Biotech Daily

Monday September 4, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: LIVING CELL UP 8%, USCOM DOWN 11%**

*** BIOTECH REVENUE UP 194% IN 8 YEARS TO $1.4b**

*** FDA LIFTS HOLD ON PRESCIENT PTX-200 FOR AML TRIAL**

*** RESAPP UPGRADES PROTOCOLS, ALGORITHMS FOR STUDY RE-RUN**

*** FDA APPROVES G MEDICAL PRIZMA; 70m 'PERFORMANCE' RIGHTS**

*** OBJ RESPONDS TO 2nd ASX AWARE QUERY**

*** PHARMAUST TAKES 100% OF NIHON AMINO-ACETONITRILE IP**

*** STEMCELL UNITED TO RELEASE 248m ASX ESCROW SHARES**

*** COCHLEAR APPOINTS SIRTEX'S DR DAVID CADE CMO**

*** NUHEARA IQBUDS WIN 2 BERLIN RADIO SHOW AWARDS**

MARKET REPORT

The Australian stock market fell 0.39 percent on Monday September 4, 2017 with the ASX200 down 22.6 points to 5,702.0 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Living Cell was the best, up one cent or 7.7 percent to 14 cents with 970,627 shares traded. Compumedics climbed 6.8 percent; Orthocell was up 5.3 percent; Actinogen, Benitec, Cellmid, Impedimed, Polynovo and Prima improved more than four percent; Universal Biosensors was up 3.95 percent; Ellex and Psivida rose more than two percent; with Admedus, Airxpanders, Factor Therapeutics, LBT, Mesoblast and Pharmaxis up more than one percent.

Uscom led the falls, down two cents or 10.8 percent to 16.5 cents with 38,400 shares traded.

Avita lost 7.25 percent; Bionomics, Genetic Signatures, Neuren and Osprey fell more than four percent; Nanosonics and Oncosil were down more than three percent; ITL, Sirtex and Starpharma shed two percent or more; Acrux and Pro Medicus were down more than one percent; with Clinuvel, Cochlear, CSL and Resmed down by less than one percent.

BIOTECH DAILY REVENUE & PROFIT ANALYSIS

In the eight years since June 30, 2009 the total biotechnology sector revenue – excluding the three Big Caps – has climbed 194.1 percent from $464.3 million to $1.366 billion.

For two years around the Global Financial Crisis, Biotech Daily kept a record of revenue and profits posted by companies with revenue of more than $1 million a year.

Following the calming of the markets, we discontinued the somewhat onerous collection of the data.

At the suggestion of a new publication, Stockhead, which re-publishes the Dr Boreham Crucible, we again collected data from this financial year.

The 21 companies covered in the 2008-'09 financial reporting season showed a total revenue of $7.3 billion with a total net profit after tax of $1.54 billion.

Most of the revenue and profit was generated by the three Big Caps of Cochlear, CSL and Resmed, which are large and stable and hence distort the greater volatility of the rest of the sector.

In 2009-'10, as the GFC receded, total revenue for the sector slipped 3.0 percent or $217 million to $7.1 billion, while total profit was down 0.4 percent (or $6.4 million) to $1.5 billion.

For the reporting season just closed, total revenue was $11.686 billion up 39.4 percent compared to 2009-'10, with total profit up 24.4 percent to $1.9 billion.

Compared to 2008-'09 revenue was up 60.0 percent.

While the revenue figure is strong – again skewed by the three Big Caps – the profit figure includes the losses of the smaller companies.

In 2008-'09, Biotech Daily covered 21 companies with revenue of more than $1 million for the year. In 2009-'10 the number rose to 27, and for the reporting season just concluded we have 56 companies reporting revenue of more than $1 million. Many of them still have product in development, with changing profit and loss statements.

For example, Mesoblast receives licencing revenue, milestone payments and last year claimed $US22.5 million ($A29.9 million) in revenue which was an accounting procedure of non-cash recognition of Teva Pharmaceutical's return of the cardiac program. So the dramatic fall in revenue of 94.3 percent to $3 million and consequent leap in loss of 1,761.3 percent to $96.1 million is more accountancy-related than actual changes.

There's been a lot of accountancy games played this year, with impairment costs written off and Sirtex claiming it had a $26.3 million loss when in the real world of money in the bank its net profit after tax was down 20.9 percent to $42.4 million.

