Biotech Daily

Friday August 18, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PRIMA UP 10%, DIMERIX DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: SUDA**

*** CYCLOPHARM, HMRI EVALUATE TECHNEGAS RESPIRATORY DIAGNOSES**

*** PRO MEDICUS REVENUE UP 15% to $32m, PROFIT UP 46% TO $9m**

*** MEDICAL DEVELOPMENTS REVENUE UP 20% to $19m, PROFIT $1.8m**

*** REDHILL TO MARKET PARAPRO'S ESOMEPRAZOLE (NEXIUM)**

*** PBAC BACKS FUNDING PHARMAXIS BRONCHITOL WITH PULMOZYME**

*** CANN PLEADS SCHULTZ TO ASX 15.5% QUERY**

*** RHS APPOINTS ALWIN HUI CHIEF COMMERCIAL OFFICER**

MARKET REPORT

The Australian stock market fell 0.56 percent on Friday August 18, 2017 with the ASX200 down 32.1 points to 5,747.1 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and five were untraded. All three Big Caps were up.

Prima was the best, up 0.2 cents or 10.0 percent to 2.2 cents with 5.5 million shares traded.

Atcor climbed 6.1 percent; Cellmid, Cyclopharm, Neuren and Pro Medicus improved more than four percent; Airxpanders, Clinuvel and Compumedics were up more than three percent; Admedus, Cochlear, ITL, Nanosonics and Viralytics rose more than two percent; CSL was up 1.3 percent; with Ellex, Resmed and Starpharma up less than one percent.

Dimerix led the falls for a second day in a row, down 0.1 cents or 10 percent to 0.9 cents with 2.0 million shares traded.

Acrux lost 5.4 percent; both Actinogen and Prana were down 3.6 percent; Bionomics, Mesoblast, Polynovo and Universal Biosensors shed more than two percent; Avita fell 1.3 percent; with Impedimed, Opthea, Psivida and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: SUDA

By TIM BOREHAM

ASX Code: SUD

Share price: 2.0 cents; **Shares on issue:** 1,219,858,520; **Market cap:** $24.4 million

Chief executive officer: Stephen Carter

Board: Michael Stewart (chairman), Stephen Carter, Joseph Ohayon (CFO).

Financials (June quarterly report): receipts $1.843 million (full year $7.134 million); cash burn $448,000 ($908,000); cash $1.77 million, estimated current quarter cash burn $2.175 million.

Identifiable shareholders*: Michael Stewart 2%, James Richardson 2%

***** No shareholder owns more than 5%

If Suda has its way, Viagra users won't have to wait 30 minutes – and crucial ones at that -- for the effects of the so-called Pfizer Riser to become apparent.

With Suda's reformulated oral-spray version of the drug, the active ingredients will hit the blood stream (and hence the targeted appendage) pretty much immediately.

Concurrently, Suda is well advanced with a similar spray-based iteration of the insomnia drug zolpidem tartrate – better known as Stilnox - which raises the prospect of the flesh being willing but the mind being …. zzzzz.

Such conflicting endpoints aside, Suda is at a crucial juncture in its decade-long quest to develop its 300-plus patent portfolio. In each case, the intellectual property is all about allowing drugs to be absorbed directly through the mouth lining, rather than taking the diluted route through the stomach.

According to Suda chief executive officer Stephen Carter, only about 10 to 30 percent of the active ingredients of a tablet reaches the targeted area. Of course drugs injected into the bloodstream remain the most effective, but this involves scary big syringes.

To obtain regulatory approval, Suda only needs to show the sprays are safe and at least as effective as the tablet equivalent.

Wheeling and dealing

Suda isn't re-inventing the wheel with green-fields drug development, but it's very keen on wheeling and dealing with big pharma keen on extending the life of their popular drugs.

After dabbling for more than a decade, Suda is gaining traction with three commercial deals – that is, ones involving decent money changing hands -- inked to date.

In the most substantive one, Chinese drug house Eddingpharm entered an exclusive deal to commercialise Zolpimist (Suda's spray version of zolpidem) in China. Zolpimist is approved and selling in the US, but Suda does not have the rights in this geography.

Stephen Carter says 590 million Chinese have trouble sleeping, which is not surprise when you live next door to North Korea.

Separately, Teva has a similar deal to commercialize Zolpimist in the land of the siesta, Latin America (specifically Brazil, Mexico and China).

The value of the Eddingpharm deal "could exceed" $34 million, with an upfront payment of $400,000 and a $300,000 milestone on registration of the product.

The Teva deal is potentially worth more than $55 million, with an upfront payment of $400,000 and milestones of $2.3 million and double-digit royalties.

Other partnerships are at the courtship (collaboration) phase.

In the case of Pfizer, the world's biggest drug company came to Suda seeking a spray formulation for two unnamed over-the-counter drugs (not Viagra).

Pfizer slung Suda a few bob for its work, but within the next 10 months Pfizer will decide whether to negotiate a broader commercial licence involving upfront royalties and milestones.

"It (a deal) has the potential to be a game changer but it is also a validation of our technology," Mr Carter says.

