



Biotech Daily

Friday January 31, 2020

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: NEXT SCIENCE UP 13%; OPTISCAN DOWN 9%
- * DR BOREHAM'S CRUCIBLE: INVION
- * RESMED H1 REVENUE UP 14% TO \$2.1b, PROFIT UP 22% TO \$418m
- * AVITA H1 REVENUE UP 95.4% TO \$13.5m
- * CLINUVEL H1 REVENUE UP 2% TO \$13.5m
- * ADMEDUS RECEIPTS DOWN 35% TO \$18.4m
- * MEDADVISOR H1 RECEIPTS UP 33% TO \$4.8m
- * IQ3 H1 RECEIPTS UP 17% TO \$4.4m
- * MEDLAB H1 RECEIPTS UP 63% TO \$4m
- * PHARMAXIS H1 RECEIPTS UP 27% TO \$4.0m
- * OSPREY RECEIPTS UP 52% TO \$5.5m
- * THC RECEIPTS UP 83% TO \$4.7m
- * BIOXYNE H1 RECEIPTS UP 105% TO \$2m
- * TOTAL BRAIN H1 RECEIPTS UP 12% TO \$1.7m
- * RHINOMED H1 RECEIPTS UP 59% TO \$1.6m
- * NUHEARA H1 RECEIPTS DOWN 2% TO \$1.4m
- * DORSAVI H1 RECEIPTS DOWN 39% TO \$1.2m
- * NOXOPHARM LESS THAN 1 QUARTER CASH; \$26m FACILITY
- * MEDIBIO HAS 2 QUARTERS CASH
- * ESENSE-LAB HAS LESS THAN TWO QUARTERS CASH
- * REGENEUS HAS 1 QUARTER CASH
- * MGC HAS LESS THAN 1 QUARTER CASH
- * OPTISCAN MEETS US FDA FOR INVIVAGE; CARL ZEISS ORDERS
- * EGP CAPITAL TAKES 5% OF ADHERIUM
- * PAUL COZZI TAKES 13% OF CARDIEX; C2 DILUTED TO 21%

MARKET REPORT

The Australian stock market was up 0.13 percent on Friday January 31, with the ASX200 up 8.8 points to 7,017.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell and eight traded unchanged. All three Big Caps were up.

Next Science was the best, up 30 cents or 12.55 percent to \$2.69, with 311,546 shares traded, followed by Kazia up 12.4 percent to 63.5 cents with 93,287 shares traded. Ellex climbed 11.1 percent; Uscom was up 8.7 percent; Avita and Orthocell were up more than five percent; Resmed was up three percent; Clinuvel, Cynata, Opthea, Paradigm, Starpharma and Universal Biosensors rose more than two percent; Cochlear, Mesoblast and Nanosonics were up by more than one percent; with CSL and Pro Medicus up by less than one percent.

Optiscan led the falls, down 0.3 cents or 8.8 percent to 3.1 cents, with 123,800 shares traded. Osprey lost 7.4 percent; Patrys and Polynovo shed five percent or more; Alterity, Amplia, Genetic Signatures and Immutep fell four percent or more; Compumedics and Proteomics were down more than three percent; Imugene, Oncosil and Resonance shed more than two percent; Telix and Volpara were down more than one percent; with Medical Developments and Neuren down by less than one percent.

DR BOREHAM'S CRUCIBLE: INVION

By Tim BOREHAM

ASX Code: IVX

Share price: 1.2 cents; **Market cap:** \$66.0 million; **Shares on issue:** 5,500,606,300

Chief executive officer: Craig Newton

Board: Thian Chew (chairman), Mr Newton, Alan Yamahita, Melanie Farris*

Financials (December quarter 2019): receipts \$645,000, cash burn \$447,000, cash on hand \$119,000; all research costs are covered by the Cho Group

Identifiable shareholders: Unlimited Innovation Group (Cho Group) 51.16%, Polar Ventures (Thian Chew) 9.91%, Mr Honsue Cho 5.17%

* Company secretary, Ms Farris replaced Dr James Campbell (who is also CEO of the listed Patrys) in December 2019.

When US Supreme Court judge Louis Brandeis in 1914 opined that sunlight was the best disinfectant, he was referring to the desirability of transparent legal and government processes.

