Biotech Daily

Friday April 13, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 23%; ACTINOGEN DOWN 4%**

*** DR BOREHAM'S CRUCIBLE: INVION**

*** INVITROCUE LAUNCHES ONCO-PDO PERSONALIZED CANCER TEST**

*** IMMUTEP PLAN RAISES $6.3m, TOTAL $13.2m**

*** FACTOR RIGHTS OFFER RAISES $4.2m**

*** FEDERAL GOVERNMENT $55m FOR DIGITAL HEALTH CRC**

*** ZELDA US MARIJUANA AUTISM STUDY APPROVED**

*** AVITA CLAIMS 'POTENTIAL' FOR RECELL FACIAL BURNS**

*** EYEPOINT (PSIVIDA) ALLOWED 2 US PATENTS**

*** PLATINUM REDUCES BELOW 5% IN IMUGENE**

*** REGAL BELOW 5% IN AIRXPANDERS; SCOTT DODSON 7m OPTIONS**

*** UNIVERSAL BIOSENSORS LOSES HEAD OF TECH GARRY CHAMBERS**

MARKET REPORT

The Australian stock market was up 0.23 percent on Friday April 13, 2018 with the ASX200 up 13.6 points to 5,829.1 points. Fourteen Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and three were untraded. All three Big Caps rose.

Uscom was the best on no news, up 4.5 cents or 22.5 percent to 24.5 cents with 205,337 shares traded. Eyepoint (Psivida) climbed 15.5 percent; Airxpanders was up 9.7 percent; Opthea improved six percent; Avita and Benitec were up five percent or more; Bionomics rose 4.4 percent; ITL was up 3.7 percent; Factor Therapeutics and Resmed rose more than two percent; Cochlear, Compumedics and Orthocell were up more than one percent; with CSL, Nanosonics, Polynovo and Sirtex up by less than one percent.

Actinogen led the falls, down 0.2 cents or 4.2 percent to 4.6 cents with 1.5 million shares traded. Immutep and Optiscan fell four percent or more; Genetic Signatures, Oncosil and Telix were down more than three percent; Impedimed and Medical Developments shed more than two percent; Admedus, Ellex, Pharmaxis, Pro Medicus and Volpara were down more than one percent; with Clinuvel, Mesoblast and Neuren down less than one percent.

DR BOREHAM'S CRUCIBLE: INVION

By TIM BOREHAM

ASX Code: IVX

Share price: 3.6 cents; **Shares on issue:** 5,451,522,967; **Market cap:** $196.3 million

Chief executive officer: Dr Greg Collier

Board: Thian Chew (chairman), Dr Greg Collier, Dr Mitchell Glass, Dr James Campbell, Warren Brown, Greg Brown (alternate director).

Financials (December half)*: total income $46,283 (down 73%), net loss $1.2 million (previously $1.0 million loss), cash $281,513 (down 69%)

***** Before $2.5 million rights issue

Identifiable shareholders: Unlimited Innovation Group (Cho Group) 70.58 percent.

In the crudest of summaries beloved of editors globally, Invion's quest is about taking a treatment known for more than a century and improving it to tackle solid cancers.

There's nothing about reinvention, of course: the machines that roll off BMW and Boeing assembly lines are also based on technology that was state of the art 100 years ago.

A few months back, Invion shares were as unloved as a grey ghost hovering outside an emergency hospital. The company had sought to commercialize its anti-inflammatory lead program INV102 (nadolol) as a smoking cessation aid, but couldn't interest any partners despite looking for two years.

"We were stuck in a hard place," CEO Dr Greg Collier says. "The company's market cap drifted below $10 million and the company went on ice for two years."

A 'virtual' company with three employees, Invion's prospects were boosted by a key deal last year that injected a new asset: a light-based cancer treatment called Photosoft.

"We have plans in skin, ovarian and prostate cancers and other orphan indications, but our strategy is yet to be rolled out," he says.

What's the big deal?

The seminal transaction involved an exclusive distribution and licence agreement to commercialise and develop Cho's Photosoft, a so-called photodynamic therapy (PDT).

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

Invion issued Cho Group $5.5 million in shares at 0.2 cents and Cho agreed to underwrite a $2.5 million rights issue at the same price. This compact involved Mr Cho himself taking a 15 percent Invion stake.

The clincher is that Cho Group funds all research and development and clinical trials for the cancer indications Invion will target.

In a separate tie-up, the local research institute Hudson Institute of Medical Research last month said it would partner with Invion to research and develop the next-generation PDT.

Hudson (formerly Prince Henry's and Monash research units) will provide research and clinical expertise, while Cho Group will continue to stump up the spendoolies.

Bonanza!

