Biotech Daily

Friday June 2, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: DIMERIX UP 14%, BENITEC DOWN 6.5%**

*** DR BOREHAM'S CRUCIBLE: ANALYTICA**

*** MRCF $6m FOR ONCORES BREAST CANCER SURGERY IMAGING**

*** STARPHARMA RECEIVES $2.6m ASTRAZENECA MILESTONE**

*** P&G PAYS OBJ 1st SALES ROYALTY, LICENCE $296k**

*** NZ AMBULANCE BACKS MEDICAL DEVELOPMENTS PENTHROX**

*** POLYNOVO'S PROF JOHN GREENWOOD BURN CARE LECTURE**

*** MACH7 SELLS 3D, BREAKEVEN 2018, CEO SEARCH, MIKE LAMPRON COO**

*** IMMURON SPONSORS SPAIN MEETING, TRAVELAN REVENUE UP**

*** ZELDA: 'IN-VITRO STUDIES BACK MARIJUANA FOR CANCER'**

*** REPRODUCTIVE HEALTH TAKES FUNDING HALT TO SUSPENSION**

*** BIOXYNE UNMARKETABLE PARCEL FACILITY**

*** DIRECTOR DR MICHAEL PERRY REPLACES AVITA CEO ADAM KELLIHER**

*** CORRECTION: PERRON INSTITUTE (WANRI)**

*** GI DYNAMICS LOSES 13-YEAR DIRECTOR MIKE CARUSI**

*** SUE MACLEMAN WINS BIO-MELBOURNE WOMEN LEADERSHIP AWARD**

MARKET REPORT

The Australian stock market was up 0.87 percent on Friday June 2, 2017 with the ASX200 up 50.0 points to 5,788.1 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, 13 traded unchanged and one was untraded. All three Big Caps were up.

Dimerix was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 100,000 shares traded. Avita climbed 8.9 percent; Medical Developments was up 5.6 percent; Factor Therapeutics improved 4.6 percent; Cellmid and Starpharma were up more than three percent; Acrux and Bionomics rose more than two percent; Orthocell and Resmed were up more than one percent; with Cochlear, CSL and Sirtex up by less than one percent.

Benitec led the falls, down one cent or 6.45 percent to 14.5 cents with 161,680 shares traded. Oncosil and Viralytics fell more than four percent; Admedus and Airxpanders lost more than three percent; Genetic Signatures, Mesoblast and Polynovo shed more than two percent; Actinogen, Impedimed, Nanosonics, Neuren, Opthea, Osprey and Pro Medicus were down more than one percent; with Clinuvel down by less than one percent.

DR BOREHAM'S CRUCIBLE: ANALYTICA

By TIM BOREHAM

ASX Code: ALT

Market cap: $13 million; **Share price:** 0.5 cents; **Shares on issue:** 2.549 billion

Chief executive officer: Geoff Daly

Board: Dr Michael Monsour (chairman), Ross Mangelsdorf, Warren Brooks, Carl Stubbings, Dr Thomas Lonngren, Dr Peter Corr

Financials (March 2017 quarter): revenue $23,000, cash outflows $888,000, cash on hand $1.234 million*****. December half 2016: revenue of $1.99 million, loss of $938,700, estimated current quarter cash burn $955,000

Major shareholders: Dr Michael Monsour 22%, Dr Peter Corr 13%, Ross Mangelsdorf 2.4%.

***** Excludes $1.02 million of proceeds from $1.887 million share placement, received in April.

Of all the noble intentions in the biotech sector, it's hard to top Analytica's lofty charter of mitigating urinary incontinence and giving women better orgasms.

And, we can only hope, thrilling shareholders along the way.

Analytica's weapon is Pericoach, a web-enabled device to encourage women with leakage issues to do their pelvic floor exercises.

Chief executive officer Geoff Daly reckons one in six women are afflicted with incontinence problems, typically after childbirth.