But he could well have been talking about the role of light in shrinking tumors, a treatment that has been known about for a similar amount of time.

Formerly focused on a smoking cessation drug, Invion is emerging as a local exponent of so-called photodynamic therapy.

Invion's solid tumor targets include ovarian cancer, skin cancer and ano-genital cancer, which is as gruesome as it sounds.

Invion created a squeak of excitement in late November when it reported that its Photosoft treatment halved the size of tumors of mice induced with ovarian cancer over three weeks.

The "immediate and specific" death of the tumor tissues was also accompanied by an influx of immune cells, indicating an immune response.

The stock more than doubled after the results of the 48-mouse study, carried out by the Hudson Institute, at Melbourne's Monash University.

After prodding from the ASX, the company admitted the study "was not powered for statistical significance and no statistical analysis was undertaken".

The study, of course, was early stage and rodent studies are notorious for producing encouraging results.

The Hudson Institute is now working over the data ahead of a phase Ib trial to treat non-melanoma skin cancers.

In a separate arrangement, Melbourne's Peter MacCallum Cancer Centre will tackle ano-genital cancer. This effort will be overseen by leading cancer research scientist Prof Robert Ramsay, the joint head of Peter Mac's gastrointestinal cancer program.

"We will choose to collaborate with various institutions and hospitals where the expertise fits," says Invion's new CEO Craig Newton.

He notes that 1,500 new cases of ovarian cancer are detected in Australia each year, with 4,000 to 5,000 women already suffering the disease. There are 240,000 patients globally.

"The grim reality is that nearly half of those diagnosed with the cancer will succumb to the disease within five years."

Cho is the go for funding

For a minnow, Invion is in the unusual position of not having to worry too much about fundraising.

That's because it is 51-percent owned by Hong Kong's Cho Group, which stumps up the dough for all trial work under a research and development agreement.

"This gives us a measure of certainty that doesn't exist with other biotechs," Mr Newton says.

Cho is the corporate vehicle of the Melbourne-based entrepreneur Michael Cho, who was aware of the common use of photodynamic therapy in China.

Ancient history

Formerly known as Cbio, the company listed on the ASX in 2010, raising \$7 million of a hoped-for \$30 million, presumably for an easy exit for its founders, but by August 2011, a 155-patient phase IIa trial showed that XToll (chaperonin 10) failed to meet the primary endpoints for rheumatoid arthritis. It was pretty much all downhill from there.

The company changed its name to Invion in August 2012 and sought to commercialize its anti-inflammatory lead program INV102 (nadolol) as a smoking cessation aid, but could not interest any partners despite looking for two years.

Director and former Chemgenex COO Dr James Campbell brought former Chemgenex CEO Dr Greg Collier into the company in 2013.

In a back-door listing deal in late 2017, the company entered an exclusive distribution and licence agreement to commercialize and develop Cho's Photosoft.

The deal involved Cho Group subscribing for \$5.5 million of shares at 0.2 cents each and Cho underwriting a \$2.5 million rights issue at the same price.

In a 2019 deal, the Hudson Institute said it would partner with Invion to research and develop the next-generation photodynamic therapy.

Hudson will provide research and clinical expertise, while Cho Group will continue to stump up the spendoolies.

In October last year, the company and Peter Mac announced a collaboration to research ano-genital cancers.

The trouble with penile and anal cancers is that sufferers are too embarrassed to see their doctor until it's too late.

The company's CEO for six and a half years, Dr Greg Collier retired in October last year and was replaced by Mr Newton, the company's chief operating officer since April 2018.

(Dr Collier founded Chemgenex, which won regulatory approval for its chronic myeloid leukaemia drug before being taken over by Cephalon for \$230 million in 2011).

In September 2018, Invion said it would package up its respiratory assets - nadolol and a respiratory treatment called zafirlukast - and spin them off as a separate unlisted entity focused on the China market.

In February last year, Chronic Airways Therapies was born, with Invion holders receiving shares on a one-for-one basis as part of the in-specie distribution. Invion also undertook a 0.3 cents a share capital return.

“Fundamentally the trajectory remains the same,” Mr Newton says.

