Biotech Daily

Friday July 26, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ONCOSIL UP 15%; AVITA DOWN 6%**

*** DR BOREHAM'S CRUCIBLE: IMUGENE**

*** RESMED REVENUE UP 11% TO $3.8b, PROFIT UP 4% TO $758m**

*** CELLMID RECEIPTS UP 19% TO $6.4m; 6 MONTHS CASH; PROFIT 2019-'20**

*** NEXT SCIENCE RECEIPTS $2.8m**

*** ONCOSIL PLEADS SCHULTZ TO ASX 31% QUERY**

*** OVENTUS $7m PLACEMENT, $2.3m 1-FOR-20 RIGHTS ISSUE**

*** PROTEOMICS $418k LINEAR CONTRACT**

*** CANN WINS MARIJUANA MANUFACTURE LICENCES**

*** FEDERAL COURT GRANTS MICRO-X 2 DAYS FOR CLEANSING NOTICES**

*** NEUROSCIENTIFIC RELEASES 1.16m SHARES FROM ASX ESCROW**

*** KEMPER SHAW REDUCES TO 10% IN IMAGION**

*** WILLIAM TAYLOR NOMINEES REDUCE TO 7% IN IMAGION**

MARKET REPORT

The Australian stock market fell 0.36 percent on Friday July 26, 2019, with the ASX200 down 24.6 points to 6,793.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and one was untraded.

Oncosil was the best, up 0.8 cents or 14.55 percent to 6.3 cents, with 6.0 million shares traded. Alterity climbed 10.3 percent; Imugene was up 9.1 percent; Antisense rose 8.9 percent; Dimerix and Resmed improved five percent or more; Cyclopharm was up 3.2 percent; Compumedics, Ellex and Neuren rose more than two percent; Kazia and Volpara were up more than one percent; with Clinuvel, Paradigm and Polynovo up by less than one percent.

Avita led the falls, down 2.5 cents or 6.25 percent to 37.5 cents, with 4.3 million shares traded. Both Optiscan and Orthocell lost 6.1 percent; both Immutep and Prescient fell 4.55 percent; Impedimed and Telix were down more than three percent; Opthea shed 2.75 percent; Cochlear, Medical Developments, Nanosonics, Pro Medicus and Proteomics were down more than one percent; with CSL, Cynata and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMUGENE

By TIM BOREHAM

ASX code: IMU

Share price: 2.4c

Shares on issue: 3,609,847,749

Market cap: $86.6 million

Chief executive officer: Leslie Chong

Board: Paul Hopper (executive chairman), Charles Walker, Dr Axel Hoos, Leslie Chong, Dr Lesley Russell, Dr Jens Eckstein

Financials (Year to June 30, 2019): revenue nil, cash outflows $7.6 million, cash balance $19.05 million, estimated September quarter outflows $8.6 million.

Identifiable holders: Private Portfolio Managers 6.2%, Platinum Asset Management 3.6%, Dr Nicholas Smith 3.2%, Paul Hopper 2.1%, Sarah Cameron 1.7%.

Move over Thomas the Tank Engine - the Oncolytic Express is about to leave the station!

The railway analogy is not our own, but the work of Imugene chief Leslie Chong after the company signed a deal to buy an immuno-oncology drug developer from Vaxinia, a private company linked to Imugene executive chairman Paul Hopper.

Yes! That's the Paul Hopper who early last year sold the ASX-listed Viralytics to Merck for $502 million.

"The Oncolytic Express is fuelled up and the conductor has called all aboard," Ms Chong writes in the company's normally staid newsletter.

"It's full steam ahead."

The lowdown on the deal

Imugene has acquired the global licence for CF33, a chimeric vaccinia (pox) virus developed by Professor Yuman Fong, the chair of surgery at California's City of Hope Comprehensive Cancer Centre.

The technology in effect is held by the unlisted Australian private entity Vaxinia, of which Mr Hopper is the chairman and major shareholder.

Also a former Viralytics executive, Prof Fong is also a Vaxinia investor and your columnist is also running out of “alsos”.

CF33 shows early promise in inciting a “local and systemic’’ tumor response in mice, in standard xenograft models of breast, pancreatic and colorectal cancers.

Of course, everything works in mice. As the former Prime Minister might have said “There’s never been a better time to be a mouse with cancer.” Or as his replacement might say: “How good are mice?”

The virus is known as chimeric because it was formed from several other viruses. Normally, a virus attacks only one kind of cell, such as hepatitis on liver cells and meningitis on brain cells.