And the Pfizer Riser? There's no hard proposal so to speak, but Pfizer is almost certain to at least explore Suda's Duromist, its product name for the reformulated sildenafil, sold as Viagra.

With Viagra coming off patent, Teva and Mylan (which make generic versions) may also be interested.

Multiple opportunities

While Duromist is still in the clinical trial stage, Suda is more advanced with its spray versions of the malaria drug artemether, the migraine headache treatment, sumatriptan and the anti-chemotherapy-related nausea drug ondansetron.

Another interesting one - albeit at an earlier stage of development - is a spray version of midazolam, used to treat epileptic seizures.

Shire Pharmaceuticals markets the drug as Buccolam in 2012 and generates $US300 million of sales.

The problem is that because patients present with strong muscular convulsions, the drug is difficult to administer in tablet or injectable form.

Suda also owns a non-core business called Westcoast Surgical & Medical Supplies, which distributes medical products such as gauzes and ultrasound devices.

While it's likely to be sold, the business generates handy revenue ($7 million last year) that keeps the lights on at Perth HQ.

Financials

Mr Carter laments that Suda's $24 million market cap remains unchanged between 2013 and now. Back then, Suda had one patent and one product, compared with 300 products and 30 patents now. "We have been so busy adding value that we haven't told people what we have done," he says.

Given your columnist's catch-up was wedged between investor appointments on Suda's recent road show, the shy wallflowers have come of age.

A road show usually infers that a cash-hungry company is priming the market for a capital raising. With about $1.5 million in the bank, Suda has no immediate need to do so but management admits that finances will be tight for the next 12 months.

Unusually, Suda braves a three-year revenue and profit projection.

Including the Westcoast contribution, management expects turnover of $9.3 million in 2017-'18, $15.6 million in 2018-'19 and $24 million in 2019-'20.

This will generate current-year net cash of $560,000, rising to $2.7 million in 2018-'19 and $14.1 million in 2019-'20.

Dr Boreham's diagnosis:

A question keeping your Zolpimist-deprived scribe awake at night is why the big pharma companies haven't developed their own spray-based delivery systems.

Mr Carter says it's because they tend to have a monolithic focus on getting blockbuster drugs to market in the first place, rather than managing their life cycle.

"It's difficult for them to make a decision quickly," Mr Carter says.

Like that expectant Viagra user, Suda's $24 million market valuation does not reflect its potential full glory.

But the company's patent position needs to be tickety-boo and we assume that's the case.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he will rise to the occasion anyway.

CYCLOPHARM, HUNTER MEDICAL RESEARCH INSTITUTE

Cyclopharm says the first patient has been enrolled in a 100-patient study of respiratory diagnosis and lung function using its Technegas imaging system.

A joint media release from Cyclopharm, the University Of Newcastle, and the Hunter Medical Research Institute said that Cyclopharm was providing $665,000 for the trial to assess lung function using its Technegas radioactive ventilation tracer, along with pulmonary perfusion imaging and low dose computed tomography (CT) imaging.

The media release said that Technegas was traditionally used for patients suspected of having a pulmonary embolism, or clot, and to rule out lung abnormalities.

The Hunter Medical Research Institute's Prof Peter Gibson said that new methods for treating respiratory illness recognised there were differences in disease pathology between individual patients, but current lung function tests provided "limited insight into changes in lung ventilation".

Prof Gibson said that objective measurements we required to predict whether individuals were likely to respond to a targeted treatment and monitor of treatment response.

The media release said that study participants would breathe Technegas and undergo three-dimensional nuclear medicine imaging in parallel with a low dose computed tomography scan and the combined scans would illustrate detailed images of airspaces and blood vessels in the lungs, with 30 patients having follow-up images to provide insights into early treatment response.

Co-investigator Prof Vanessa McDonald said the study would evaluate Technegas combined with quantitative lung imaging techniques "as an objective assessment that allows us to characterize asthma and [chronic obstructive pulmonary disease] subgroups".

"We hope this will lead to an important advance in precision-based medicine of asthma and COPD," Prof McDonald said.

Cyclopharm chief executive officer James McBrayer said that with complementary nuclear medicine technology and hybrid imaging, Technegas could be used in new applications.

"This initiative has the potential to lead toward new methodologies in diagnosing and managing patients suffering from a variety of respiratory diseases," Mr McBrayer said.

Hunter Medical Research Institute director Prof Michael Nilsson said the study would "provide hope for respiratory patients with specific disease sub-types, for whom standard treatments are ineffective, by clearing the path for targeted therapies".

Cyclopharm was up four cents or 4.7 percent to 88.5 cents.

PRO MEDICUS

Pro Medicus says that revenue for the 12 months to June 30, 2017 was up 14.7 percent to $31,619,000 with net profit after tax up 46.4 percent to $9,321,000.

Pro Medicus said that Australian revenue was up 28.6 percent as a result of new sales of its Visage imaging products, with North America revenue up 27.6 percent and European revenue decreased by 58.2 percent, "due to a large capital sale to a German government hospital in the prior year".

The company said that a fully franked dividend of 2.5 cents per share would be paid on September 28, for holders on the record date of September 8, 2017, following an interim unfranked dividend of 1.5 cents a share.