“The company’s efforts are built around building Photosoft technology as a basis for ... getting through relevant regulatory scrutiny.”

Seeing the light

Light therapy dates back to 1903, when Faroe Islander and Danish physiologist Prof Niels Finsen snagged a Nobel Prize for his work in the area. At least 500 trials have been carried out since.

“Light therapy has been around for a long time but for various reasons it hasn’t taken off,” Mr Newton says.

He notes the so-called first-generation light treatments were problematic in a few ways: they were derived from toxic materials and it took two to three months for the body to clear them. They also had limited membrane penetration and thus efficacy.

Photosoft uses non-toxic photo-sensitizers that react with visible light and oxygen to kill malignant cells in a chain reaction.

Photodynamic therapies are thought to kill malignant cells, shut down tumors and stimulate the immune system.

Photosoft uses a laser light activation method based on short, pulsating ‘near infrared’ wavelengths. Photosoft is chlorophyll (plant) based and only accumulates in the actual cancer cells. It produces singlet oxygen, a cytotoxic reactive agent that allows more effective zapping of the bad cells.

In the late 1970s, the New Jersey-based Roswell Park Cancer Institute developed photodynamic therapies. In the 1990s, they were used for prostate cancer. In 1995, the US Food and Drug Administration agreed the truth indeed was out there and approved the use of the therapy for oesophageal cancer.

In 2017, Israeli biotech Steba Biotech won European approval for its light therapy prostate cancer treatment, Tookad.

With skin cancer, the company is targeting basal cell carcinomas and squamous cell carcinomas, the non-melanoma ones that are not generally life threatening.

The current standard-of-care involves cutting or freezing them off.

“Cosmetically, the results are poor,” Mr Newton says. “This market represents low hanging fruit for a topical formulation.”

Mr Newton says the therapy potentially could also be used as an adjunct to surgery or chemotherapy.

Other tumors of interest are lung cancers, including mesothelioma.

Financials and performance

As we noted previously, Invion is pre-revenue and externally funded so the company’s financials are more of a case of ‘nothing to see here, move on’.

For the record, Invion burnt \$447,000 of cash in the December quarter and ended 2019 with cash of \$119,000. The burn rate was affected by the timing of invoices, as pre-agreed between the parties.

In the last year Invion shares have traded between 0.8 cents (ahead of the November 26 trial results) and 2.6 cents (April 11). Historically the stock has traded as high as 4.8 cents (April 4, 2018).

Dr Boreham’s diagnosis:

As the only ASX-listed biotech in the photodynamic therapy game, Invion at least has a rarity value. Management has done well to snare the Cho and Hudson deals, but it is very much a work in progress.

The unanswered question is whether Photosoft has clear clinical advantages and much more work needs to be done. In the short term, investors can expect some skin cancer results this year.

“Things are moving quite quickly,” Mr Newton says. “We are pretty confident when we look at the penetration of the drug, we have something broadly applicable.”

Overall, he says, the key to development is to bring years of experience in photodynamic therapy development into a modern regulatory framework.

“It is essentially an established concept but the key has been to make it clinically relevant,” he says. “We are putting the support we have to good use.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He was sceptical about photodynamic therapy but has now seen the light.

RESMED

Resmed says revenue for the six months to December 31, 2019 was up 14.3 percent to \$US1,417,213,000 (\$A2,109,573,060), with net profit after tax up 21.8 percent to \$US280,702,000 (\$A418,226,330).

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 ... [and] believe this information provides investors better insight when evaluating ... performance from core operations and provides consistent financial reporting”. This report quotes the non-GAAP data.

The company said that research and development expenses were up 19.6 percent to \$US97,976,000, or 6.9 percent of total revenue, compared to prior corresponding period. Resmed said non-GAAP diluted earnings per share were up 18.2 percent to \$US2.14 and it had cash and cash equivalents of \$US204,095,000 at December 31, 2019 compared to \$US149,468,000 at December 31, 2018.

The company said it would pay a dividend of 39 US cents (58.1 Australian cents) a share for a record date of February 13, payable on March 19, 2020.

Resmed was up 74 cents or three percent to \$25.05 with 2.1 million shares traded.