The Hudson deal sent Invion shares 50 percent higher on the day - a bonanza for investors who subscribed to last month's oversubscribed rights raising at 0.2 cents.

That raising was struck at a whopping 93 percent discount to the prevailing price of 2.8 cents apiece.

The twist here is that the raising was not meant to be at a discount at all, because the shares were trading at 0.2 cents at the time of the Cho announcement last February.

But interests associated with Cho just kept on buying, pushing the shares higher ahead of the Hudson announcement. Given the discount on offer, punters queued to take up their rights and there was no shortfall for Cho Group to cover.

Holders had approved the terms of the raising at a meeting in November, so the company couldn't adjust the terms of the offer to reflect the more lustrous share price.

History

Invion was formerly Cbio, touting its XToll, or chaperonin 10, for inflammatory conditions such as rheumatoid arthritis and lupus.

In an ominous, but typically biotech signal, CBio called a July 2011 trading halt for the 155-patient, phase II trial results, then semaphored surrender with a suspension to announce the trial successfully demonstrated that the drug did not meet its primary endpoints, also known as it didn't work. But it was safe.

A board spill followed, with legal action taken to recover $1.3 million from the previous regime and in July 2012, CBio merged with Inverseon for its nadalol (INV102) for asthma and what it called "smoking cessation" and changed its name to Invion.

Former Chemgenex executive (and now Patrys chief executive officer) Dr James Campbell was hired to repair the company, and in 2013 former Chemgenex chief executive officer Dr Greg Collier was given the hot seat, inheriting the Inverseon assets.

Trials showed that INV103 also didn't work for lupus and INV102 increased abstinence and reduced the number of cigarettes consumed, which wasn't quite the original claim of "smoking cessation".

Cbio's XToll, renamed INV103, is still on the books, as is INV102, but with Photosoft taking pole position it's kind of been Photoshopped out of the picture.

Invion's oncology bent is not surprising given that Dr Collier's Chemgenex eventually won US Food and Drug Administration approval for its chronic myeloid leukaemia drug Omapro, with Cephalon (now Teva) buying Chemgenex for $225 million in 2011.

Invion has moved its HQ from Brisbane to Melbourne, making it much more convenient for the surf-loving Dr Collier to commute from his coastal Barwon Heads abode.

Photosoft explained

Photosoft uses non-toxic photosensitizers that react with visible light and oxygen to kill malignant cells in a chain reaction. Photodynamic therapy (PDT) is 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' (NIR) wavelengths.

PDT was developed by the Roswell Park Cancer Institute in the late 1970s. Roswell Park, just to clarify, is in Buffalo, New Jersey and not the New Mexico alien-spotting precinct.

PDTs have been used here to treat superficial skin cancers in a non-invasive manner.

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

In the 1990s it was used for prostate cancer and in 1995 the FDA approved the use of PDT for oesophageal cancer.

Last year Israel's Steba Biotech won European approval for its light therapy prostate cancer treatment Tookad.

In the clinic

The Cho Group has funded two small prostate cancer trials in the past, which showed promising reduction in prostate size and stabilization of prostate specific antigen (PSA) levels.

"We have plans in skin, ovarian and prostate cancers, as well as other orphan indications," Dr Collier says. "But our strategy has not yet been rolled out."

Under the tie-up with Hudson, Invion initially plans to focus on ovarian cancer, which kills about 1,000 Australian women annually (with 1,600 new cases every year).

Because ovarian cancer is normally detected too late, it's hoped the treatment will reduce the incidence of ovaries removal.

Why Photosoft?

The so-called first generation PDT 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.

These PDTs also had limited membrane penetration and thus efficacy.

Photosoft is chlorophyll (plant) based and only accumulates in the actual cancer cells.

It produces singlet oxygen, which is not a reference to the respiratory trends of Bali bogans in Bintang tops. Rather, singlet oxygen is a cytotoxic reactive agent that allows more effective zapping of the bad cells.

Dr Boreham's diagnosis:

Invion's billions of shares on issue remind everyone of its tortured history as Cbio, but one shouldn't dwell on the past.

Dr Collier says the company has no need to raise more capital, so at least billions of shares won't be added to.

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

"We are at an early stage of restructuring Invion; there will be a lot more to come," Dr Collier says.

The unanswered question is whether Photosoft has clear clinical advantages and much more work needs to be done.

Buffalo may be thousands of miles from New Mexico, but the truth is out there.

Cue spooky synthesised music.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He may have been abducted by aliens, but what's normal anyway, these days?

