Volpara Enterprise: automated tools used by clinics to improve the efficiency and performance of sites with multiple x-ray machines.

The company then launched Volpara Live! - a tool to assist clinicians in real time.

Volpara Enterprise enables clinicians to detect a sub-standard image before the patient has left the clinic, avoiding the need for an expensive recall.

Users of Volpara Enterprise include New York's Sloan Kettering Cancer Centre, the Houston Texas MD Anderson, California's Stanford University Hospital, the University of Virginia Medical Centre, Women's Breast Imaging Perth, the Auckland Breast Centre and Auckland Mercy Radiology.

The Seattle-based MRS Systems provides mammography reporting systems to more than 1,600 US breast clinics and hospitals.

The MRS purchase also added two radiology reporting platforms, Aspen Breast and Aspen Lung.

While Volpara's products and services are approved and used in 38 countries, the US accounts for 90 percent to 95 percent of revenue and this is unlikely to change in a hurry.

"The US had Federal regulations around breast cancer screening, but individual sites have more choices about what they can do," Dr Highnam says.

"They are all keen at being at the leading edge of the curve, which is where we want to be as well."

Volpara sells directly, as well as through partners including GE Healthcare.

Volpara has some interesting backers in Australian entrepreneur Roger Allen, founder of Computer Power group and the venture capital firm Allen & Buckeridge.

Founding director Prof Mike Brady is a professor of oncology imaging at Oxford University.

Dr Saini is a former medical director of GE Health and a breast screening guru. Mr Reid and Mr Diddams are serial company directors in Australia and NZ.

Lung screening has breath-taking potential

Via the Aspen Lung addition, lung imaging contributes only modest revenues. But the potential is clear in that about 600,000 people get lung cancer screening annually, while the eligible market in the US alone is close to six million people.

“Eligible means high risk: you have smoked or you’re over a certain age,” Dr Highnam says. “Currently referring doctors don’t yet know the full benefits, so referrals to screening are low.”

Each lung computerized tomography (CT) scan in the US is reimbursed at $US250 ($A362). So, if Aspen Lung can snare five percent of the market, that’s $US75 million of annual recurring revenue.

As for the global market, you can pretty much double that figure.

Finances and performance

Volpara’s revenue has been transitioning from capital purchases to ‘software as a service’ subscription revenues, which allows for smoother annuity income (like breasts, the less lumpy the better).

Typically, the clinics are on five-year contracts, with subs paid a year in advance.

While Volpara posted revenue of $NZ12 million last year, perhaps the most meaningful number is annualized recurring revenue of $NZ18 million, up 170 percent.

Average revenue per unit improved from 94 US cents in the three months to June 30, 2019, to $US1.04 in the March 2020 quarter.

We should note that Volpara also posted a $NZ20.3 million loss, up from the previous $NZ11.7 million deficit. This resulted from operating costs more than doubling to $NZ36 million, which management attributes to organic growth and the costs of the MRS acquisition.

Management has taken action to pare these operating costs by 10 percent to 15 percent.

The company has not proffered earning guidance for the 2020-’21 year. “It’s so far, so good with Covid-19, but sales are slow and things are uncertain in the US,” Dr Highnam says. “We’ll reconsider [guidance] at the end of the second [June] quarter.”

As of balance date, the MRS breast product was installed across 1,570 sites and Volpara Enterprise at 587. The lung screening product was installed at 177 sites. Over time, the MRS revenues will move from up-front capital sales to the internet ‘cloud’ subscription model.

Volpara’s capital raising involved a $28 million institutional placement and a $7 million share purchase plan, both at $1.30 (a modest 10 percent discount).

The share purchase plan was expanded to $9 million after the company received $11 million of subscriptions.

During the February and March meltdown, the shares slumped from $1.90 to a low of 81 cents. Since listing they have traded as high as $2.09 (November 2019) and as low as 30 cents (May 2017).

Volpara was the second-best performer of the Biotech Daily top 40 biotech stocks in 2018, surging 200 percent.

Dr Boreham's diagnosis:

Volpara's quest to dominate the US market is being helped by an expanding number of states issuing breast density screening guidelines. In February, Georgia became the 38th State to do so, with the guidelines now covering close to 90 percent of US women.

In the US, Volpara products have been used for 27 percent of all women screened - 10 million patients - compared with seven percent a year previously. So, while that represents stellar growth it's still a case of a (breast) cup half-full.

Dr Highnam notes the US Food and Drug Administration recently issued guidelines to improve the quality of mammography and provide more information to patients, especially about breast density. These guidelines had remained untouched since 1997.