Some companies have reported in "constant currency" which is what the result would have been if they used volatile exchange rates from previous year.

Biotech Daily tries very hard to make accurate comparisons. The actual money received is what matters, not what it might have been. Worse, a number of companies have reported different data for the previous year, compared to the previous year's report.

Some companies describe receipt of the 43.5 percent Federal Government Research and Development Tax Incentive as "revenue", when there has been no sale of product, milestone payments or licence fees. They are not included in the data.

Non-Big Cap Revenue and Profit

Stripping out the three Big Caps of Cochlear, CSL and Resmed, in 2008-'09 the other 18 companies in the sector with revenue of more than $1 million posted a collective revenue of $464.3 million and a cumulative profit of $68.24 million.

In 2009-'10, the then 24 companies recorded collective revenue up 9.5 percent to $508.33 million with profit up 42.4 percent to $97.2 million.

For the 2016-'17 financial year the 53 companies with more than $1 million in revenue announced total revenue up 168.7 percent over seven years to $1.366 billion, but overall profit down 16.9 percent to $83.15 million.

Excluding the loss-makers, the cumulative profit this year was $198.8 million, most of it thanks to Mayne Pharma, Sirtex, Nanosonics and Pro Medicus.

As the number of innovation companies earning their first revenues increase, they bring with them their investment in research and development and consequent losses.

As they mature, the revenues (hopefully) increase and the losses turn to profits.

For some companies it can be very lumpy with the first few years of solid revenue coinciding with turnaround maiden profits, followed by the loss of a single contract returning them to losses.

But the eight year pattern is unmistakable. We have nearly three times the number of companies earning significant revenues and many of them are learning how to manage their businesses accounts.

Companies like Ellex, Compumedics, Medical Developments, ITL, Acrux, Cyclopharm, Admedus and Uscom are selling product world-wide and earning substantial export income and all are on the verge of moving from losses to sustainable profits.

Biotech Revenue & Profit 2008-'17

Year	Revenue (All)	Revenue (-Big Caps) $m	Profit $m	Profit (-Big Caps) $m
2008-09	$7,296.46	**$464.31**	$1,519.24	$68.24
2009-10	$7,079.13	**$508.33**	$1,512.80	$97.2
2016-17	$11,685.85	**$1,365.65**	$1,881.75	$83.15

PRESCIENT THERAPEUTICS

Prescient says the US Food and Drug Administration has lifted the clinical hold on its phase Ib/II trial of PTX-200 for refractory or relapsed acute myeloid leukaemia.
In May, Prescient paused recruitment to trials of PTX-200 following the death of the last of 29 patients in its phase Ib breast cancer trial (BD: May 29, 2017).
Prescient was trialling PTX-200, previously known as triciribine phosphate monohydrate (TCN-P) for breast, lung and oesophageal cancer, as well as acute myeloid leukaemia and ovarian cancer and in April said PTX-200 and Paclitaxel were safe and had shown signs of efficacy for breast cancer (BD: Apr 6, 2017).
Today, Prescient said it was preparing to resume recruitment of patients in the acute myeloid leukaemia trial and was in the process of responding to FDA requests on its breast and ovarian cancer studies which were currently on hold.
The company said it paused its three clinical trials of PTX-200 in May following the death of a patient with late-stage breast cancer who experienced liver failure.
Prescient said the patient had metastatic disease, compromised liver function and was being administered several concomitant medications.
The company said severe adverse events were not unusual in cancer studies where patients were very ill and existing therapies had potentially serious adverse effects.
Prescient said it had revised the trial inclusion criteria to exclude anyone with a history of liver disease and it would conduct a liver function test prior to administering each dose.
Prescient was up 0.4 cents or 7.4 percent to 5.8 cents.