AVITA MEDICAL

Avita says revenue for the six months to December 31, 2019 was up 95.4 percent to \$13,530,000.

Avita said US sales of its Recell burns treatment increased from \$1,102,000 to \$9,274,000 and non-US sales fell from \$711,000 to \$410,000.

The company said other income, including its US Biomedical Advanced Research and Development Authority contract fell from \$5,113,000 to \$3,846,000 for the six months.

Avita said receipts from customers for the six months to December 31 were up 646.8 percent to \$8,999,000, it had cash and cash equivalents of \$124,658,000 at December 31 and expected to spend \$12,334,000 for the three months to March 31, 2020.

Avita was up 3.5 cents or 5.5 percent to 67.5 cents with 16.5 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says receipts from customers for the six months to December 31, 2019 were up 1.5 percent to \$13,516,000 compared to the previous corresponding period.

Clinuvel said receipts from customers for the three months to December 31, 2019 increased 43.2 percent to \$3,734,000, it had cash and cash equivalents of \$57,435,000 at December 31 and expected to spend \$5,015,000 for the three months to March 31, 2020.

Clinuvel was up 78 cents or 2.9 percent to \$27.70 with 368,380 shares traded.

ADMEDUS

Admedus says receipts from customers for the year to December 31, 2019 fell 34.5 percent to \$18,435,000 compared to the previous corresponding period.

Admedus said receipts from customers for the three months to December 31 fell 55.0 percent to \$2,898,000, it had cash and cash equivalents of \$8,968,000 at December 31 and expected a cash burn of \$8,367,000 for the three months to March 31, 2020.

The company said it had sold its cardiac patch business to Lemaitre Vascular for \$36.2 million, including an upfront payment of \$21.2 million (BD: Oct 14, Oct 15, 2019).

Admedus fell 0.7 cents or 8.1 percent to 7.9 cents with 2.9 million shares traded.

MEDADVISOR

Medadvisor says receipts from customers for the six months to December 31, 2019 were up 32.5 percent to \$4,800,000 compared to the previous corresponding period.

Medadvisor said receipts from customers for the three months to December 31 rose 42.2 percent to \$2,516,000, it had cash and cash equivalents of \$16,388,000 at December 31, 2019 and expected to spend \$6,000,000 for the three months to March 31, 2020.

Medadvisor fell six cents or 10.9 percent to 49 cents.

IQ3CORP

IQ3 says receipts from customers for the six months to December 31, 2019 were up 16.8 percent to \$4,359,000 compared to the previous corresponding period.

IQ3 said that it had cash and cash equivalents of \$453,000 at December 31, 2019 and expected to spend \$2,482,000 for the three months to March 31, 2020.

IQ3 was untraded at 20 cents.

MEDLAB CLINICAL

Medlab says receipts from customers for the six months to December 31, 2019 were up 62.5 percent to \$4,044,000, with a three-month cash burn of \$1,724,000.

Medlab said receipts from customers were up 29.3 percent to \$1,641,000 for the three months to December 31, 2019 and it had cash and cash equivalents of \$9,689,000 at December 31.

Medlab was up 1.5 cents or 4.8 percent to 33 cents.

PHARMAXIS

Pharmaxis says receipts from customers for the six months to December 31, 2019 were up 26.9 percent to \$3,973,000 compared to the previous corresponding period.

Pharmaxis said receipts from customers for the three months to December 31, were up 148.5 percent to \$2,420,000, it had cash and cash equivalents of \$25,864,000 at December 31 and expected a cash burn of \$7,715,000 for the three months to March 31, 2020.

Pharmaxis was unchanged at 11.5 cents with 1.2 million shares traded.

OSPREY MEDICAL

Osprey says receipts from customers for the year to December 31, 2019 were up 51.7 percent to \$US3,701,000 (\$A5,509,123.55) compared to the previous corresponding period.

Osprey said receipts from customers for the three months to December 31, 2019 rose 45.0 percent to \$US948,000, it had cash and cash equivalents of \$US8,277,000 at December 31 and expected a cash burn of \$US5,950,000 for the three months to March 31, 2020.

Osprey fell 0.2 cents or 7.4 percent to 2.5 cents with 2.9 million shares traded.