But athletes with high core body strength are also vulnerable, because the small act of sneezing can send shock waves to the pelvic area.

The condition is also related to menopause.

When vaginally inserted, the dildo-like device measures the movement and then wirelessly sends the data to a mobile phone. This allows doctors to check that the exercises are being done and done so effectively.

"As well as improving incontinence, stronger pelvic floor muscles can also improve sexual sensation and orgasm potential," the company says.

(Orgasms are also thought to improve pelvic floor strength, so we're talking about a virtuous cycle).

Analytica's 2015 annual report sharply defined the company's goals: prove the gizmo works, define the market and then do a deal.

In terms of the proof, Analytica is most of the way there, given the device has been approved by Australian, European and US authorities (it is available via subscription in the US).

While Pericoach mark one has been available since November 2014, the latest iteration, Pericoach V3, has been available since May 1, 2017.

Added features include a gyroscope function so that the device can better scrutinize the required "squeeze and lift" muscle action for a decent pelvic workout.

But a key point is that beyond a Facebook page, the device is not being marketed.

"Most women think incontinence is part and parcel of being a mum and getting older," Mr Daly says. "In order to get the message out you need a massive marketing budget. So our strategy is to develop the product and licence it to someone with the clout to do that."

While not required for approval, the company has carried out a post-marketing trial of the version-two device, which required the participants to visit a clinic eight times over 20 weeks.

Such a level of intervention would not normally happen, but it was the only way of collecting the data. Indeed, Pericoach is designed for both solely at-home use, or in conjunction with a caring physician.

Given the clunky visitation requirement, the trial was discontinued after 47 of the targeted 90 patients were recruited.

The bad news is that there was no statistically significant difference with the measured weight of the incontinence pads, a key endpoint for the trial.

But – dim the lights -- the participants reported a "highly significant" increase in sexual satisfaction.

Analytica evolved from a back-door listing, initially as a developer of an automated burette for better intravenous fluid delivery.

Value leakage:

Revenues from the first two Pericoach iterations have been modest, with the $2.1 million of revenue struck in 2015-'16 the best number to date.

But as we said, the device isn't being actively marketed and the endgame is a licencing deal.

The company admits limited capital has been a "challenge over the years".

Despite the oodles of stock on issue most investors hold their shares, causing the stock to be thinly traded.

Management asserts the exiting investors “don’t appreciate the lead times for successful development … [and are] beating down the share price”.

Or maybe they have just lost patience after five years of Pericoach development and see better returns on their capital elsewhere.

Dr Boreham’s diagnosis:

Our best analogy with this one is the get-fit aspirant who joins a gym in January but then has lapsed to their slovenly ways by February.

Like a personal trainer, Pericoach gives the push along to carry out the exercises, which - like push ups - are otherwise straightforward.

Given the incontinence pad market is worth $7 billion in the US alone, Analytica might be onto something.

We have no problems with the device, which Mr Daly describes as the “only serious medical device using evidence to target this enormous and mostly hidden issue of pelvic floor health”.

We wonder how many women will take up the device at $300 a pop, but we guess that is a small price to pay for a better orgasm alone.

With cash of just over $2 million and a burn rate of $955,000, Analytica looks to be running out of time and that’s reflected in the sub 1 cent share price.

But Mr Daly says: “I’m not worried about raising money. We have people wanting to throw money at us but we are not taking it because we don’t want to dilute (the share base).”

Analytica’s recent $1,887,000 share placement was strongly supported by cornerstone holder Dr Michael Mansour, who ponied up for $383,000.

If there’s no need for the spendoolies, this implies management is confident of a licencing deal in the near future.

One chap who should be able to help here is director and major holder Peter Corr, former head of Pfizer’s R&D arm and a seasoned dealmaker.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Daily he thanks the greater powers that he has never given birth.

ONCORES MEDICAL

Oncores says the Medical Research Commercialisation Fund has invested $6 million to develop an imaging tool to improve the outcome of breast cancer surgery.

