Biotech Daily

Friday December 11, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMMUTEP UP 22%; LBT DOWN 7%**

*** DR BOREHAM'S CRUCIBLE: IMEX HEALTH SERVICES**

*** CSL, UQ CLOSE V451 COVID-19 VACCINE TRIAL**

*** ANU, JANSSEN WORK ON TYPE 1 DIABETES TESTS**

*** CHIMERIC 'OVER-SUBSCRIBED' $35m IPO CLOSES EARLY**

*** CYNATA PLACEMENT RAISES $15m, RIGHTS OFFER FOR $5.5m MORE**

*** BOD PLACEMENT RAISES $8m**

*** PATRYS RIGHTS RAISE $2.4m, $2.4m SHORTFALL; TOTAL $7.3m**

*** L1, OBSIDIAN CONVERT $3m CANN GLOBAL NOTES FOR SHARES**

*** ZELIRA RECEIVES $1.4m R&D TAX INCENTIVE**

*** ALTHEA REQUESTS CAPITAL RAISING TRADING HALT**

*** REGAL FUNDS INCREASES, DILUTED TO 5% OF MEDADVISOR**

*** CRESO MARIJUANA FOR MARTIN & PLEASANCE**

MARKET REPORT

The Australian stock market fell 0.61 percent on Friday December 11, 2020, with the ASX200 down 40.5 points to 6,642.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and three were untraded. All three Big Caps fell.

Immutep was the best for the second day in a row, despite missing trial endpoints, up 17 cents or 60.7 percent to 45 cents, with 84.9 million shares traded. Telix climbed 13.3 percent; Proteomics rose 10.1 percent; Osprey was up 4.8 percent; Genetic Signatures improved 3.8 percent; Clinuvel and Mesoblast rose more than two percent; Kazia, Neuren, Orthocell and Polynovo were up more than one percent; with Starpharma and Volpara up by less than one percent.

LBT led the falls, down one cent or 6.9 percent to 13.5 cents, with 5.1 million shares traded. Alterity lost 6.1 percent; Cynata and Uscom fell more than five percent; Antisense, Cochlear, CSL, Cyclopharm, Optiscan and Resmed were down more than three percent; Nova, Opthea, Paradigm and Pharmaxis shed more than one percent; with Avita, Nanosonics, Next Science and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMEX HEALTH SERVICES

By Tim BOREHAM

ASX code: IME

Market cap: $49.0 million; **Share price:** $1.65***; Shares on issue:** 29,699,842*****

***** Post 50:1 share consolidation

Co-founder and chief executive officer: Dr German Arango

Board: Doug Flynn (chair), Carlos Palacio, Dr Arango, Dr Douglas Lingard, Damian Banks

Financials (September quarter): receipts $1.7 million, cash outflows $996,000, cash balance $3.8 million, loan facilities $1.7 million, quarters of available funding 3.85

First half to June 2020: revenue $4.49 million (up 68%), loss of $2.36 million (previously $2.17 million loss).

Identifiable major holders: Digital Imaging Solutions SAS 10.6%, Perennial Value Management 7.8%, Milla Paula Inari Palacio 6.99%, Jaava Asesores integrates SAS 6.98%, Volegna Holdings (CSA Trust) 4.1%

At Planet Crucible we're always wary of labeling a stock or sector the 'next big thing', as such pronouncements are just as likely to deliver the kiss of death.

Having said that, the radiological diagnostics sector has been on a tear, the result of improvements in artificial intelligence, internet cloud-based delivery and regulatory requirements for centralized and digitized patient records.

Oh, and we're all getting older, which increases demand for the core product.

Awed shareholders in the home-grown, ASX-listed Pro Medicus have seen their investment emerge from small-cap to a global provider now worth more than $3 billion.

Specializing in breast cancer diagnostics, the Kiwi-based Volpara Health Technologies is now valued at around $350 million.

Mach7 Technologies has emerged from nowhere at, well, mach speed and is now valued at $300 million. (We covered this one on November 6 this year).

This brings us to the obscure Imex, the Latin American-based diagnostics play which back-door listed on the ASX in 2018 and has been as quiet as a church rodent ever since.

Few investors would be able to pronounce the company's name. But this is likely to change as the company expands from its South American foothold into the US market, as well as Europe and Australia.

