ISSN 1443-850X

In this edition...
Two companies, Biota and ChemGenex Pharmaceuticals, updated the market on their 'to do' lists this week. ChemGenex, which is steaming ahead towards a new drug filing with the FDA this year, said that it was aiming to secure a European marketing partner by year's end.

Biota wants to add more projects to its pipeline of drugs in development and may take advantage of distressed company asset sales to bolster its portfolio.

We also look at Pallane Medical which is seeking a backdoor listing through Dia-B Tech. The technology for this diagnostic company emanates from the Royal Children's Hospital in Melbourne. The company is listing with a hefty valuation.

The Editors
Companies Covered: BTA,CXS, Pallane Medical IPO

	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 - Current)	11.0%
Cumulative Gain	**115%**
Av Annual Gain (8 yrs)	**14.7%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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

Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 315 (12 June 2009)
ISSN 1443-850X

Bioshares

12 June 2009
Edition 315

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

ChemGenex Sets Target for EU Partner in 2009

ChemGenex Pharmaceuticals (CXS: 66 cents) is making very solid progress with its clinical development of omacetaxine, which is being developed to treat chronic myeloid leukemia (CML) patients who test positive for the T315I mutation and have failed tyrosine kinase inhibitor therapy with Gleevec. The compound is also being developed to treat patients who failed multiple tyrosine kinase inhibitor therapy, and it may also potentially be used to treat patients with myelo-proliferative disorders and patients with acute myeloid leukemia (AML).

The company has set a goal to obtain a European marketing partner by the end of 2009. This goal is additional to the company's objective of submitting its New Drug Application with the FDA in the 2009 Q3, followed by approval and launch in 2010 Q1 and with a submission to the EMEA in 2010 Q1.

The process ChemGenex is using to submit omacetaxine to the FDA is a rolling submission unders Fast Track designation. The company has submitted both the non-clinical and manufacturing (CMC) sections with the third and final clinical section to be submitted in 2009 Q3.

Study 203 – A Phase II/III Study

In *Bioshares* 314 we discussed ChemGenex's presentation of data from its Phase II/III '202 trial at the American Society of Clinical Oncology (ASCO) meeting. The '202 study evaluated patients who have failed imatinib therapy and have the T315I mutation. More recently the company has made available data from its '203 trial, which evaluates patients who have failed treatment with two or more tyrosine kinase inhibitors. Twenty-four out of thirty patients in the chronic phase (80%) recorded a complete hematologic response (CHR). The CHR rates for the acute phase and blast phase patients were 80% and 53% respectively.

Survival Data

For the '203 study, the overall survival rate at 18 months was 100% for chronic phase patients. The median survival time for blast phase patients was 12.6 months. However, the median survival times for acute and chronic phase patients could not be calculated due to the continued progression free survival of patients in these groups. (Note, for the

Cont'd on page 4

Biota's Goal: A Portfolio of 10-12 Projects over Three to Five Years

There are two separate contractions taking place in the world of therapeutic product development. On the one hand, large pharmaceutical companies (Big Pharma) are merging with other large pharmaceutical firms. **Roche** has now acquired the 40% of **Genentech** it did not already own for US$47 billion; **Pfizer** is paying US$68 billion to acquire **Wyeth**, and **Merck** is merging with **Schering Plough** (for US$41 billion).

At the other end of the spectrum are dozens of small discovery and development stage companies facing corporate extinction or at best very constrained and uncertain future. According to Steve Burrill in his State of the Industry address at this year's BIO conference, 135 of 342 listed biotechs covered by his firm hold less than one year's cash and 42% of those hold less than six months of cash. We estimate that upwards of 25 biotechs in North America have filed for bankruptcy or initiated winding-up activities since October 2008.

Large pharmaceutical company mergers are being driven by a failure to sustain sales and profits made worse by the significant losses that are and will occur as branded drugs become open to generic competition. By merging the best of two pipelines (discarding the lower rated projects) and re-trenching both sales and R&D staff, the Big Pharma hope is that profits can be sustained. For example, the merged Merck-Schering Plough entity prior to the takeover had 106,000 people on the payroll, but expects to reduce this number by 16,000.

However, earnings management through M&A actions has never really addressed the general productivity problem that has beset Big Pharma over the last 20 years. From 2006 to 2008, Big Pharma accounted for only 30% of new chemical entity drug approvals at the FDA. The Chief Strategy Officer of **Merck**, Mervyn Turner, was quoted recently as saying that 80% of blockbuster drugs originated from outside Big Pharma and that two thirds of those products changed hands during development.