Oncores said that the Brandon Capital-managed Medical Research Commercialisation Fund (MRCF) investment would assist in the development of a handheld imaging probe and console to provide real-time intra-operative guidance to surgeons by showing the delineation of tumor from healthy tissue, at a microscopic level, with clinical trials expected within two years.

The company said that breast cancer had the second highest mortality rate of all cancers in women, with about 16,000 new cases of breast cancer diagnosed in Australia and about 250,000 new cases diagnosed in the US in 2016.

Oncores said that surgical removal of the tumor was a central component of treatment and the most common procedure was breast-conserving surgery which aimed to remove the cancerous tissue while ensuring a good cosmetic outcome.

The company said that complete removal of the tumor was challenging requiring accurate, microscopic identification of the tumor during surgery.

Oncores said that currently a pathologist examined the removed tissue post-operatively and if there were cancer cells in the margin surrounding the removed tissue, the patient would require additional surgery to remove the residual tumor.

The company said that about 25 percent of patients would require a second surgery to remove residual malignant tissue not removed in the initial operation.

Oncores said it hoped to provide surgeons with an image to identify residual cancerous tissue in the breast so it could be removed during surgery, reducing repeat surgery.

The company said that a multidisciplinary team of biomedical engineers from the University of Western Australia, with surgeons and pathologists from the Western Australian Department of Health had developed a technology to address this problem by exploring how light and pressure could be used to enhance the microscopic visualization of tissue stiffness, a property which could be used to differentiate between healthy and cancerous tissues in the surgical suite.

Oncores said that previous grant funding enabled the researchers to demonstrate on more than 100 specimens that the technology had the potential to accurately delineate malignant tissue at the microscopic level.

The company said the team included the University of Western Australia's Dr Brendan Kennedy, Dr Robert McLaughlin, Dr Kelsey Kennedy and Prof David Sampson in collaboration with breast surgeon Prof Christobel Saunders and pathologist Dr Bruce Latham and Dr Kennedy would lead the development work.

"Our vision is to provide the surgeon with more information and the patient with a better outcome," Dr Kennedy said.

"If we can reduce the number of repeat surgeries by removing all of the tumor in the first operation, it will directly impact the lives of patients and reduce the considerable healthcare costs associated with repeat surgeries," Dr Kennedy said.

Oncores said it would establish a scientific advisory board to provide guidance with Prof Saunders the first appointment.

Brandon Capital Sydney managing-director and Oncores chairman Stephen Thompson said that "from an MRCF perspective, this investment is consistent with our belief in funding medical research with significant commercialization prospects".

Oncores said it would develop the technology in partnership with a team led by Dr Kennedy at the Harry Perkins Institute of Medical Research and the University of Western Australia and Prof Saunders at the Department of Health.

Oncores is a private company.

STARPHARMA

Starpharma says it has received a $2.6 million milestone payment from Astrazeneca for its undisclosed first dendrimer-enhanced oncology product (DEP) candidate.
Starpharma said the payment was the final pre-clinical payment relating to the new oncology molecule in Astrazeneca's portfolio (BD: Jul 28, 2016; Apr 20, 2017).
The company said that the payment followed the completion of testing and scale-up activities by Astrazeneca under the multiproduct DEP licence which included potential development, launch and sales milestones of $US124 million for the first Astrazeneca DEP product and $US93.3 million for each subsequent qualifying product.
Starpharma said it would receive tiered royalties on net sales on resultant Astrazeneca DEP products, with Astrazeneca funding the development costs).
Starpharma was up 2.5 cents or 3.8 percent to 69 cents.