Still, investors might be wondering when Volpara will turn a quid. Broker Morgans plugs in an $NZ8.3 million loss for the current year to March 31, 2021, but then a $NZ2.63 million surplus in 2021-'22 and a $NZ18.3 million profit in 2022-'23.

Bell Potter's biotech watchers are more cautious and expect the company's red ink to persist over these three years.

A rough measure of Volpara's potential is that 75 million women are screened worldwide each year, so if the company can reach targeted annual revenue per unit of $US10 (compared to the March 2020 quarter $US1.04) that's a $US750 million a year market.

Asian markets are likely to present opportunities, given the increasing breast cancer rates for dietary and lifestyle reasons.

Bear in mind that building an internet 'cloud' subscription business entails up-front expenditure to woo customers, with the revenue recognized over the life of the contract.

But as the customer book builds, revenue and earnings 'do a Dolly Parton' and swell exponentially.

Disclosure: Dr Boreham is not a qualified medical practitioner. He does not possess a doctorate of any sort but does sport impressive man boobs that would put Dolly to shame

CSL

CSL says it will manufacture, develop, and distribute the University of Queensland's Covid-19 vaccine with the Coalition for Epidemic Preparedness Innovations.

In February, CSL said it had partnered with Brisbane's University of Queensland for its coronavirus disease-19 (Covid-19) vaccine program to combine with its influenza subsidiary Seqirus's MF59 adjuvant (BD: Feb 12, 2020).

Today, the company said it would share the costs associated with the clinical development and manufacture of the vaccine candidate with the Oslo, Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) and divide the resulting vaccines in proportion to the funding given to production costs.

CSL said that in January 2019, the University of Queensland had signed an agreement with CEPI, who would provide up to $US10.6 million ($A15.3 million) to develop the University's rapid response "molecular clamp" vaccine platform for rapid vaccine design and production against outbreak viral pathogens, by locking unstable, pre-fusion versions of the surface proteins while allowing the immune system to respond more effectively.

The company said the molecular camp technology locked the proteins in their native virus surface form, from which the synthetic protein can be manufactured into a vaccine.

CSL said that in January 2020, CEPI expanded its partnership with the University of Queensland to use the vaccine platform to produce a vaccine candidate for Covid-19, which the university expected to begin phase I trials for in July 2020.

The company said the initial phase of large-scale production of the vaccine would take place at its Melbourne manufacturing facilities once critical milestones were met.

CSL said it had the capacity to produce up to 100 million doses and would subcontract other manufacturers to increase the production volume and broaden the geographical distribution of vaccine production and if clinical trials were successful, "a vaccine could be available for distribution in 2021".

CSL chief scientific officer Prof Andrew Cuthbertson said that CSL would contribute to the University of Queensland's vaccine with its MF59 adjuvant, along with expertise in process science and scale-up at its Australian facilities.

"Should trials be successful, this vaccine holds the potential to provide protection against this urgent public health emergency for Australians and those around the world vulnerable to this devastating virus," Prof Cuthbertson said.

CSL fell $8.90 or three percent to $285.33 with 1.7 million shares traded.

ATOMO DIAGNOSTICS

Atomo says it will distribute a Covid-19 antibody test in Australia, New Zealand and parts of South East Asia, branded as Atomo Rapid Covid-19 (IgG/IgM).

In April, when Atomo listed on the ASX, the company said the Guipry, France-based NG Biotech SAS would buy up-to 2.5 million Atomo rapid blood self-tests for Covid-19 in 2020 for sale in France and the UK (BD: Apr 16, 2020).

Today, the company said it had expanded its agreement with NG Biotech for exclusive rights to market and distribute the Covid-19 test in Australia, New Zealand and nine countries in South East Asia, subject to regulatory approvals.

Atomo said the test would be branded as the 'Atomo Rapid Covid-19 (IgG/IgM)' for its target domains of immunoglobulin-G and immunoglobin-M.

Atomo said that the pricing arrangements with NG Biotech were limited to a price payable for each unit and did not include any licence fees or royalties and the companies were negotiating a long-term supply agreement.

Atomo was up 1.5 cents or 4.8 percent to 33 cents with 19.8 million shares traded.

HERAMED

Heramed says it has commitments to raise $2.32 million in a placement at nine cents a share and hopes to raise a further $1.5 million in a share plan at the same price.
Heramed said the share price was a 21 percent discount to the closing price on May 29, 2020 and an 18 percent discount to the five-day value weighted average price.
The company said the share plan would offer eligible shareholders at the record of May 29 up $30,000 in new shares at nine cents each.
Heramed said that the offer was expected to close on June 26, 2020.
Heramed chief executive officer David Groberman said that “since the start of Covid-19, there has been a substantial increase in interest in our telehealth maternity care platform from healthcare professionals globally and these funds will ensure we capitalize on these opportunities”.
Heramed fell half a cent or 4.35 percent to 11 cents.