Some argue the mega-merger strategy has been a major cause of the failure to create a sufficient number of new medicines because the process has often gutted internal drug discovery ability and culture. Pedro Cuatrescasus, a former head of research at **Warner Lambert** in *Nature Reviews Drug Discovery* recently, said "instead of trying to assimilate knowledge or learn from acquired companies, they are simply eliminated, except for their products. The loss of intellectual knowledge base and specialised staff has had almost incalculable destructive consequences."

Big Pharma's innovation weakness and poduct deficit has been, and will be a driver for the growth of the biotech sector, where 'biotech' represents both innovation advantage and a cheaper, more flexible approach to designing and developing new medicines.

This driver will develop even more momentum because large pharmaceutical companies will experience pressures on profits from comparative medicine initiatives that are expected to emerge in the US under reforms instigated by President Obama.

Such external factors bode well for cashed up biotechs with a proven ability to develop new drugs with Biota (BTA: $1.37) a compelling example of the type of company that has a very strong future. We estimate Biota currently has cash resources, including royalties paid in arrears, of $65-70 million. Relenza royalties are likely to increase in future because **GlaxoSmithKline** is doubling its production of Relenza to 60 million treatment packs per year, with some talk of increasing the capacity even further through a alternative dose forms (read new inhaler if allowed by regulators). At 60 million courses, the royalty flow to Biota would reach $105 million per annum.

Business Model

Biota is an infectious diseases drug development company. Its business is to develop small molecule compounds through to the earlier clinical stage of development and then license these compounds to pharmaceutical marketing partners, although if appropriate it would advance a compound into later stages of clinical development.

In 2008, the company articulated its desire to increase the number of projects under management. It has more recently stated that its intention is to build a portfolio of 10-12 projects over three to five years.

Biota's commercial strengths stem from its coordination of opportunity analysis and business development with clinical trial management skills and expertise in microbiology, virology, drug screening and drug design, and its ballooning cash balance.

The company's portfolio of projects comprises a long acting neuraminidase inhibitor program (LANI) partnered with **Daiichi Sankyo** that has completed Phase III development in Japan, a HCV program partnered with **Boehringer Ingelheim**, a respiratory syncytial virus (RSV) program partnered with **AstraZeneca**, and a human rhinovirus program, which recently demonstrated proof of concept in a Phase IIa trial.

How to grow the portfolio?

The question for Biota is how to grow the portfolio. The company has three options. One is to conduct research in-house that joins market research with advances in disease research and screen and develop new compounds accordingly. A second strategy is to in-license or acquire discoveries from academic medical researchers for small upfront payments. A third strategy that would appear to have become very attractive of late is to acquire projects from companies that are forced to divest non-core assets to preserve cash for priority projects or from companies that are in distress and are selling assets on a liquidation basis.

Our expectation is that Biota will take advantage of current market circumstances to judiciously add one or two projects in the next 12-18 months, sourced from divesting or distressed biotechs.

Conscious of the failure rate in drug development, the development of a 10-12 project portfolio would support Biota's ultimate

Cont'd on page 4

IPO (Backdoor Listing) Preview: Pallane Medical

Details of Offer
Issue price: 25 cents a share
Funds to be raised: $12.5 million (with up to $2.5 million in oversubscriptions)
Post market capitalisation: $100 million
Fully underwritten by Winteray Capital
Offer opens: 28 May
Offer closes: 26 June
Prospectus available at www.dia-btech.com.au

Pallane Medical is conducting a backdoor listing onto the ASX, with the company to be acquired by listed biotech Dia-B Tech. Dia-B Tech has previously brought a diabetes treatment candidate into Phase I studies with a second product in preclinical development for diabetic neuropathy. Following the acquisition of Pallane Medical, Dia-B Tech will be renamed Pallane Medical Ltd and will focus on the new business activities of Pallane.

Pallane Medical has developed a proprietary method for rapid diagnosis of viral infection, called RECTIF (Rapid Enhanced Tissue Culture ImmunoFluorescence). The technology is applicable to detecting a range of viruses very quickly (within 24 hours) with a high level of accuracy and the ability to detect multiple infections. The technology was developed by Dr Robert Alexander and has been in use by the Royal Children's Hospital in Melbourne in more than one million tests for over 10 years.

The test is believed to be as good as the more time consuming PCR test however can be used to detect any virus a person may have within 24 hours.

Core Technology

The core technology for the company appears to be in the growth media which expedites the growth of the virus into cells. The technology allows only qualitative detection of virus, which is suitable for most viral disease infections. Once the virus is been grown, use of traditional monoclonal antibody and immunofluorescence detection techniques are used.

The RECTIF kits will be differentiated by different cell lines in the kits which are preselected for detection of specific virus families. The RECTIF technology can be used to detect infection by respiratory viruses, such as influenza, rhinovirus or RSV, enteroviruses or non-repiratory viruses such as measles and herpes.

