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In this edition...
Technical challenges are a norm in medical product development. Such is the case with Sunshine Heart and its C-Pulse heart assist device. Although it has implanted at least eight patients in its feasibility trial, it has had to develop less invasive surgical techniques for surgeons worried about implanting the device with patients that aren't at the end stage of heart failure. Regulatory challenges are an unpleasant fact of life was well, and we take a closer look at the FDA's ODAC panel's review of Omapro. Our opinion is the FDA has acted inconsistently to set a precedent for personalised cancer medicines.
We also update readers on Benitec and trends in the RNAi therapeutics space.
The Editors
Companies Covered: BLT, CXS, SHC

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	-0.1%
Cumulative Gain	**189%**
Av Annual Gain (9 yrs)	**18.5%**

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au
David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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Bioshares

4 June 2010
Edition 362

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Cardiologists Warm to Sunshine Heart's Device

Commercialising medical products is a lengthy, difficult and complicated process. There are times when companies pass a critical point that changes their investment perspective. **Neuren Pharmaceuticals**, featured in last week's Bioshares is one example. When **Benitec** renegotiated its license agreement with the CSIRO earlier this year, it was also a pivotal event. Sunshine Heart (SHC: 3.6 cents), which has been developing the C-Pulse device for 11 years, may have also just reached a crucial turning point.

The C-Pulse device is a cuff that is sown around the ascending aorta. The cuff is inflated in a counter-pulsating rhythm to the heart, to assist cardiac output. The key advantage to this system over the LVADs (left ventricular assist devices) is that it does not contact the blood and can be switched off at any time without any safety issues. The C-Pulse is designed for use in patients with predominantly Class III heart failure. LVADS are designed for use in patients with Class IV heart failure.

Feasibility Study – 20 Patients

Sunshine Heart is currently conducting a feasibility study with its device in a 20 patient trial. Enrolment into this trial has been slow, with only five patients recruited in the first 12 months. However in the last four weeks the trial has seen a further four patients implanted with the device (including one patient who was due to be implanted late this week).

The faster enrolment rate is for two reasons. Firstly, cardiologists involved with the trial are seeing positive outcomes from the first five implants. Secondly, cardiologists are finding that the device can successfully be implanted using a minimally invasive procedure that does not involve splitting the chest (sternotomy).

The FDA trial protocol allows the device to be implanted in a minimally invasive way. Sunshine Heart has been working on, and continues to develop, tools to allow device implantation through this method.

This is a major issue for this technology. Because the suitable patients are generally less ill than those who are eligible for an LVAD, the easier the procedure is to implant the device, the more frequently the system should be adopted with the therapy more appropriately justifying the surgical and medical intervention.

Minimally invasive delivery of this device will reduce surgery time, but also severely reduce patient recovery time, with expected hospitalization reduced from seven days to only three.

– Cont'd over

Results to Date

In the patients implanted to date, four patients have had the device for more than six months, and one patient for more than nine months. One of our concerns previously has been that of infection. In the current trial to date, only site infections, where the tubing enters the body, have been recorded in a small number of patients and these infections have been easily treated with oral antibiotics. There have been no strokes, bleeding or device related issues in the trial to date.

Every patient implanted is apparently feeling physically better however the specific overall improvement will not be known until after the trial.

Infection is a considerable issue with LVADs. In 30% of LVAD implants (Heartmate II), a second operation is required to resolve bleeding issues, and around 10% of patients require a second operation due to device issues.

The company is seeking to complete enrolment in this trial by September this year. There will be a six month follow-up, which should see results released in the second quarter of 2011. If all goes well, the plan is to commence a pivotal study in July 2011. The design of that study is in the planning. It could either be comparing the efficacy of C-Pulse against medical therapy, which would include around 260 patients, or against an LVAD (Heartmate II) which would require around 175 patients. The latter would be a non-inferiority trial and would take up to two years to complete.

Funding

The company has sufficient funding until the end of this year, with $6.1 million in cash at the end of March. There is considerable interest in the technology from US investors according to CEO Dave Rosa. We would expect that venture capital shareholders, GBS Venture Partners and CM Capital, would commit further funding to the company. The next round would allow the company to start the pivotal study, and fund operation out to early 2012.

Exit for Major Shareholders

The most likely exit for major shareholders is through a trade sale of the company to one of the major medical device groups, in our view, one of the pacemaker/implantable defibrillator majors. The company this week also raised the prospect of an IPO on the US market.

Ideal Market Entry Gap

One of the appeals of this technology is its potential to work in with existing cardiac therapeutic device businesses, specifically the pacemaker/implantable defibrillator market. Of the patients who receive a pacemaker or defibrillator, in 24% of cases the device is ineffective. In a further 25% of recipients there is only a partial response.