RESAPP HEALTH

Resapp says that further analysis of its Smartcough-C trial data and confirms “the study was not a representative evaluation of [its] Resappdx”.
Last month, Resapp fell 82.3 percent on news that its 1,245-patient trial failed to meet its endpoints for the accurate diagnosis of respiratory disease (BD Aug 9, 2017).
Resapp said that “contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds [and] a high number of recordings were also found to contain a second person’s cough sounds or an unacceptable amount of background noise and interference”.
In June, the company published data from an Australian 1,127 patient paediatric trial, claiming accuracy ranging from 70 percent to 97 percent (BD: Jun 22, 2017).
Today, Resapp said it would “restart the study this US winter after implementing an array of enhanced procedures and features”.
The company said that to improve data-gathering it would be present onsite, conducting team training, reviewing enrolment procedures and verifying data to help ensure that high-quality cough sounds were collected as early as possible during the patient’s hospital visit and prior to any treatment known to affect cough analysis.
Resapp said that every cough sound collected would be quality checked within days of its recording to ensure it was uncorrupted and high fidelity.
The company said its algorithms had been modified “to reduce the impact of the low frequency electronic interference found in nearly 15 percent of the … study recordings”.
Resapp chief executive officer Dr Tony Keating said that “the first US study was not a reliable evaluation of Resapp’s algorithms and … the top line results do not reflect the actual performance of Resapp’s technology”.
“The environment and the clinical diagnostic procedures in busy US hospitals differed more than expected from those encountered during our Australian studies,” he said.
Resapp climbed 3.2 cents or 47.8 percent to 9.9 cents with 143.5 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it has been granted US Food and Drug Administration 510(k), class II approval to sell its Prizma medical smartphone jacket.
In July, G Medical said the Shandong Boletong Information S&T Co would distribute a minimum of $84 million) of its products and services in China including a minimum quantity of the Prizma phone jackets which had sensors to measure vital signs and biometric parameters and could continuously collect, consolidate and analyze medical data to detect trends over time (BD: Jul 27, 2017).
G Medical said the Prizma sent configurable, automatic alerts, notifications and reminders and enabled patients to instantly share data with predefined third parties, and the data could be stored in the internet 'cloud' subject to privacy policies.
Today, G Medical said that similar regulatory approvals were in progress in China, Europe, Australia and other markets in line with the Company's priorities.
G Medical chief executive officer Dr Yacov Geva said the FDA approval was "a very significant milestone".
The company said the approval triggered the conversion of 70,000,000 class A performance rights into shares, which would remain in escrow until May 10, 2019.
G Medical was unchanged at 44.5 cents with 9.65 million shares traded.

OBJ

OBJ has responded to a second ASX 'Aware' query relating to the issue of $3.54 million in performance shares.
Last month, the company published its financial reports and the following day said that $3.54 million of salaries and consultants expenses were "a provision in the accounts for the expense of two … performance milestones" (BD: Aug 23, 24, 2017).
OBJ said in August that the milestones were approved at the 2014 annual general meeting, were required to be published in the Appendix 4E and the $3.54 million figure was "based on the prevailing share price at the time shareholders approved the performance milestones in November 2014" when the company was trading at 9.5 cents.
OBJ said that its auditors took the view that the $3.54 million figure should be published "based on independent legal advice … that performance milestones 1 and 2 have been met, though these shares have not yet been approved … to be issued".
On August 25 the ASX asked OBJ to explain whether the performance milestone was "information that a reasonable person would expect to have a material effect on the price or value of its securities" and when it became aware of the milestone information.
On August 30, the ASX noted the response to the previous question "does not state when the entity first became aware" of the satisfaction of the milestones.
Today, OBJ provided a detailed response including that it had told the ASX on April 27 and May 24, 2017 that payments for the milestones would be made.
OBJ said that on receipt of the payment it prepared the announcement that was provided to the ASX on June 2, 2017 but the timing difference was due having the form of the announcement approved by the licencee.
The company said it previously announced market the expected receipt of licence fees and provided guidance on May 24 on the aggregate amount.
OBJ said it became "aware" that the underlying circumstances associated with milestone 1 were satisfied on May 28 and on June 2, 2017 and the underlying circumstances associated with milestone 1 were part of the 2014 annual general meeting papers.
The company said it determined the securities would be issued on August 22, 2017.
OBJ fell 0.1 cents or 2.2 percent to 4.5 cents with 1.3 million shares traded.

PHARMAUST

Pharmaust says it has acquired the remaining 50 percent of a join patent portfolio held with the Tokyo-based Nihon Nohyaku Co, in exchange for royalties on sales.