OBJ

OBJ says it expects to receive $US94,290 ($A127,400) from Proctor & Gamble in royalties for skincare launches in Asia for the three months to March 31, 2017.
OBJ said it had received, ahead of expectations, the first standstill payment not to licence to any competitor, and royalty fees for the second technology licenced to Proctor & Gamble of $US125,000 ($A168,900).
OBJ chairman Glyn Denison said the royalties included the brief promotional period for Wave I magnetic array transdermal products to coincide with Chinese New Year as well as the first introduction to the market of the second brand using Wave I.
"Wave II products are due to be launched in Asia during the September quarter," Mr Denison said. "It is also very pleasing that we have received the first standstill and royalty payments for the second technology ahead of our initial expectations."
OBJ was up 0.4 cents or 7.7 percent to 5.6 cents with 2.9 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says New Zealand's, St John Ambulance 2016-'18 Clinical Procedures and Guidelines recommends Penthrox replace nitrous oxide.
The Guidelines state: "Entonox [nitrous oxide] will be discontinued in 2017 and methoxyflurane will be the only inhaled analgesic administered."
"A timeline for the changeover has not yet been determined and this will be communicated separately," the St John's Ambulance Guidelines said.
Medical Developments Penthrox inhaler uses 3ml methoxyflurane as the active inhaled analgesic.
The company said that St John's Ambulance was the leading provider of ambulance services in New Zealand.
Medical Developments chief executive officer John Sharman said that "recent developments in New Zealand are very positive".
"We expect similar things to happen in other ambulance services around the world and especially in Europe as Penthrox is rolled out," Mr Sharman said.
"It is exciting to see Penthrox play a major role in providing critical analgesia and improve patient care in the pre-hospital setting," Mr Sharman said.
Medical Developments said that Penthrox sales in New Zealand recorded significant growth of 500 percent in the 2016-'17 financial year with further expansion expected in the coming year, but did not quantify the level of sales.
Medical Developments was up 27 cents or 5.6 percent to $5.07.

POLYNOVO

Polynovo says the Royal College of Surgeons has published Prof John Greenwood's 2016 Hunterian Lecture describing the evolution of burn care to the use of Novosorb.
Polynovo said that the Hunterian Lecture was delivered at the Winter Meeting of the British Association of Plastic, Reconstructive and Aesthetic Surgeons in London in November 2016, with Prof Greenwood discussing the potential shift in patient care through the development of its Novosorb biodegradable temporizing matrix (BTM).
The Lecture is available at: https://doi.org/10.1308/rcsann.2017.0110.
The company said that the article provided an overview of the Novosorb BTM development and the steps taken to ensure product safety and efficacy.
Polynovo said the biodegradable polyurethane Novosorb polymer had "outstanding biocompatibility" and was the basis of its medical devices, with prototype materials being tested in rabbits for breast reconstruction and augmentation as well as hernia products.
Polynovo chief executive officer Paul Brennan said the company was "excited that Novosorb BTM has been acknowledged in such a prestigious surgical journal through John's pioneering work".
"Our Novosorb polymer enables clinicians to deliver novel and game changing treatments for surgical wounds and burns with significant clinical improvement," Mr Brennan said.
Polynovo said that Novosorb BTM was on sale in the US, South Africa and New Zealand.
Polynovo fell half a cent or 2.4 percent to 20.5 cents.

MACH7 TECHNOLOGIES

Mach7 says it will sell 3D Medical and despite executing two contracts worth more than $2.7 million, its targeted breakeven would be in the next financial year.
Mach7 said it would divest its 3D Medical three-dimensional titanium printing operations and cited "the competitive environment and market opportunities for the 3D Medical business and the synergies expected to be realized being much less than expected".
Mach7 back-door listed in 3D Medical (BD: Oct 28, 2015; Apr 8, 2016).
The company said that following the 3D Medical divestment and other initiatives, it expected costs savings of more than $1.2 million a year.
Mach7 said one of the signed contracts was with an unnamed existing customer for the expansion of the enterprise imaging platform at its 303 beds in the US and the second was for its cross-enterprise product to an unnamed Middle East customer.
The company said that both contracts contained an upfront software licence fee, implementation and training fees and annual support fees over the life of the contracts.
Mach7 said that in addition to the contracts it was in the final stages of contract drafting with two prospective new customers in the US, one of which was unlikely to be signed by June 30, 2017 so the earnings before interest, tax, depreciation and amortisation (EBITDA) break-even target was likely to be met in the year to June 30, 2018, rather than by June 30, 2017.
Mach7 said that managing director and chief executive officer Albert Liong had left the company and a short-list for a replacement was being considered with an announcement expected by June 30, 2017.
The company said that Mike Lampron had been appointed chief operating officer.
Mach7 said that Mr Lampron had more than 20 years of business management experience in healthcare imaging and informatics product and service organizations and most recently was the head of services at Icad Inc, which sold computer aided detection and workflow products for the diagnosis of breast, prostate and colorectal cancers.
Mach7 was unchanged at 17.5 cents.