Each of the patients in the C-Pulse trial has been implanted with either a pacemaker or defibrillator. The C-Pulse device, if it reaches the market, would be an ideal product extension for one of these major device companies that sells pacemaker and defibrillators. The pacemaker market alone is valued at US$8 billion a year. Securing a product such as C-Pulse would also give one of these potential acquirers a more complete solution which would help build market share even with existing products.

Risks

There are several risks associated with Sunshine Heart. The first relates to the clinical trial and achieving an improvement in patient health with what needs to be relatively good safety profile. The current trial suggests the program is on track with this aspect.

The second risk is financing, with the company needing to raise funds later this year and a pivotal study costing in the order of US$40 million. If the trial continues to progress well and with the support of its good quality share register, medium term financing risk we would view as low.

The third risk is that of trial recruitment. Recruitment was initially slow. However the emerging positive results together with progress in moving towards a minimally invasive surgical procedure should give a good chance that full recruitment in the current trial will meet its target date (September 2010).

Summary

Sunshine Heart has six granted patents around its technology with 130 allowed claims. It employs six people. The recently appointed CEO is based in Minnesota, where many of the leading medical device companies are located. The C-Pulse will sell for US$54,000.

Sunshine Heart is passing through a crucial turning point in the commercialisation of its C-Pulse technology after 11 years of development. Improving the implant procedure to one that is minimally invasive is a crucial development for the company to have it readily adopted by cardiologists both in clinical studies and in commercial practice.

Other improvements, such as reducing the size of the batter back are in progress. The company also has plans to work on a completely implantable system, which it believes it could have in people within 18 months. Such a system, which if delivered through minimally invasive surgery, we believe would have the potential to make this a multi-billion dollar market. It is this possibility that no doubt that has attracted the venture capital investors onto the register.

Sunshine Heart is capitalised at $20 million.

Bioshares recommendation: **Speculative Buy Class B**

Sunshine Heart is not without risk. However the potential return we believe has moved to outweigh the associated risk and we have added the stock to the Bioshares Model Portfolio at 3.6 cents.

Bioshares

Chemgenex Pharmaceuticals: 1,144 People Plead with FDA to Bring Omapro to Market

Chemgenex Pharmaceuticals has had a rough year. Earlier this year the FDA put a halt on approving its drug candidate, Omapro, having its Oncologic Drug Advisory Committee vote only on whether Chemgenex should have a validated diagnostic test approved first before it even considered the risk/benefit profile of Omapro and approving the drug candidate.

On-Line Petition

An on-line petition has now been formed by patients and others affected by the disease the Chemgenex drug candidate is designed to treat. That petition can be viewed at http://www.petitiononline.com/FDAOMACE/petition.html . To date 1,144 people have signed this petition. It is worth viewing, particularly for the comments from many of the patients. A full transcript of the FDA ODAC meeting held in March can also be viewed at this site.

Reading through the meeting transcript clarifies the position Chemgenex is currently in. The main concern the ODAC members had was that if there was not an accurate (validated) test available, patients with chronic myeloid leukemia could be incorrectly prescribed Omapro after having failed Gleevec treatment, when there are more effective tyrosine kinase inhibitor drugs available (Sprycel and Tasigna) that achieve a much higher response rate according to Dr Amy McKee from the FDA who reviewed Chemgenex's NDA.

Five Tests Available

As detailed in the patient petition is that there are several commercial tests (five) currently available, and the test can be widely performed in university and commercial labs. The petition states that while these tests/assays have not been approved by the FDA, they are validated tools that have been in use for decades, and that is true.

Chemgenex has been blindsided by the FDA on the diagnostics issue. The company has grounds to be disappointed with the FDA for raising this issue about a validated diagnostic upon review of the company's drug approval review process, rather than three years ago when the pivotal study was being planned and the expectation was that existing commercial tests would be acceptable.

A Precedent Candidate?

It is quite likely the FDA has chosen Omapro as a precedent candidate for personalised medicine treatment, where a validated (FDA approved) diagnostic will now almost certainly be required when seeking to have a drug approved for treating a 'molecularly defined subset of patients'. As one ODAC panellist, Dr Brent Logan, put it, "I think it's crucial, if we're going to have personalised medicine, that we have reliability established across labs."

Chemgenex is keeping relatively quiet on its views. Rather than waging a public argument with the FDA, it is arguing its case privately with the FDA. The next step for the company is to set up a Type-A meeting, which we expect should occur in the next three months. The resolutions from that meeting will be binding and will give Chemgenex clear direction on what it needs to do to bring its drug to market.