Pharmaust said that the portfolio consisted of two patent families entitled 'Anticancer agent comprising amino-acetonitrile compound as active ingredient' which related to a library of novel amino-acetonitrile (AADs) compounds, originally patented by Nihon Nohyaku, as anticancer agents.

Pharmaust chief executive officer Dr Richard Hopkins told Biotech Daily the patent families were previously owned in a 50-50 arrangement with Nihon Nohyaku.

The company said that the AADs were related to, but distinct from, monepantel or PPL-1, which it was developing for trials in humans and dogs with cancer.

Dr Hopkins said the company was "delighted Nihon Nohyaku has agreed to assign its joint intellectual property rights to Pharmaust".

"This means Pharmaust now fully owns rights to over 50 novel AAD compounds, which can potentially be used to develop a proprietary pipeline of anti-cancer compounds," Dr Hopkins said.

"This complements endeavours to develop monepantel as a lead therapy to treat cancers in dogs and humans," Dr Hopkins said.

Pharmaust said it was recently granted patents covering methods of use for monepantel in cancer and non-cancer fields and was progressing licencing discussions with Elanco, which currently owned the rights to monepantel and had registered the drug for use in animals.

Pharmaust said that subsidiary Epichem would synthesize and optimize selected AAD candidates from the library for screening in anti-cancer assays.

Dr Hopkins said that Epichem had optimized several drugs in late-stage clinical trials.

Pharmaust fell 0.1 cents or 1.6 percent to 6.2 cents.

STEMCELL UNITED

Stemcell says 248,494,410 shares will be release from holding locks, or ASX escrow, on September 14, 2017.

Stemcell said its top five shareholders agreed to put 87.5 percent of their shares, or 221,447,254 shares, into voluntary escrow until March 14, 2018.

According to the company's most recent Appendix 3B announcement, it had 260,543,262 shares on issue and available for trading with a further 125,494,410 shares not quoted on the ASX.

The company did not disclose the whereabouts of the 248,494,410 ASX escrow shares.

Stemcell's preliminary final report said it had revenue for the year to June 30, 2017 down 58 percent to $31,619 with a net loss after tax down 93 percent from $35,618,359 to $2,399,753.

Stemcell's most recent announcements were that it hoped to raise up to $25 million at 10 cents to fund its dendrobium business and explore opportunities in the cannabis business and an ASX price query (BD: May 1, 18, 2017).

Stemcell announced its move to medical marijuana in March, having changed its name in 2015 from On Q Group to extract Resina from Daemonorops draco blume (Dragon's Blood) for traditional Chinese medicines to be marketed as essence-infused mask.

On May 1 the company told the ASX in response to an 83.3 percent share price rise from 12 cents to 22 cents that it was mentioned in an article on marijuana companies in the Fairfax media over the weekend.

Stemcell was unchanged at six cents.

COCHLEAR, SIRTEX MEDICAL

Dr David Cade will join Cochlear as its chief medical officer from October 3, 2017.
In June, Sirtex said that Dr Cade would be leaving “to take on a new opportunity” after 14 years with the company (BD: Jun 28, 2017).
Dr Cade told Biotech Daily that he would finish at Sirtex in three weeks and start with Cochlear a week later.
Dr Cade was previously a management consultant with Booze & Co.
He holds a Bachelor of Medicine and a Bachelor of Surgery from Monash University and a Masters of Business Administration from the Melbourne Business School.
Cochlear fell $1.39 or 0.9 percent to $155.26 with 66,608 shares traded.
Sirtex fell 33 cents or 2.1 percent to $15.08 with 135,477 shares traded.

NUHEARA

Nuheara says it has won two Information Handling Services Markit innovation awards at the Internationale Funkausstellung Berlin (International Radio Eehibition Berlin).
Nuheara said that the Internationale Funkausstellung Berlin was also known as the Berlin Radio Show which began in 1924 and was one of the oldest industrial exhibitions in Germany.
The company said its Iqbuds sound filtering and hearing ear buds won the augmented reality, virtual reality and gaming category and was runner up in the fitness, wearables and health devices category.
Nuheara said it was one of 1,805 exhibitors at the Berlin event.
The company said it had won a total of seven global innovation awards in 2017, including five presented at the world’s two largest technology trade shows.
Nuheara was up 0.3 cents or 4.5 percent to seven cents with 3.1 million shares traded.