It’s IMEXHS, not INXS

The company’s moniker, by the way, abbreviates “imaging experts and healthcare services” and has nothing to do with the great Aussie rock band InXS. To simplify matters, Biotech Daily uses the short-form Imex, but you still can’t use it to watch movies on big screens.

Imex is headquartered in Sydney’s Mascot but most of its activities are carried out from the Colombian capital of Bogota.

Based on its patented software called Hiruko, Imex has three product lines covering radiology (Aquila), pathology (Alula) and cardiology (Anteros). Hiruko is approved in the US and Europe.

In May this year, the company launched Aquila in the Cloud (AIC), an off-the-shelf product which is aimed at small to mid-sized facilities with small budgets.

The Imex product suite covers radiology information systems (RIS) and picture archiving and communications system (PACS). RIS is all about workflow management of patient data and imaging. PACS is about capturing, storing and viewing the images.

The functions include ordering patient scans, booking the patient with the radiographer and sending the image to a radiologist for interpretation and back to the referring doctor.

Imex also facilitates “tele-radiology”: the ability of practitioners to view and interpret data from their device anywhere at any time.

Yep – no need to leave the nineteenth hole at the golf course.

Currently Imex operates in 15 regions: 12 Latin American nations, Spain and Florida and Texas in the US. Imex also has a fledgling presence in Australia, if only to show local shareholders what it’s up to.

Cut another way, the company’s products (mainly Hiruko) are used across 270 sites by more than 600 radiologists.

How the ‘band’ was formed

Imex was co-founded in 2012 by Latin American neuro-radiologists Dr German Arango and Dr Jorge Marin, as well as radiology software industry veteran Andres Vanegas.

Dr Arango is currently on the neuro-radiology staff at Bogata’s University of Rosario’s Hospital Universitario Mayor-Mederi.

Dr Marin is at the Hospital Universitario San Jose in Bogota and is the company’s chief medical officer, while Mr Vanegas is chief sales officer.

Dr Arango says the founders were motivated by the need to solve “specific aspects” of their work practices, such as downloading bulky images from remote parts of the Amazon.

“When practicing in Colombia, a developing country, it was challenging to find an efficient tele-radiology tool because of bandwidth restrictions,” Dr Arango says.

Dr Arango says that with two engineers they worked out their own platform for teleradiology and the decided to create the company around initial product.

The company listed here in September 2018 on the back of investor relations application developer Omni Market Tide, after raising $5.5 million at 2.5 cents apiece ($1.25 post consolidation).

Imex’s recently-anointed chair Doug Flynn is an experienced ASX-listed company board hand who also chairs the data centre giant Next DC.

Aquila in the Crowd

Dr Arango says while the pandemic is “challenging” it did no harm to Aquila in the Cloud’s prospects after its May launch, given the tool allows for efficient remote teleradiology.

Aquila in the Cloud is aimed at the low to mid end of the market and is pitched as easy to use. Think of it as the imaging equivalent of the trans-Tasman accounting software company Xero, the first to migrate its small business offering to a ‘cloud’ software-as-a-service (SaaS) business.

In an update in early December, Imex said it had signed 28 Aquila deals in six countries, equating to $675,000 in annual recurring revenue

Dr Arango says the company is devoting the same effort to its legacy products and Aquila in the Cloud, but expects the latter will gain more traction “because the whole market is moving in that direction”. As always, price is a key competitive factor.

“We can be 50 percent cheaper than our competitors and still have very good margins,” he says.

Brazil and beyond

The company plans to focus on developing markets, which doesn’t mean it will ignore Latin America. In fact, it’s not yet operating in Brazil, the region’s biggest market. But the company’s products are approved there and management has enrolled in a Portuguese language crash course.

China and greater Asia also beckon - but not yet.

In the US, the company recently appointed its first salesperson and two distributors and has just signed up its first client (in Miami) on a 30-day trial.

Under its “land and expand” strategy, the company will focus on the radiologists before selling to pathologists and cardiologists.

“We already have a platform for radiology and pathology and cardiology but the plan is to deliver a few more ‘ologies’ [such as gastroenterology and haematology],” Dr Arango says.

One client is even involved in airport x-ray screening, which is a routine screening for improvement (read all about mobile x-ray specialist Micro-X’s airport plans next week, in our final report for the year).

In the shadow of giants

Given the segmented nature of the radiology market, Imex competes with different suppliers in different sectors. At the high end - the mature clinics - it’s most likely to bump into Agfa, Fuji, GE Health and Carestream (formerly Kodak).