“I took nine different vaccine strains, put them into a cancer cell and allowed them to combine and make brand new viruses,” Prof Fong says.

“I picked out hundreds of new viruses that never existed in nature. Instead of trying to be smart and genetically engineering them, we let nature do that.”

Like other oncolytic viruses in development, CF33 multiplies in tumor cells, causing them to rupture.

The virus then trains the immune system to recognize the cells and attack them. With extreme prejudice.

Prof Fong says the use of cancer viruses has been hampered to date because cautious regulators have demanded an initial single-dose approach.

As a result, viruses are “just too safe” and it may take a decade for drug developers to be allowed to increase the dose.

“Not only are viruses barely able to kill cancer, [the owners] are running out of [intellectual property],” he says.

“We have turned out products that were good for working papers but few have reached man [approval stage].”

A feature of CF33 is that it has a higher potency, which means its works at a much lower dosage than other viruses.

CF33’s potency was compared - favorably of course - with that that of Amgen’s approved oncolytic virus T-vec, as well as a vaccinia-based virus being developed by Genelux.

Value combo pack

Imugene intends to develop CF33 as a combination treatment with existing checkpoint inhibitors on the market (such as the skin cancer drug Keytruda).

Checkpoint inhibitors target immune checkpoints, which devious tumors use to protect themselves from attacks by the immune system.

“We are in the age of combination [therapies] because a single agent is not doing the work is needs to do,” Ms Chong says.

She says checkpoint inhibitors might produce a 20 to 30 percent response, “but when you add something like an oncolytic virus, that can increase [the response] three to four-fold”.

Ms Chong describes CF33 as “especially impressive” as it can shrink multiple types of cancer at low doses.

The mice models also have showed the bizarre, but apparently !!! well-known, ‘abscopal effect’, in which untreated tumors shrink when tumors are treated elsewhere in the body.

The CF33 virus is considered safe because it’s a tricked-up version of the active constituent of the vaccine that eradicated smallpox.

“Therefore, it’s been given to millions of people in the world,” Prof Fong says.

“It’s arguably the most important therapy ever produced by man because it wiped out smallpox.”

Other deals

The Vaxinia compact is the second in-licencing deal for Imugene in the last 12 months, with the company acquiring the rights to a line of B-cell peptide vaccines from Ohio State University and Mayo Clinic, in August last year.

Both deals build on Imugene’s existing work originating from the Medical University of Vienna.

Imugene’s lead molecule HER-Vaxx targets HER-2, as in human epidermal growth factor receptor, which is over expressed in 10 to 30 percent of breast, ovarian and pancreatic cancers.

The blockbuster cancer drug Herceptin also targets HER-2, but Imugene hopes that it can do so more cheaply and with more efficacy.

HER-Vaxx is a mimotope: a small molecule, often a peptide, which mimics the structure of an epitope (the specific target the antibody binds to).

The mimotopes cause the B-cells to produce millions more antibodies to fight the cancer.

Imugene is also developing a checkpoint inhibitor called PD-1 (programmed cell death-1, for those who really want to know) which is in preclinical stage.

What's next?

With CF33, Imugene plans to knock on the door of the US Food and Administration by the end of 2019, ahead of a planned investigational new drug application.

If the FDA is favorably inclined, Imugene will initiate a phase I trial next year, covering 30-patients with mixed advanced solid tumors (including lung, melanoma, bladder and gastro-intestinal).

The trial is budgeted at $US4.5 million ($A6.4 million).

An ensuing phase I/II trial would select tumor types from the first phase and enroll about 30 patients across four cohorts. Envisaged to start in late 2021, the trial would cost around $US18 million.

Separately, a phase II trial of HER-Vaxx - targeting gastric cancer - is in progress.

A second phase II trial, B-Vaxx also targets HER-2 for a broad range of tumors, funded by Ohio State University, has enrolled patients who want to forego chemotherapy.

Depending on how the data is cut and patient survival factors, Imugene may be able to post interim results later this year.

Finance and performance

Being a related-party transaction, the Vaxinia deal is subject to shareholder approval at a meeting to be convened on September 9 (the date is subject to change).

We'll assume Mr Hopper left the Imugene board room for some urgent errands when the deal was being thrashed out.

The deal involves an upfront cash payment of $462,500 and the issue of $1.6 million of Imugene shares.

Vaxinia's shareholders are also entitled to payments on milestones including an investigational new drug application to the FDA, dosing the first phase I patient and the trial meeting its safety endpoint.

California's City of Hope is also entitled to undisclosed upfront licence fees, annual maintenance fees and royalties, as well as milestones. All upfront licence payments will be funded through Imugene's existing cash reserves.