THC GLOBAL (FORMERLY THE HYDROPONICS COMPANY)

THC says that receipts from hydroponics equipment customers for the year to December 31, 2019 were up 82.7 percent to \$4,727,000

THC said receipts from customers increased 188.9 percent to \$1,869,000 for the three months to December 31, 2019.

The company said it had \$3,555,000 in cash and cash equivalents at December 31, 2019 and expected to spend \$1,936,000 for the three months to March 31, 2020.

THC was up half a cent or 1.3 percent to 38 cents.

BIOXYNE

Bioxyne says receipts from customers for the six months to December 31, 2019 were up 105.0 percent to \$2,021,000 compared to the previous corresponding period.

Bioxyne said receipts from customers for the three months to December 31, 2019 were up 121.9 percent to \$761,000, its net operating cash burn was \$140,000 for the three months and it had cash and equivalents of \$2,056,000 at December 31, 2019.

Bioxyne was untraded at 1.7 cents.

TOTAL BRAIN

Total Brain says receipts from customers for the six months to December 31, 2019 were up 11.7 percent to \$1,747,000 compared to the previous corresponding period.

Total Brain said receipts from customers for the three months to December 31, 2019, were up 8.4 percent to \$699,000, it had cash and cash equivalents of \$7,624,000 at December 31 and expected to spend \$3,336,000 for the three months to March 31, 2020.

Total Brain was unchanged at 75 cents.

RHINOMED

Rhinomed says receipts from customers for the six months to December 31, 2019 were up 58.7 percent to \$1,554,000 compared to the previous corresponding period.

Rhinomed said receipts from customers for the three months to December 31, 2019 rose 101.3 percent to \$920,000, it had cash and cash equivalents of \$3,594,000 at December 31, 2019 and expected to spend \$1,794,000 for the three months to March 31, 2020.

The company said that a 2017 \$2 million drawdown facility, provided from an entity related to chairman Ron Dewhurst, would be able to be drawn upon in multiples of \$250,000 plus interest, and has been rolled over, repayable by July 31, 2020.

Rhinomed fell half a cent or 2.7 percent to 18 cents.

NUHEARA

Nuheara says receipts from customers for the six months to December 31, 2019 fell 1.7 percent to \$1,362,000 compared to the previous corresponding period.

Nuheara said that receipts from customers for its Iqbuds wireless sound filtering buds, were up 25.5 percent to \$910,000 for the three months to December 31, 2019.

The company said its \$3,543,000 in cash and cash equivalents at December 31, 2019 had since been supplemented by a 24-month, \$2.5 million convertible note facility with Lind Partners, exercisable at 5.0 cents within four years (BD: Jan 24, 2020).

Nuheara said it expected to spend \$4,960,000 in the three months to March 31, 2020.

Nuheara fell 0.2 cents or 6.45 percent to 2.9 cents with 4.8 million shares traded.

DORSAVI

Dorsavi says receipts from customers for the six months to December 31, 2019 fell 38.6 percent to \$1,232,000 compared to the previous corresponding period.

Dorsavi said receipts from customers were up 22.2 percent to \$656,000 for the three months to December 31, 2019, it had cash and cash equivalents of \$2,562,000 at December 31, 2019 and it expected to spend \$1,171,000 for the three months to March 31, 2020.

Dorsavi was unchanged at 2.6 cents.

NOXOPHARM

Noxopharm says its net operating cash burn for the three months to December 31, 2019 was \$4,100,000 with cash at the end of the quarter of \$1,651,000.

Noxopharm said it expected to spend \$2,950,000 in the three months to March 31, 2020. In December, the company said it had a \$2.4 million draw down equity facility with Lind Global Macro Fund and CST Investment Funds and expected to be repaid \$500,000 by Nyrada in February (BD: Dec 3, 2019).

In July, the company said it had an \$26 million draw-down equity facility with New York's Lind Global and Toronto's CST Investment (BD: Jul 19, 2019).

Noxopharm was up half a cent or 2.1 percent to 24.5 cents.

MEDIBIO

Medibio says its net operating cash burn to December 31, 2019 was \$1,428,000 with cash and cash equivalents of \$2,216,000.