“But there’s a big gap,” he says. “In the US, 80 percent of the market is rural and low end. It’s not well attended by the main players.”

At the top end of the market, it’s usually hard to displace an existing provider, given the amount of data that needs to be migrated to the new system.

As for the company’s ASX exemplars, he says they are ‘same but different’ in terms of the markets they tackle.

Mach7 is only in the PACS sector (not RIS) while Volpara is breast-centric, so to speak.

“Pro Medicus is an amazing company; as a radiologist I have to say the [product] they have is top end,” Dr Arango says.

He says Imex has enjoyed the positive “collateral effect” from the “good behavior” of the ASX imaging houses, which has stirred investor appetite for medical imaging companies.

Finances and performance

Imex reported revenue of $4.49 million in the six months to June 30, 2020, up 68 percent. But September quarter recurring revenue came in at a Covid-afflicted $1.9 million, 16 percent lower.

At the end of September, the company held a light cash balance of $3.8 million but In October raised $8.3 million in a placement. The previous October the company rustled up $10 million, also in a placement.

What’s wrong with clockwork reliability?

The company derives revenue from a combination of ‘software as a service’ (SaaS), ‘platform as a service’ (PaaS) and one-off sales. SaaS deals are typically over three to five years. As the name implies, the client pays subscription fees along the way.

PaaS includes hardware and other “modalities”.

While the company prefers recurring revenue - who wouldn't? - it's common to record a chunk of one-off sales as clients seek to use their budgets by the end of the financial year.

In November, Imex underwent a 50-for-one share consolidation, which means the stock trades at around $1.70 rather than at a penny dreadful level of 3.4 cents.

Your columnist ponders whether such consolidations ever have helped a share price in real terms, but it certainly makes for a better look.

Allowing for the consolidation, Imex shares have traded as high as $2.45 (January 22 this year) and as low as 75 cents (March 24 this year).

Dr Arango says the company is happy with being singularly ASX listed.

"We have good connections with Austrade and the [Australian] embassies, they have been very supportive in Latin America and the US," he says.

Dr Boreham's diagnosis:

Like its (almost) namesake rock band, Imex is better known overseas than here.

But it's no use pretending … overall it ranks at close to zero in the investor recognition stakes and perhaps this makes for an opportunity given the company's lowly circa $50 million market valuation.

On estimates from data cruncher Research and Markets, the overall RIS/PACS market was worth $US2.7 billion ($A3.6 billion) in 2018 and is forecast to grow to $US5 billion by 2027, an annual growth rate of 7.4 percent.

But Imex small to mid-market focus could prove the winning formula.

"I have been astonished by the number of clinics and medical imaging centres that have been completely overlooked by the large on-premise suppliers," Dr Arango says.

More broadly, Imex taps the megatrends of artificial intelligence, the digitization of healthcare and cloud computing and storage.

Like a dodgy lump on an x-ray, Imex is one to monitor closely as it seeks to achieve earnings break-even status by early next year.

And beyond that, could it become the New Sensation in the ASX-listed medical imaging space?

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he does possess a white coat and clipboard so hopefully no-one will know the difference, particularly at an InXS gig or in a dark IMAX cinema.

CSL, UNIVERSITY OF QUEENSLAND

CSL says the phase I trial of the UQ-CSL V451 Covid-19 vaccine "is not going ahead as planned" due to false positive HIV results.

CSL said that the phase I data showed the generation of antibodies directed towards fragments of the gp41 protein, a component used to stabilize the vaccine.

In a media release, the company said "it was unexpected that the levels induced would interfere with certain HIV tests".

CSL said there was "no possibility the vaccine causes infection, and routine follow up tests confirmed there is no HIV virus present".

The company said the implications of the issue meant that "significant changes would need to be made to well-established HIV testing procedures … to accommodate rollout of this vaccine".

CSL said that the vaccine "elicits a robust response towards the virus and has a strong safety profile".

In an internet 'webinar' the University of Queensland's Prof Trent Munro said the researchers were "positive about the data [and] the trial was not stopping, but it was not going ahead as planned".

"It was not a safety issue but a diagnostic interference issue," Prof Munro said.

CSL said the randomized, double-blinded, placebo-controlled, dose escalation trial recruited 120 subjects aged 18 to 55 years of age and 96 subjects aged 56 years and above.

"Eighty-five percent of those receiving two doses had immune responses greater than the convalescent [Covid-19] population," Prof Munro said.