PAINCHEK

Painchek says it has received $1.25 million from the Federal Government for providing 25,000 Painchek pain recognition software licences to aged care facilities.
In March, Painchek said it had a $5 million grant agreement with the Federal Government to distribute Painchek to residents living with dementia or cognitive impairment and had received the first $1.25 million tranche for the first 25,000 licences provided, aiming to roll out 100,000 Federal Government funded dementia bed licences by the end of 2020 (BD: Mar 19, 2020).
Today, the company said the Dementia grant initiative timeline to deliver the 100,000 Painchek licences had been extended to June 2021.
Painchek was unchanged at 16 cents with 1.8 million shares traded.

LBT INNOVATIONS

LBT says it has reduced its employees’ standard working hours and pay by 20 percent, effective from June 1, 2020, to conserve cashflow amid the Covid-19 crisis.
LBT said that the standard working week would be four days until September 27, 2020.
The company said that 83 percent of eligible employees were participating in the incentive place, which gave them the option to work four days a week for four days’ pay or a five-day week, with 20 percent of their salary paid in shares.
LBT said that a maximum of 1,028,094 shares could be issued under the incentive plan between July 27 and September 28, 2020, offered at 10 cents a share, a four percent discount to the five-day volume weighted average price to April 29, 2020.
The company said the wage and work week reduction were intended “to balance the company’s needs to conserve cash whilst also maintaining its focus on further technology development and execution on existing sales prospects”.
LBT fell half a cent or 3.45 percent to 14 cents.

AVITA MEDICAL

Avita says the Foreign Investment Review Board has confirmed that the Federal Government has “no objection” to the company’s proposed move to the US.
In April, Avita said it intended to relocate to the US to “reduce the costs, burden, resourcing and risks” of operating in both Australia and the US (BD: Apr 21, 2020).
Avita was unchanged at 49 cents with 10 million shares traded.

CYCLOPHARM

Cyclopharm says its annual general meeting will vote to issue managing-director James McBrayer 1,015,500 shares and re-elect director David Heaney.
Cyclopharm said the shares would be issued to Mr McBrayer in three tranches as a long-term employment incentive and as a loan.
The company said the first tranche of 500,000 would vest in 2022 if Mr McBrayer continued as the managing director and if a loan from the company to Mr McBrayer equal to 500,000 shares had been repaid, with the second tranche of 257,750 shares fully-vested and immediately available, and the third tranche of 257,750 shares fully-vested but locked until Mr McBrayer repaid a 2015 loan of 1,532,183 by May 9, 2022.
The company said it would vote to adopt the remuneration report and re-elect Mr Heaney.
The meeting will be held virtually via the online meeting platform, Lumi, accessible at https://web.lumiagm.com/?fromUrl=356876028 on July 9, 2020 at 11:30am (AEST).
Cyclopharm fell 10 cents or 6.6 percent to $1.41.

MEDIBIO

Medibio has requested a trading halt pending an "announcement regarding a capital raise".
Trading will resume on June 10, 2020 or on an earlier announcement.
Medibio last traded at 0.6 cents.

SUDA PHARMACEUTICALS

Suda has requested a voluntary suspension to follow a trading halt "in relation to a proposed material licencing transaction and capital raising" (BD: Jun 1, 2020).
Trading will resume on June 9, 2020 or on an earlier announcement.
Suda last traded at 4.2 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a trading halt "pending the release of an announcement clarifying disclosures made in the investor presentation" on June 5, 2020.
Trading will resume on June 10, 2020 or on an earlier announcement.
Proteomics closed up 6.5 cents or 16.9 percent at 45 cents.

MACH7 TECHNOLOGIES

JM Financial Group and No Plan B Pty Ltd say they have increased and been diluted in Mach7 from 23,439,232 shares (15.89%) to 26,238,486 (14.35%).
The Melbourne-based JM Financial and No Plan B said that they bought and sold shares between April 10, 2019 and May 27, 2020, with the single largest purchase 4,917,516 shares for $3,048,860 or 62 cents a share in Mach7's $20 million December placement and the single largest sale on May 25, 2020 of 2,114,382 shares for $1,454,478.15 or 68.8 cents a share (BD: Dec 3, 2019).
Mach7 was up three cents or 4.05 percent to 77 cents.