Pro Medicus said that net tangible assets per share was up 35.3 percent to 17 cents, with diluted earnings per share up 44.4 percent to 8.95 cents for the year to June 30, 2017.

The company said it had in cash and cash equivalents of $22,775,000 at June 30, 2017, compared to $17,107,000 at the end of the previous financial year.

Pro Medicus was up 20 cents or 4.1 percent to $5.09.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that revenue for the 12 months to June 30, 2017 was up 20.0 percent to $18,904,000 with net profit after tax up 16.0 percent to $1,820,000.
Medical Developments said it would pay a fully-franked final dividend of two cents for holders at the record date of September 1 on October 6, 2017, following the fully-franked two cents dividend paid in April (BD: Feb 20, 2017).
The company said that sales of its Penthrox inhaled methoxyflurane analgesic increased and its Breathatech asthma spacer sales were up 182 percent for the year to June 30, 2017.
Medical Developments said its ambition was “to make Penthrox a main stream analgesic of choice around the world and our respiratory devices global leaders in their field”.
The company said that in the next 12 months it expected to have Penthrox approved for sale in more than 37 countries; begin production in its Melbourne manufacturing facility; conclude additional distribution partnerships for Penthrox and respiratory devices for new countries; advance work on producing new manufacturing technologies for small molecule pharmaceuticals; and continue a clinical program focussed on gathering the data needed to open a US Food and Drug Administration investigational new drug application and submit a new drug application for Penthrox and extend its use indications.
Medical Developments said that net tangible asset backing per share was negative 4.0 cents compared to negative 2.8 cents for the year to June 30, 2016.
The company said that diluted earnings per share was up 14.8 percent to 3.1 cents and it had cash and cash equivalents of $1,691,000 at June 30 2017 compared to $5,620,000 at June 30, 2016.
Medical Developments was unchanged at $5.15.

REDHILL BIOPHARMA

Redhill says it has a three-year deal with Parapro LLC to promote esomeprazole strontium delayed-release capsules to gastroenterologists in certain US territories.
Esomeprazole is a proton pump inhibitor marketed by Pfizer as Nexium.
Redhill said that the Carmel, Indiana-based Parapro’s esomeprazole strontium 49.3mg capsules were US Food and Drug Administration-approved and indicated for adults for the treatment of gastroesophageal reflux disease, risk reduction of non-steroidal anti-inflammatory drug-associated gastric ulcer, Helicobacter pylori eradication, to reduce the risk of duodenal ulcer recurrence and for pathological hyper-secretory conditions, including Zollinger-Ellison syndrome.
Redhill head of business operations Craig Miller said that the company had “a gastrointestinal-focused sales force of 40 sales representatives promoting Donnatal and Enteragam in select US territories [and were] excited to promote a third GI specialty commercial product”.
“Redhill is pursuing additional commercial opportunities in the specialty [gastro-intestinal] area to further expand its commercial presence in the US,” Mr Miller said.
Redhill said it was not required to make any upfront or milestone payments and the parties would share the revenues generated from the promotion of the esomeprazole capsules.
The company said it expected to begin US promotion “in the coming weeks”.
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 was up 23 US cents or 2.69 percent to $US8.77 ($A11.13) with 49,051 shares traded.

PHARMAXIS

Pharmaxis says the Australian Pharmaceutical Benefits Advisory Committee (PBAC) has recommended expanded reimbursement for Bronchitol for cystic fibrosis.

Pharmaxis said the PBAC previously cleared the way for the existing Pharmaceutical Benefits Scheme (PBS) funding of Bronchitol alone, and had added the combination with Pulmozyme, another cystic fibrosis medication, after considering a submission from Pharmaxis at its most recent meeting.

Pharmaxis chief financial officer David McGarvey told Biotech Daily that previously the PBS allowed reimbursement for either Bronchitol or Pulmozyme, but not both.

"Now cystic fibrosis patients can have both at the same time on the PBS," Mr McGarvey said.

In a media release, Pharmaxis chief executive officer Gary Phillips said the submission for broader access to Bronchitol was "strongly supported by the cystic fibrosis community with patients, families, patient organisations and … clinic teams taking part in the feedback process".

"We look forward to discussing the positive … recommendation with the Australian Government to enable the PBS listing that will allow appropriate patients taking Pulmozyme to add reimbursed Bronchitol to their treatment regime," Mr Phillips said.

Pharmaxis was unchanged at 27 cents.

CANN GROUP

Cann 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 15.5 percent from $1.29 to $1.49 today, August 18, 2017, but did not note a significant increase in trading volume.

Cann closed up 10 cents or 7.8 percent at $1.38 with two million shares traded.

RHS (REPRODUCTIVE HEALTH SCIENCES)

RHS says it has appointed Alwin Hui as its chief commercial officer.

RHS said that Mr Hui was most recently the Sydney-based Genea Biomedx sales and marketing director and would be responsible for sales and marketing of RHS products for both in-vitro fertilization (IVF) and non-IVF products.

RHS was up half a cent or 3.85 percent to 13.5 cents.