Prof Munro said there were also T-cell responses and in terms of safety the trial showed "very very positive data" with adverse events of moderate intensity and short duration.

"In the light of these results, it's a particularly disappointing day for the team," Prof Munro said.

The University of Queensland's Prof Paul Young said that the 'molecular clamp' used to make the unstable severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) more stable had two fragments of the HIV protein, which was detected in rapid and point-of-care tests, and then ruled out in more formal laboratory testing.

Prof Young said that it was a "risk-based decision to use HIV in the molecular clamp", but given the time lines the group did, demonstrating that it was a very powerful technique.

Prof Young said that in the light of other vaccine data "and if the others weren't [so far progressed] we would have continued".

CSL said that trial participants were fully informed of the possibility of a partial immune response to this component, but it was unexpected that the levels induced would interfere with certain HIV tests.

The company said the phase I trial would continue, with further analysis to show how long the HIV antibodies persist, with studies so far showing that levels are already falling.

Prof Young said that although it was possible to re-engineer the vaccine, the team "did not have the luxury of time needed".

"Doing so would set back development by another 12 or so months, and while this is a tough decision to take, the urgent need for a vaccine has to be everyone's priority," Prof Young said.

"I said at the start of vaccine development that there were no guarantees, but what is really encouraging is that the core technology approach we used has passed the major clinical test," Prof Young said. "It is a safe and well-tolerated vaccine, producing the strong virus-neutralizing effect that we were hoping to see."

CSL fell $9.76 or 3.2 percent to $291.53 with 1.1 million shares traded.

AUSTRALIAN NATIONAL UNIVERSITY
JANSSEN RESEARCH & DEVELOPMENT, JOHNSON & JOHNSON.

The Australian National University says it will collaborate with Janssen Research and Development LLC to improve the early diagnosis and monitoring of type 1 diabetes.
The Canberra-based Australian National University (ANU) said type 1 diabetes was an autoimmune disease that attacked "the body's ability to process sugar by destroying insulin-producing beta cells in the pancreas" and the research project would develop new methods for measuring and monitoring disease activity.
The University said the work with the Raritan, New Jersey-based Janssen would aim to identify individuals at risk of type 1 diabetes and track markers and influences in childhood to identify the opportunity and means to intervene early in the course of disease.
ANU said its researchers would test methods of monitoring the damage done to the pancreas as part of the wider effort to develop preventive measures and therapies.
The University said the collaboration was facilitated by Johnson & Johnson Innovation.
Prof Charmaine Simeonovic, the chief investigator of the research project, said the goal of the initiative was "to discover avenues for interception that will enable a brighter future for individuals at risk of developing symptomatic [type 1 diabetes]".
The ANU said the project would build on research supported by the Juvenile Diabetes Research Foundation to eliminate type 1 diabetes.

CHIMERIC THERAPEUTICS

Chimeric says its "over-subscribed" $35 million initial public offer at 20 cents a share has closed and the company expects to open on the ASX in January 18, 2021.
Chimeric said it was on schedule to open on the ASX in January, under the code CHM to develop chimeric antigen receptor T-cells for glioblastoma (BD: Nov 19, 2020).
Chimeric executive chair Paul Hopper said the company's chlorotoxin chimeric antigen receptor (CLTX-Car) T-cell therapy, licenced from the Duarte, California-based City of Hope, was "an extremely promising technology … and this [initial public offer] allows us to further develop the therapy, focusing initially on glioblastoma with other cancers to follow".
The company said an 18-patient, open label, phase I trial of CLTX-Car T-cell was underway, with two patients dosed and expected to be complete within 15 to 24 months.
Chimeric is a public unlisted company.

CYNATA THERAPEUTICS

Cynata says it has raised $15 million in a placement at 70 cents a share and hopes to raise a further $5.5 million in a one-for-15 rights offer at the same price.
Cynata said the placement was supported by a $10 million cornerstone investment from Bioscience Managers through Phillip Asset Management as trustee for the Bioscience Managers Translation Fund I.
The company said the share price was a 9.6 percent discount to the five-day volume weights average price to December 8, 2020.
Cynata said the funds would be used to expand the pipeline and development of its Cymerus mesenchymal stem cells to include indications for idiopathic pulmonary fibrosis, renal transplantation and diabetic foot ulcers, increase manufacturing capabilities and for general working capital.
The company said the rights offer for shareholders at the record date of December 16, would open on December 21 and close on January 13, 2021.
Cynata fell 4.5 cents or 5.7 percent to 74 cents.