ODAC Panel Vote

The ODAC panel vote in March voted seven against one in favour that a validated diagnostic should be developed. Some of the panel member comments however could be very interesting to investors. The one panel member, Dr Ellin Berman, who voted against the test being required also stated that Omapro should be approved based on the data supplied.

The Chair of the Panel, Dr Gail Eckhardt, agreed with Dr Berman that Omapro is an "active drug,….potentially in this population", and that the assay development should not be very complicated.

Dr Mikkael Sekeres who voted for the development of a validated test stated "I want to be clear about something. If we had been asked to deliberate about recommending approval based on safety and efficacy, I would have voted yes".

Dr Berman also made another interesting comment about the diagnostic issue if patients were incorrectly diagnosed. "The worst case scenario is they get HHT (Omapro). (If) it doesn't work, then they go on to dasatinib (Sprycel) or nilotinib (Tasigna) because that's all there is out there. So patients aren't going to be harmed by this. It's not going to be a waste of time for their clinical response."

Dr William Kelly strongly recommended for a validated test but stated that he did think the drug has clinical activity and may have some clinical benefit.

And reinforcing our argument that this is a clear precedent setting case for the FDA, the FDA's Dr Richard Pazdur stated *"The message here that the agency (FDA) would like to get across is attention has to be paid to these in vitro diagnostics. They're not just something to put off, that somebody else will do. And the fact that it has widespread usage in the community…so what?"*

Patient Views

The ODAC meeting also heard from patients in the Chemgenex study. The strong side effect issues was noted by each of the two patients who addressed the meeting. However, both indicated how those side effects could be managed. One patient who is now in remission and still participating in the trial, stated that "I feel better today than at any time since I have been diagnosed with CML (in 2005)."

The second patient who addressed the meeting had been taking Omapro for three years now and maintained a good quality of life taking an active role with her children and grand children.

Funding Issue

As time passes for Chemgenex, another concern will need to be addressed, and that is whether the company needs to raise further

funds. The company's expenditure should reduce as its clinical trials wind down. The pivotal 202 trial on which the company's new drug application with the FDA is based, is completed, as is the 203 study, which looked at treating patients with CML who had failed two or more of the tyrosine kinase drug therapies (Gleevec, Sprycel or Tasigna).

The 203 study is of interest, as it does not involve testing for the T315I mutation and therefore removes that whole issue. The company could get its drug approved for that indication. However that is certainly not its favoured option as it would require a new drug application.

The surprise event and potentially major driver for this stock is if the European regulatory agency approves the drug. That decision should come in the fourth quarter of this year and we place a reasonably good chance that the EMA will deliver a favourable review. In Europe (the Middle East and parts of Africa) the drug will be marketed and sold by **Hospira**.

At this stage Chemgenex is not intending to raise further funds. At the end of December last year the company had $18.7 million in cash. A capital raising will be very dependent on whether European approval is received before the end of the year, which should also trigger a milestone payment from Hospira.

Other FDA Issues

The FDA also raised two other issues. The first is the vial size and the discarding of excess drug by patients at home, which will need to be addressed by the company.

The second is the low patient numbers on which the NDA was submitted. Chemgenex has now treated 100 patients in the trial and we expect this data will be made available to the FDA.

Summary of the Situation

The briefing document produced by the FDA for the ODAC panel meeting gave clear suggestion that Chemgenex's review process with the FDA would not be seamless, highlighting several issues, including the lack of a validated diagnostic, and that has certainly been the case.

Chemgenex could rightly claim that it has received an unfair evaluation process from the FDA in seeking to bring its drug candidate, Omapro, to market in the USA. It appears to us that Chemgenex been chosen as precedent setting example for the use of validated molecular diagnostics in the area of personalised medicine.

The question could be asked why the FDA specifically asked the panel to only evaluate whether a validated diagnostic should be required and why this issue could not be addressed as a supplementary item. The question could also be raised as to why the issue of a validated/FDA approved diagnostic not raised by the FDA years before the company had completed its drug development program.

The ODAC panel review appears to indicate that the drug shows efficacy and merit and our expectation is that it will eventually receive FDA approval. The validated diagnostic issue may also only be an FDA-specific concern, and there may be a reasonably good chance the drug will receive approval in Europe by year's end.

The patient petition for Omparo supports the need for this drug by patients who have no other options, and this is the pressing point. The drug has a high side effect profile, however, one that appears to be manageable and one that can maintain a good quality of life.