INVITROCUE

Invitrocue says it has screened the first commercial cancer patient-derived organoid (Onco-PDO) customer in Singapore for personalized treatment of colorectal cancer.
Invitrocue chief executive officer Dr Steven Fang told Biotech Daily that the Onco-PDO diagnostic worked by “expanding, or growing while preserving the heterogeneity of the cancer population, to maintain the individuality of each person’s cancer and is then tested against the standard-of-care drugs or any alternative approved drugs that an oncologist chooses to evaluate”.
In its media release, the company said that the Onco-PDO test provided an overview of how a patient’s cancer cells respond to different standard-of-care chemotherapies, ranking the therapeutics based on their effectiveness in delivering a positive response.
Invitrocue company said that Onco-PDO allowed oncologists to develop better informed and more personalized treatment strategies for patients.
The company said that screening the first paying customer was the start of commercial applications of its technology in the Asia Pacific region.
Invitrocue said it had identified hospitals, physicians and other medical partners in Singapore in consultation with oncologists and would receive patients from Hong Kong wanting to use the Onco-PDO platform.
The company said that all the Onco-PDO clinical work was being carried out at the joint laboratory established last year between the Genome Institute of Singapore (GIS) and Invitrocue, in the Singapore government’s Agency for Science, Technology and Research.
Dr Fang said the company was “incredibly excited to have screened our first patient in Singapore against the Onco-PDO drug sensitivity test and are encouraged by the response and interest so far from both local and international oncologists in using this technology with their patients to better inform their decision-making process when dealing with a variety of cancer types”.
Invitrocue was up 0.3 cents or 3.1 percent to 9.9 cents.

IMMUTEP

Immutep says it has raised $6,311,783 of a hoped $10,000,000, in a share purchase plan at 2.1 cents a share, taking the total raised to $13,161,823.
In March, Immutep said it had raised $6,850,040 in a placement at 2.1 cents a share, a nine percent discount to the 15-day volume weighted average price to March 9, 2018.
The company said that the placement was to Sydney-based institutional investors Platinum Asset Management and Australian Ethical Investment, the New York-based Ridgeback Capital Investments and former Immutep (then Prima Biomed) chair Lucy Turnbull (BD: March 12, 2018).
The company said the funds would be used to support its immune-oncology clinical development programs, its pre-clinical program in auto-immune disease and for general working capital.
Immutep chief executive officer Marc Voigt said the funding would provide Immutep with “cash reach well into quarter four of 2019, including funding [for] our new phase II Tacti-002 clinical trial in different cancer indications in collaboration with Merck Sharp and Dohme”.
“By that stage we will have progression-free survival data from our phase IIb active immunotherapy paclitaxel breast cancer trial, data from all four patient cohorts in our phase I Tacti-mel trial and potentially also the first data from Tacti-002,” Mr Voigt said.
Immutep fell 0.1 cents or four percent to 2.4 cents with 14.55 million shares traded.

FACTOR THERAPEUTICS

Factor says it has completed its $4,171,714 underwritten, one-for-seven, non-renounceable entitlement offer at four cents a share.
Factor said it received acceptances for 68,403,375 shares with the shortfall of 35,889,475 shares fully under-written.
In March, the company said proceeds would go to its venous leg ulcer program, the phase IIb study of VF001 for venous leg ulcers, the end-of-phase II regulatory engagements with funds to progress selected assets to their next milestones, including the ocular program, as well as discovery phase experiments (BD: March 14, 2018).
Factor chief executive officer Dr Ros Wilson said the company was “very pleased to complete the rights issue with a strong response from the company’s shareholders”.
Factor was up 0.1 cents or 2.5 percent to 4.1 cents.

FEDERAL GOVERNMENT

The Federal Government says it will provide $55 million for the Digital Health co-operative research centre (CRC) “to improve health outcomes”
A media release from the Minister for Jobs and Innovation Senator Michaelia Cash and the Assistant Minister For Science, Jobs And Innovation Senator Zed Seselja said the funding would support “the use of digital technologies which can improve access to the right health care, lower costs and increase understanding and awareness” through industry-led collaborations between industry, researchers and the community.
A spokesperson for Senator Seselja told Biotech Daily that along with other participants including State Governments investing $56 million in cash and $118 million in kind contributions such as staffing the total investment was $229 million.
The media release said that the CRC was examining better ways to share information on adverse reactions and developing better decision support applications.
Senator Cash said the CRC brought together industry and research partners to advance health, medical technologies and pharmaceutical industries in a collaborative and multidisciplinary way to “address industry issues by supporting clinical practice, improving access to quality care, fostering high value jobs and developing a digital health workforce”.
“CRCs link researchers with industry and government with a focus towards research application,” Senator Seselja said. “This is why the CRC Program continues to be at the forefront of the Coalition Government’s commitment to improving the competitiveness, productivity and sustainability of Australian industries.”
The media release said that applications for the 20th CRC selection round were expected to open in May 2018.