BOD AUSTRALIA

Bod says it has “firm commitments” to raise $8 million in a placement at 55 cents a share to institutional, professional and sophisticate investors.
Biotech Daily calculates that the share price was a 10.6 percent discount to the last trading price before the company’s trading halt (BD: Dec 10, 2020).
Bod said the funds would be used to launch new products, increase international expansion, promote medical marijuana prescriptions in Australia, and pursue growth opportunities.
The company said the placement was led by Bell Potter Securities.
Bod fell 1.5 cents or 2.4 percent to 60 cents.

PATRYS

Patrys says its fully underwritten, one-for-six rights offer has raised $2,408,564 of an expected $4.78 million, taking the total raised to $7.3 million.
Last month, Patrys said it had raised $2.5 million in a placement at 2.0 cents a share and hoped to raise a further $4,787,000 million in a rights issue.
The company said it planned to use the funds for its PAT-DX1 breast cancer trial, business and product development, and general working capital (BD: Nov 9, 2020).
Today, the company said the $2,378,527 shortfall would be placed by the capital raising underwriter and lead manager Lazarus Corporate Finance Pty Ltd.
Patrys was unchanged at 1.9 cents with 1.5 million shares traded.

CANN GLOBAL

Cann Global says L1 Capital Global Opportunities and Obsidian Global will convert their convertible notes to shares at 0.5 cents each, in lieu of cash.
Previously, Cann Global said that following capital raising arrangements and refinancing agreements, the Washington, District of Columbia-based Obsidian held 2,975,556 convertible notes and the Melbourne and New York-based L1 Capital held 680,000 convertible notes in Cann Global (BD: Nov 5, 2019; Mar 19, 2020).
Earlier this week, the company said it had raised $3,750,000 in a placement at 0.5 cents a share “to clear the company’s liabilities” including about $3 million in outstanding convertible note liabilities (BD: Dec 9, 2020).
Today, Cann Global said that L1 and Obsidian opted to “convert their outstanding notes at the placement price into equity” instead of being repaid the funds owed in cash.
Cann Global managing-director Sholom Feldman said that the resolution of the debt and the re-investment of the convertible notes was “a significant milestone for the company, that not only will the company be debt free, with a clean and strong balance sheet, but will now also no longer need to pay these liabilities, and will therefore have these additional funds available to further develop the Company’s diverse and growing businesses through what is a very active and promising period of growth for Cann Global”.
Cann Global fell 0.3 cents or 23.1 percent to one cent with 470.7 million shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it has received $1,378,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Zelira said the rebate related to research and development expenditure.
Zelira fell 0.1 cents or one percent to 9.9 cents with 5.1 million shares traded.

ALTHEA GROUP HOLDINGS

Althea has requested a trading halt "pending the release of an announcement regarding a capital raise".

Trading will resume on December 15, 2020 or on an earlier announcement.

Althea last traded at 49 cents.

MEDADVISOR

Regal Funds Management says it has increased but been diluted in Medadvisor from 15,425,373 shares (6.22%) 17,779,990 shares (5.10%).

The Sydney-based Regal Funds said that between October 28 and December 3, 2020 it bought and sold shares, with the single largest purchase 5,370,149 shares for $2,040,657 or 38 cents a share.

Regal Funds said its holding was diluted on December 8, 2020 in Medadvisor's retail rights offer at 38 cents a share, which raised $3.2 million of a hoped-for $20 million, taking the total raised for $38.2 million (BD: Dec 4, 2020).

Medadvisor was up half a cent or 1.3 percent to 38 cents with 1.05 million shares traded.

CRESO PHARMA

Creso says it will manufacture a range of cannabidiol-based products in Switzerland for sale in Australia and New Zealand under the Martin & Pleasance Pty Ltd brand.

Creso said that the Melbourne-based Martin & Pleasance was a retailer of "natural remedies and medicines" stocked in 4,000 pharmacies in Australia and New Zealand.

The company said its products were pending Australian Therapeutic Goods Administration approval the agreement would allow it to respond quickly to a favorable TGA decision and access the Australian market.

Creso said the agreement was unbinding and would be finalized on or before April 30, 2021.

Creso was up 4.5 cents or 21.4 percent to 25.5 cents with 174.4 million shares traded.