Investment Perspective

For investors the concern is that this delay is costly and the possibility that more funds will now need to be raised prior to the drug gaining FDA approval and to launch the product in the US. In 2009, the company spent around $27 million (and received $17.5 million in a license fee from Hospira). The spend rate should fall significantly with its clinical trial activity winding down. At the end of 2009 the company held $18.7 million in cash, which we estimate should be sufficient to fund the business for the next nine to 12 months.

Chemgenex is beginning to approach an attractive re-entry point notwithstanding future funding requirements which may see continued downward pressure on the share price. The outcome of the Type A meeting with the FDA will provide more clarity on requirements and timeline in gaining FDA approval.

Bioshares recommendation:**Speculative Hold Class B**

Bioshares

Benitec and RNAi Therapeutics – An Update

RNAi is a reference to a relatively new field of research that aims to turn-off genes involved in disease, using short lengths of double stranded RNA, which can interfere with gene expression.

RNAi is a naturally occurring phenomena that was first observed in plants, and Australian plant scientists at the Queensland DPI and the CSIRO were arguably among the first to discover the phenomena and consider applications of the discovery. The inventor ship argument continues before the US PTO where Benitec's ''Graham' patent is currently being reviewed.

Benitec is the only ASX-listed company with a major IP position in the global RNAi field, with other players including **Alnylam**, **Merck** (which acquired **Sirna**), and **Silence Therapeutics** (which acquired Intradigm). Benetic's approach is complementary to these other companies, possessing a technology more suitable to the treatment of long term diseases, whereas the others having potentially greater benefits in acute conditions.

Benitec was founded in 1997. However, the company has a chequered history courtesy of deal with the CSIRO over IP that had a dampening effect on building and developing other commercial arrangements. Previous management were also ineffectual in building the company, and litigation in US courts with **Nucleonics** over IP has also turned investors away from the stock.

Benitec is in fact a clinical stage company, indirectly through out licensed programs (i.e. Tacere's HCV trial - BLT holds a 4% stake), and having sponsored a now completed trial in HIV patients at the City of Hope Hospital in Los Angeles. It is looking to commence a trial in lung cancer patients.

Recent Board Appointment

Benitec recently announced the stepping down of CEO Sue Macleman, who as moved to the CEO position at **Progen**. This week the company announced the appointment of Iain Ross to the board. Iain Ross was formerly the chairman of **Silence Therapeutics**. However, Ross also has a very deep and extensive history in biotech business and is a high level addition to the board.

With a recent strategic review completed, the company may announce new directions for the company in the near term. Directions will need to take in funding options (on top of a recent $6 million convertible note) and how the company expects to properly manage the business with out a CEO.

How Drug Technologies Evolve

Technology platforms often emerge from an academic research environment to be taken up with a groundswell of enthusiasm as the first insights into the commercial potential are articulated and at the same time the first runs at grabbing IP are made.

Typically this first wave, at least in life sciences, is dampened as the tough commercial questions are posed. Can the technology be scaled for manufacturing? Does the cost of manufacturing, marketing and regulatory pathway development meet the developers cost of goods benchmarks? Do customers exist and in sufficient numbers for the products that might be made from the new technology? Can the 'new chemical entities' be administered in an acceptable way?

And then there is the 'proof of principle' where the technology, in the medical setting, can be validated in human clinical studies, demonstrate a clear cut result and an acceptable safety profile.

Few investors want to be involved before that key step-wise proof of concept event, or as is more often the case, three or four studies that collectively deliver enough evidence to argue the case. The risk is, however, that after the pivotal demonstrations, the horse may have bolted, at least where the IP is concerned.

On the Verge of Validation

The field of RNAi therapeutics is on the verge of validation in the clinic. Several therapeutic products have worked their way through human clinical trials with more in progress. Some of these are using other technologies to overcome class-limiting problems. When positive data emerges it is not unreasonable to expect to see some dramatic changes to valuations of companies in the field.

RNAi therapeutics hit the big time when **Merck** acquired **Sirna** Therapeutics in 2006 for US$1.1 billion. Even by today's standards the deal seemed extravagant, and it remains to be seen if Merck has found satisfaction from the acquisition. However, the pharmaceutical industry operates in hindsight, and the failure of Merck to capture a slice of the commercial revolution offered by antibody therapeutics was probably enough of a driver for them to treat the Sirna acquisition as an option payment of a first order. Later in July 2007, **Alnylam** struck a deal with **Roche**, permitting access by Roche to Alnylam's RNAi platform and the acquisition of its European research site, in exchange for a US$331 million upfront in cash and equity, and covering four therapeutic areas.

One thing investors can note about RNAi is that is a well established research tool for scientists. The degree of technical familiarity gained from conducting gene knock-out experiments should not be underestimated in how large pharmaceutical companies such as Merck and Novartis could have and continue to be comfortable with a relatively new technology.