ZELDA THERAPEUTICS

Zelda says it has institutional review board, or ethics approval, for its medical marijuana autism study at the Pennsylvania-based Children’s Hospital of Philadelphia.
Zelda said the study intended to identify cannabinoid-based compounds that might help in the treatment of paediatric autism.
Zelda executive chairman Harry Karelis said that “positive results will allow Zelda to potentially expand into a formal clinical trial to study the efficacy of standardized, high quality medicines”.
“This study is being conducted in parallel with our pending clinical trial in Chile leveraging the observational data generated in 2017,” Mr Karelis said.
Zelda fell half a cent or 4.8 percent to 10 cents.

AVITA MEDICAL

Avita says a study has shown its Recell spray-on-skin has “potential benefits” for the treatment of deep partial-thickness, or second degree, facial burns.

Avita said the results were presented by the North Carolina-based Wake Forest University School of Medicine’s Dr Nicholas Walker, at the American Burn Association meeting in Chicago, April 10 to 13, 2018.

The company said Dr Walker’s presentation, titled “Initial Experience with Autologous Cell Suspension for Treatment of Partial Thickness Facial Burns” reviewed results from the treatment of deep partial-thickness facial burns under the compassionate use investigational device program, which was approved for patients with life-threatening wounds that required grafting with no alternative treatments available.

Avita said 26 patients, of which five had deep partial-thickness facial burns, ranged in age from two years to 40 years and burn coverage from 35 percent to 62 percent of their total body surface area, were treated at Wake Forest University School of Medicine in Winston-Salem, North Carolina.

The company did not provide specific data on the treatment outcomes but said “Recell provided equivalent or superior results to current treatments in facial burn care in terms of wound healing, and excellent cosmetic outcomes”.

Avita was up 0.3 cents or 5.4 percent to 5.9 cents.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA)

Eyepoint says the US Patent and Trademark Office has allowed the company two patents for its Dexycu treatment.

Eyepoint said the patents would cover the company’s US Federal Drug Administration approved Dexycu long-acting intraocular product for the treatment of postoperative inflammation.

The company said the first patent, covered claims related to a method of treating inflammation of an eye following cataract surgery by delivery small amounts of dexamethasone in triethyl acetyl citrate and would provide protection until 2034.

Eyepoint said the second patent included claims related to loading and delivering a small dose volume from an injection syringe, providing protection until 2032.

Eyepoint chief executive officer Nancy Lurker said “these are significant milestones and represent the first patent allowances for Dexycu following the recently completed acquisition of Icon Bioscience”.

“Today’s allowances strengthen our Dexycu portfolio related to the product’s delivery mechanism and enhances its value by extending its exclusivity out to 2034 and 2032 respectively,” Ms Lurker said.

Eyepoint climbed 24 cents or 15.5 percent to $1.79.

IMUGENE

Platinum Investment Management says it has reduced its holding in Imugene to below the five percent substantial shareholder mark.

Platinum said that between March 12 and April 5, 2018 it bought and sold shares, with the largest sale of 10,614,675 shares for $376,235.47, or 3.54 cents a share on March 28, 2018.

In March, the company said it had reduced its Imugene holding to 171,932,643 shares (6.02%) (BD: Mar 13, 2018).

Imugene was up 0.1 cents or 3.3 percent to 3.1 cents with 12.8 million shares traded.

AIRXPANDERS

Regal Funds Management says it has fallen below the five percent substantial shareholder mark in Airxpanders.

In two announcements after the market closed, Regal said it had been diluted from 14,857,392 shares (6.25%) to 14,953,677 (5.20%), followed by an announcement saying it had sold 886,576 shares for $162,155, or 18.3 cents a share, taking it below a substantial holding of five percent.

In a separate announcement, Airxpanders said former chief executive officer Scott Dodson had been granted a total of 2,362,011 options over US shares equivalent to 7,086,033 Chess depository instruments (CDIs), exercisable at prices ranging from 25 US cents (32.2 Australian cents) to $US1.93, per US share, by July 6, 2018, with each US share converting to three CDIs.

Airxpanders was up 1.5 cents or 9.7 percent to 17 cents with 1.7 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that co-founder and head of technology development Garry Chambers has resigned “by mutual agreement” effective from April 12, 2018.

Universal Biosensors chief executive officer Rick Legleiter said that Mr Chambers had been with the company since its inception and was “instrumental in the development of the company’s products”.

“On behalf of the company I thank him for his contribution to the company,” Mr Legleiter said.

Universal Biosensors was unchanged at 27 cents.