Medibio said it expected a cash burn of \$1,263,000 for the three months March 31, 2020, including \$315,000 in one-off costs in relation to cost reduction strategies, followed by an estimated cash expenditure of \$900,000 for the three months to June 30, 2020.

Medibio was unchanged at 0.9 cents with 1.3 million shares traded.

ESENSE-LAB

Esense says its net operating cash burn for the three months to December 31, was \$US335,000 with cash and cash equivalents of \$US451,000 at December 31, 2019.

Esense said it expected to spend \$US324,000 in the three months to March 31, 2020.

Esense fell 0.2 cents or 16.7 percent to one cent with 2.2 million shares traded.

REGENEUS

Regeneus says its estimated cash burn for the three months to March 31, 2020 would be \$880,000, with cash at the end of the quarter of \$818,000.

Regeneus said its net cash burn for the three months to December 31, 2019 was \$402,000, it would continue to cut costs and anticipated to spend \$250,000 a month.

The company said it had completed a \$5.5 million placement in the December quarter and received a \$50,000 Federal Government research grant (BD: Nov 19, 2019).

Regeneus fell half a cent or 6.25 percent to 7.5 cents.

MGC PHARMACEUTICALS

MGC says its net operating cash burn for the three months to December 31, 2019 was \$2,805,000, with cash at the end of the quarter of \$1,022,000.

MGC said it expected to spend \$1,606,000 in the three months to March 31, 2020.

MGC said receipts from customers for its marijuana products increased one percent to \$888,000 for the six months to December 31, 2019.

The company said it had received the first payment of a \$25,000 grant from the Federal Government.

MGC fell 0.1 cents or 2.9 percent to 3.4 cents with 3.3 million shares traded.

OPTISCAN IMAGING

Optiscan says it has met with the US Food and Drug Administration and will send supplementary information for a proposed 510(k) submission for its Invivage system.

Optiscan said the submission would enable it to sell its Invivage system for human oral cancer surgery and oral cancer screening in the US.

The company said orders from Carl Zeiss Meditec had increased from \$550,000 to \$700,000.

Optiscan executive chairman Darren Lurie said the company "had a highly productive and positive meeting with the FDA and received valuable insight in relation to fulfilling the requirements for making our 510(k) submission for the Optiscan Invivage system in human oral cancer".

"This interaction with the FDA has provided clear guidance helping us de-risk our route toward a successful 510(k) application," Mr Lurie said.

"At the same time, we are very pleased to receive additional orders from Carl Zeiss Meditec, as they progress their commercial worldwide rollout plans for the Convivo in neurosurgery," Mr Lurie said.

Optiscan fell 0.3 cents or 8.8 percent to 3.1 cents.

ADHERIUM

EGP Capital says it has become a substantial shareholder in Adherium with 25,000,000 shares or 5.03 percent.

The Sydney-based EGP said that it acquired the shares on January 30, 2020 for \$750,000 or 3.0 cents a share.

Earlier this week, Adherium said that a rights issue at three cents a share raised \$525,519 of a hoped for \$5.4 million and it expected to meet the minimum of \$2.5 million (BD: Jan 29, 2020).

Adherium was untraded at four cents.

CARDIEX

Paul Cozzi says he has increased his substantial shareholding in Cardiex from 67,303,574 shares (9.68%) to 97,615,392 shares (12.96%).

The South Bexley, New South Wales-based Mr Cozzi said that between August 20, 2019 and January 30, 2020, he bought and sold shares, with the single largest acquisition 18,181,818 shares for \$509,091 or 2.8 cents a share on December 31, 2019 in a share issue.

Cardiex was unchanged at 2.7 cents.

CARDIEX

C2 Ventures says its 158,960,194 share-holding in Cardix has been diluted from 22.17 percent to 21.10 percent.

In December, the company said it had raised \$1.5 million in additional funding, following commitments from C2 ventures, a related company to chairman Niall Cairns and chief executive officer Craig Cooper, issued at 2.75 cents a share with a one for four attaching listed option, exercisable at 5.0 cents a share (BD: Jan 19, 2020).

Today, the Sydney-based C2 said that on December 30, 2019 it was diluted due to a placement to third parties.