IMMURON

Immuron says it has sponsored a conference in Spain and has a 13 percent increase in Australian sales of Travelan for diarrhoea for the 10 months to April 30, 2017.
Last year, Immuron posted product revenue of $1,155,523 for the 12 months to June 30, 2016 up 2.8 percent on the previous year.
Today, the company said Travelan had been “experiencing strong sales growth in both the Australian and the US travellers’ diarrhoea market” and was expected to exceed the previous year’s revenue figures.
Immuron said the increase in sales was a result of a new trade marketing strategy in the Australia.
The company said that it sponsored the Biennial Conference of the International Society of Travel Medicine in Barcelona, Spain from May 14 to 18, 2017, which was attended by more than 1,500 medical health professionals from 60 countries.
Immuron said it sponsored a satellite symposium on the “non-antibiotic options for the management of travellers’ diarrhoea, with an expert panel of three gastrointestinal health specialists who spoke on the risks of using antibiotics for the management of travellers’ diarrhoea symptoms and non-antibiotic products for this indication.
Immuron was up two cents or 3.8 percent to 55 cents.

ZELDA THERAPEUTICS

Zelda says that in-vitro pre-clinical research supports the use of cannabinoids as anti-cancer agents.
Zelda said the in-vitro studies supported mouse studies that showed that specific formulations of tetrahydrocannabinol rich oil was significantly more potent at reducing hormone receptor positive, or HER2+, breast tumor growth than pure tetrahydrocannabinol (THC) and as potent as Lapatanib in reducing tumor growth in mice hosting HER2+ human tumors.
The company said that the results showed the potential for cannabinoid-based therapies to be beneficial in a broad spectrum of breast cancer types including, HER2+ and triple negative cancer types.
Zelda said that the work was conducted by researchers at Spain’s Complutense University of Madrid.
The company said that the latest experiments tested THC-rich and cannabidiol or CBD rich extracts against a number of cell lines and demonstrated that a statistically significant anti-cancer effect was produced across multiple cell lines and across all three cancer sub-types.
Zelda said that the in-vitro study was in at least two different cell lines of each of the three cancer sub-types and measured cancer cell viability compared to controls.
The company said that the positive results provided support to continue the study of Zelda formulations as anti-cancer therapeutics in their own right or in combination with current chemotherapy and radiotherapy regimes.
The company said that a series of follow-on in-vitro studies were in progress expanding the study of CBD-rich extracts alone and in combination with THC-rich extracts to determine if there was a synergistic effect.
Zelda said that an expanded animal study was underway examining the anti-cancer effect of its extracts compared to pure THC and pure CBD as well as certain chemotherapy agents against HER2+ and triple negative human tumors in rodents, with initial results expected by October 2017.
Zelda was up 2.7 cents or 48.2 percent to 8.3 cents with 93.3 million shares traded.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health has requested a voluntary suspension to follow the trading halt requested on May 31, 2017 “pending an announcement to the market regarding a proposed capital raise” (BD: May 31, 2017).
Reproductive Health last traded at 15.5 cents.