Speaking of which, Imugene held cash of $19 million at June 30 - enough to fund the company's activities for at least the next 12 months.

Imugene raised a collective $28.8 million in three capital raisings, two in December 2017 and another in July last year.

The company will seek partnerships post any phase I success with CF33, or alternatively will raise more capital at that stage.

Imugene shares have traded between 1.4 cents and 2.4 cents over the last 12 months. They slowly gained favor since the July 14 Vaxinia announcement, before which the stock traded at 1.6 cents.

Dr Boreham's diagnosis:

Imugene is not shy about highlighting the similarities between CF33 and Viralytics' lead product Cavatak that was central to the Merck deal.

Viralytics was at a similar (phase II) stage when Big Pharma came a knockin'.

In a company-sponsored analysis, Edison Investment Research cautions the immuno-oncology field is crowded as well as promising.

"While the transaction gives Imugene a foothold in a space that has attracted a lot of pharma interest, it is also an area where there a large number of competing products in development," the report says.

"Therefore, we suspect that Imugene will need to demonstrate superior efficacy in the clinic in order to attract a pharma partner."

As reflected in Imugene's humble $87 million valuation, Imugene is still at an early stage and, returning to the choo-choos analogy, any number of loose tracks could derail this one.

But if CF33 - or indeed, any other Imugene programs - attracts Big Pharma's gaze, shareholders are in for an upgrade from the caboose to the first-class carriage.

"I hope you're on board," Ms Chong tells investors.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. When it comes to decent investment proposition, he tends to be left on the platform while the train steams away.

RESMED

Resmed says that revenue for the 12 months to June 30, 2019 was up 11.4 percent to $US2,606,600,000 ($A3,752,917,515) with net profit after tax up 3.6 percent to $US526,400,000 ($A757,897,560).

Resmed cited both US generally accepted accounting principles (GAAP) and non-GAAP data, saying it "uses non-GAAP information internally in planning, forecasting, and evaluating the results of operations in the current period and in comparing it to past periods … [and] believe this information provides consistent financial reporting".

This report quotes the non-GAAP data.

Resmed said that cash and cash equivalents at June 30, 2019 was $US147,128,000, down 22.0 percent from $US188,701,000 at June 30 2018, with non-GAAP diluted earnings per share up 3.1 percent to $US3.64.

The company said it would pay a dividend of 39 US cents a share for the three months to June 30, 2019 for the record date of August 15 and to be paid on September 19, 2019 compared to 37 US cents for the three months to March 31, 2019.

Resmed was up $1.00 or 5.6 percent to $18.99 with 1.5 million shares traded.

CELLMID

Cellmid says that receipts from customers for its hair growth products was up 18.6 percent to $6,381,000 for the year to June 30, 2019.

In its Appendix 4C quarterly report, Cellmid said that receipts from customers was up 74.3 percent to $1,304,000 for the three months to June 30, 2019, primarily from sales of its Évolis hair care products.

The company said it had a cash burn of $1,811,000 for the three months to June 30, with cash and cash equivalents of $3,082,000 at June 30 and an estimated cash outflow for the three months to September 30 of $2,560,000.

Cellmid said that "despite the cash variations, the operating performance of the company continues to improve".

The company said it expected "an operational loss of less than $1 million" in the 2019-'20 year and it was "confident that our revenue growth and operating leverage will lead to profitability in our consumer health business in 2019-'20".

Cellmid fell one cent or 4.35 percent to 22 cents.

NEXT SCIENCE

Next Science says it has receipts from customers for its Blastx wound gel and Bactisure surgical lavage of US$1,937,000 ($A2,789,572) for the six months to June 30, 2019.

Next Science said it had cash and cash equivalents of US$22,980,000 at June 30, following its April initial public offer, with an expected cash outflow of $US5,226,000 for the three months to September 30, 2019.

Next Science fell 19 cents or 5.9 percent to $3.05 with 2.2 million shares traded.

ONCOSIL MEDICAL

Oncosil 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 31.4 percent from 5.1 cents on July 12 to 6.7 cents on July 26, 2019 and noted a "significant increase" in trading volumes.

Oncosil was up 0.8 cents or 14.55 percent to 6.3 cents with 6.0 million shares traded.