The Progressive Development of Antibody Drugs

Followers of antibody technologies and drugs may remember that the very first wave of mouse derived antibodies did not deliver success. It wasn't until re-engineering technologies were developed that saw the replacement of murine (mouse) proteins in the antibodies with human proteins, that the field took off.

Even today, even so called fully human antibodies are not natural antibodies, instead are highly re-engineered murine antibodies.

It is somewhat ironic that still today, after more than 25 years of antibody drug development, that only a few human derived antibodies, such as those being developed by **Patrys**, are in development, essentially because only manufacturing issues have been surmounted and other formatting challenges (see *Bioshares* 361) have been addressed.

– Cont'd over

Bioshares Model Portfolio (4 June 2010)

Company	Price (current)	Price added to portfolio	Date added
Sunshine Heart	$0.036	$0.036	June 2010
Biota Holdings	$1.06	$1.09	May 2010
Tissue Therapies	$0.17	$0.21	January 2010
QRxPharma	$1.12	$0.25	December 2008
Hexima	$0.29	$0.60	October 2008
Atcor Medical	$0.15	$0.10	October 2008
CathRx	$0.20	$0.70	October 2008
Impedimed	$0.65	$0.70	August 2008
Mesoblast	$1.80	$1.25	August 2008
Circadian Technologies	$0.67	$1.03	February 2008
Patrys	$0.12	$0.50	December 2007
Bionomics	$0.32	$0.42	December 2007
Cogstate	$0.25	$0.13	November 2007
Sirtex Medical	$5.11	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.25	$0.66	September 2007
Starpharma Holdings	$0.57	$0.37	August 2007
Pharmaxis	$3.02	$3.15	August 2007
Universal Biosensors	$1.32	$1.23	June 2007
Probiotec	$1.35	$1.12	February 2007
Acrux	$1.95	$0.83	November 2004
Alchemia	$0.56	$0.67	May 2004

Portfolio Changes – 4 June 2010

IN:
We have added Sunshine Heart (SHC) - See article on page 1.

OUT:
We have removed Biodiem (BDM), with more attractive investment options having emerged elsewhere.

RNAi Therapy Challenges

One of the challenges that RNAi has had to overcome has been delivery to the required site of action, within cells in disease-affected tissues. The problem is one of cellular delivery.

Cellular delivery is made more difficult because RNAi constructs have difficulty crossing the cell membrane. They are bigger in size than many small molecule drugs and are highly negatively charged making cellular membrane passage, which is also highly negatively charged, a real problem.

The Vancouver company **Tekmira** has developed a lipid based encapsulation approach (lipid nanoparticles) for the delivery of RNAi constructs across cell membranes. The use of lipids to solve the problem of delivering hydrophobic molecules across a cell wall has been understood for some time, however, Tekmira has simply applied this know-how in the RNAi field. Tekmira recently partnered its stable nucleic acid-lipid particles formulations (SNALP) with **Bristol Myers Squibb** for a $3 million up-front payment. It also has ApoB SNALP for the treatment of hypercholesterolemia and PLK SNALP (a cancer treatment) in development.

Alnylam is progressing an RNAi construct through clinical trials using Tekmira's lipid nanoparticle technology.

Roche has also elected to develop two candidates using Tekmira's SNALPs. This complements its in-house approach that uses polymer conjugates, obtained through the acquisition of **Mirus Bio** for US$126 million in July 2008.

Similar to Tekmira, Silence Therapeutics developed the AtuPlex delivery platform which stabilises siRNA within a liposome and through its merger with Intradigm, also has a biodegradable, synthetic peptide-based polymer technology.

And **MDRNA** has also developed a liposomal platform, over which it recently signed separate access and R&D evaluation agreements with Novartis.

The use of peptides, dendrimers, fusion proteins, carbohydrate molecules, gold nanoparticles and polymers have been tested to meet the cell transport challenge.

Benitec, unlike the nano-particle companies that aim to deliver a construct, uses a natural mechanism to transport dsRNAi into the cell. The Benitec approach is DNA-directed RNAi. It relies on the double-stranded RNAi being expressed in the cell from a DNA construct, after which a gene silencing event takes place. Cell delivery of the DNA construct may be achieved using a benign viral vector.

Summary

The solving of the RNAi cell delivery problems is not complete, and the field is still in its infancy. As more and more clinical programs are completed, the potential for this very specific and spectacularly easy chemistry in so far as design of the elemental constructs goes, will be revealed.

Benitec

Benitec is capitalised at $15 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd, Tissue Therapies, Viralytics

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