BIOXYNE

Bioxyne says it will provide a share sale facility for shareholders to sell unmarketable parcels without incurring any brokerage or handling costs.
Bioxyne said the facility was available to shareholders at the record date of May 31, 2017 who held parcels of shares worth less than $500 based on a price of 1.6 cents a share.
Bioxyne was up 0.1 cents or 6.25 percent to 1.7 cents.

AVITA MEDICAL

Avita says that director Dr Michael (Mike) Perry has been appointed chief executive officer replacing Adam Kelliher.
Avita said that Dr Perry had been a non-executive director since February 2013 and was formerly Novartis AG cell and gene therapy chief scientific officer.
The company said that prior to that he was head of Novartis Pharmaceuticals integrated hospital care and head of stem cell therapy.
Avita said that previously Dr Perry was with Baxter Healthcare and Novartis subsidiaries Systemix Inc and Genetic Therapy Inc, Schering-Plough Corp and chairman, chief executive officer or chief medical officer for several early stage biotech companies and was was a venture partner with Bay City Capital in San Francisco.
The company said that Dr Perry currently was a director Arrowhead Pharmaceuticals and Ampliphi Biosciences Corp and held academic affiliations with the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine and with the Houston Methodist Research Institute.
Avita said that Dr Perry currently was a director and operating partner of Bioscience Managers Pty Ltd.
The company said that US-focused milestones would “largely drive company value and as such, a decision was made to retain a US-based chief executive to optimize shareholder value”.
Avita said that the London-based Mr Kelliher did not want to relocate to the US and had resigned, but would remain a consultant to the board of directors.
Avita was up 0.7 cents or 8.9 percent to 8.6 cents.

PERRON INSTITUTE FOR NEUROLOGICAL AND TRANSLATIONAL SCIENCE

Last night’s edition said that the Perron Institute for Neurological and Translational Science “changed its name in January 2017 following a donation from Stan and Jean Perron”.
The Institute said that “Western Australia’s longest established medical research institute” changed its name from the 35 year old Western Australian Neuroscience Research Institute “to acknowledge the longstanding support of Stan and Jean Perron and their family”.
Biotech Daily apologizes unreservedly for the mistake.

GI DYNAMICS

GI Dynamics says that 13-year non-executive director Mike Carusi has resigned.
GI Dynamics said that Mr Carusi joined the company in 2004 and due to commitments with Advanced Technology Ventures and Lightstone Ventures had resigned.
GI Dynamics was up 0.3 cents or 5.3 percent to six cents.

BIO-MELBOURNE NETWORK, MTP CONNECT

The Bio-Melbourne Network says that MTP Connect chief executive officer Sue MacLeman has won the 2017 Women in Leadership award.
The Network said the award was presented by the Governor of Victoria Linda Dessau and recognised Ms MacLeman's "leadership and outstanding contributions" to the medical technology, biotechnology and pharmaceutical (MTP) sector.
The Network said that Ms MacLeman had more than 25 years' experience as a life sciences executive with roles in corporate, medical, commercial and business development at Schering-Plough Corp, now Merck, Amgen and Bristol-Myers Squibb.
The industry organization said that Ms MacLeman was a director of public and private entities, including Oventus, Reproductive Health Sciences and Dalroar and was a consultant to Mesoblast.
The Bio-Melbourne Network said that Ms MacLeman was "passionate about addressing the skills gap in the sector, up-skilling the current workforce with the necessary business and commercialization skills and creating pathways for students to easily transition from university to industry".
The Network said that Ms MacLeman was a mentor in the Industry Mentoring Network in Science Technology Engineering and Mathematics, supporting second-year Doctorate of Philosophy students looking to extend their professional networks.
Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "Sue MacLeman's leadership skills have shone through at all stages of her career, not only her technical and corporate skills, but her ability to lead and inspire the people around her".
"Sue has risen to the challenge of leading the new Industry Growth Centre, MTP Connect, and has shown outstanding leadership in her ability to unify key sector stakeholders around a shared vision for the future of our industry," Dr Evans said.