OVENTUS MEDICAL

Oventus says it has commitments for a $7 million placement at 38 cents a share and expects to raise $2.3 million in a fully-underwritten, one-for-20 rights issue.
Oventus said the “heavily oversubscribed” two-tranche placement was co-led by Bell Potter Securities and Patersons Securities.
The company said the rights issue had been fully underwritten by Bell Potter.
Oventus said the record date for the rights issue was August 5, with the offer opening on August 8 and closing on August 21, 2019.
The company said it would use the funds to strengthen its balance sheet, continue the roll out of its O2Vent sleep treatment platform, and offer its laboratory inside a laboratory, or ‘lab-in-lab,’ business model in the sleep apnoea and dental industries (BD: Jun 24, 2019).
Dr Hart said the company expected to announce further agreements with sleep groups in Canada and the US in anticipation of US Food and Drug Administration approval.
Oventus was up 9.5 cents or 20.4 percent to 56 cents with 1.1 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has two new contracts worth $418,000 with Perth’s Linear Clinical Research for pharmaco-kinetic analyses of new autoimmune disease drugs.
In 2016, Proteomics said it signed a partnership with Linear Clinical Research to offer a combined analytical testing and clinical trials from January 2017 (BD: Nov 15, 2016).
Today, the company said the contracts would form part of its on-going partnership with Linear and include phase I clinical studies over the next three to 10 months which would examine the safety performance of novel autoimmune disease drugs for two China-based pharmaceutical companies.
Proteomics managing-director Dr Richard Lipscombe said the contracts “further validate Proteomics International’s pharmacokinetic testing capabilities and highlight the growth potential of our analytical services business”.
“These specialist services will continue to present opportunities to generate valuable revenues, which help offset the cost of developing and commercializing the company’s portfolio of pioneering diagnostics,” Dr Lipscombe said.
Proteomics fell half a cent or 1.5 percent to 33 cents.

CANN GROUP

Cann says the Australian Office of Drug Control has approved manufacturing licences for its Northern and Southern Melbourne marijuana growing and manufacturing facilities.
Cann said the licences would allow it to manufacture, package, store, transport and dispose of medical marijuana in final dose and intermediate forms.
The company said it held all cultivation, production, manufacture, import and export licences, but would require additional permits for specific activities under the licences.
Cann chief executive officer Peter Crock said that securing the manufacturing licences was “an important milestone that supports our fully integrated business model strategy”.
“The ability to undertake these activities at both our Northern and Southern facilities gives us considerable flexibility as we continue to progress the development of our new state-of-the-art cultivation facility near Mildura,” Mr Crock said.
Mr Crock said the licences would complement its manufacturing agreement with IDT Australia’s facilities, that gave it “immediate access to proven expertise in pharmaceutical manufacturing while we continue to develop our own capabilities”.
Cann fell four cents or 1.8 percent to $2.16 with 816,360 million shares traded.

MICRO-X

Micro-X says the Federal Court of Australia has allowed it two days from the making of orders to file its cleansing notices for recent share issues.
Yesterday, Micro-X requested a trading halt pending an application to the Federal Court for orders after it failed to give the ASX a cleansing notice" (BD: Jul 25, 2019).
Today, the company said it did not submit cleansing notices within five business days of the issue of shares due to "an inadvertent administrative oversight".
Micro-X said it identified the issue and reported it to the ASX and the Australian Securities and Investments Commission.
Micro-X was up half a cent or 1.5 percent to 33 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has released 1,160,000 shares previously held under ASX escrow.
In an Appendix 3B new issue announcement, Neuroscientific said it had 58,649,511 shares quoted on the ASX and a further 19,349,506 shares subject to ASX escrow until July 27, 2020.
Neuroscientific was up one cent or 3.3 percent to 31 cents.

IMAGION BIOSYSTEMS

The Sydney-based Kemper Shaw says he has decreased his substantial shareholding in Imagion from 36,798,818 shares (11.40%) to 31,789,818 shares (9.82%).
In a substantial shareholder notice Mr Shaw said that on July 22, 2019 he sold 5,000,000 shares for $279,000 or 5.6 cents a share.
In January, Mr Shaw and William Taylor Nominees said in separate filings that they had become substantial shareholders in Imagion, each acquiring 11.4 percent of the company, and a spokesperson for Imagion told Biotech Daily that the two identical holdings were held by Mr Shaw and William Taylor, who both worked for the same company (BD: Jan 31, 2019).
Imagion fell 0.3 cents or 6.4 percent to 4.4 cents with 43.1 million shares traded.

IMAGION BIOSYSTEMS

William Taylor Nominees says it has reduced its substantial shareholding in Imagion from 36,798,818 shares (11.4%) to 21,700,000 shares (6.7%).
In a substantial shareholder notice William Taylor said on July 22, 2019 he sold 15,098,818 shares for $1,007,385 or 6.7 cents a share.