The RECTIF process is designed to be aligned with existing pathology sample processing hardware and procedures.

Regulatory Approval

This diagnostic technology does not evaluation in the US, being a variation of existing cell culture procedures. In Europe, CE Mark approval is required, which will take several months. Dialogue with European regulators has not yet been initiated. Pallane will also need to seek reimbursement classification for its tests in the markets it seeks to enter. Pallane will be selling its products to existing public and private pathology laboratories.

Commercialisation Strategy

The company expects to be in a position to be commercially manufacturing the RECTIF test kits in 12 months time, with a launch into major global healthcare markets between the next 12 - 36 months. The company will seek to have third parties manufacture the test kits.

Use of Funds

Of the $12.5 million being raised, $2 million will be paid to the inventor, Dr Robert Alexander, for assignment of the intellectual property. Dr Alexander will own 35.5 % of the company (through Alphavir). A further $300,000 in loans will be repaid to Octav, a related party to the CEO and Executive Chairman, Peter King. A further $2.94 million will be used to repay a loan facility. After costs of the capital raising, Pallane Medical Ltd will have $5.9 million for working capital expenses.

Patent Position

There is only one granted patent over the technology, and that has been issued in Australia. There are no pending patent applications in other regions for this first patent. Two subsequent patent families were filed in 2008. These patents are pending in all major regions except for South Africa, where they have been granted. With the technology having been in use for over 10 years, there may be a challenge for the company to secure an intellectual property position around parts of the technology because of prior use. The first publication around the technology was in the period 1998-1999 and the IP was first conceived and developed in the 1970's by Dr Alexander. The core IP for the company is around the growth media used in the process.

Board & Management

The inventor of the technology is currently head of virology at the Royal Children's Hospital in Melbourne. At the completion of the acquisition, Dr Alexander will become the Chief Scientific Officer of Pallane Medical on a full time basis. Peter King, the CEO and Executive Chairman, previously developed and ran a successful medical device business. Other board members include Dr Michael Wooldridge, Dr Jaydeep Biswas, from Winteray Ltd which is presumably linked to Winteray Capital, the underwriters of the raising, and Santino Di-Giacomo, who has previously been a founding member of Psimedica (part of Psivida), Australian Cancer Technology, Resonance Health, and a director for Rockeby Biomed.

Comments

The valuation of the company will be $100 million post-money at listing. This seemingly high figure suggests the company believes it has a highly valuable technology that will create a major change in the detection of viral infections.

It is a very bold move by the company to list a new technology (through a backdoor listing) in the current climate and to place a $100 million valuation for a technology that has yet to generate revenue for Pallane. The IP position has also yet to be secured through globally granted patents.

Cont'd over

ChemGenex cont'd

'202 study the median survival time for the acute phase patients was 18.75 months.)

The results of the 65 patient '203 trial are consistent with the 66 patient '202 trial, although median survival times for blast phase patients in the '203 trial of 12.6 months (15 patients) far exceeded the '202 median of 1.8 months (10 patients).

What we see with both trials are positive data that indicate the potential clinical benefit of omacetaxine, although the '203 study has not been running as long as the '202 study. Dr Jorge Cortes, a lead investigator on the '203 study said that for patients in the chronic phase who were not showing a cytogenic response, it at least looked like the compound was stabilising their disease and conferring a survival advantage.

Summary

ChemGenex is one of several Tier-1 biotechs that are confidently tracking towards major milestones over the next twelve months. Securing a European partner will be an important achievement for the company in the next half year period.

ChemGenex is capitalised at $178 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Pallane cont'd

One of the difficulties the company may have is generating a global rollout of the technology with the remaining $5.9 million in funds post listing and the company may need to raise further funds prior to reaching sustainability. That the test kits will have only a 10 day shelf life will mean that efficient distribution channels for a global rollout will need to be in place. Specific accuracy levels of the technology also has not been detailed.

These factors may contribute in providing a more attractive entry opportunity into the stock post listing.

Investors are required to read the prospectus prior to subscribing to shares under the offer.

Bioshares

Biota cont'd

objective to see two or three licensed products on market generating royalty revenues in the next few years.

Biota is capitalised at $239 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (12 June 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.33	$0.30	December 2008
QRxPharma	$0.41	$0.25	December 2008
Hexima	$0.38	$0.60	October 2008
Atcor Medical	$0.19	$0.10	October 2008
CathRx	$0.57	$0.70	October 2008
Impedimed	$0.69	$0.70	August 2008
Mesoblast	$0.83	$1.25	August 2008
Cellestis	$2.96	$2.27	April 2008
IDT	$1.52	$1.90	March 2008
Circadian Technologies	$0.75	$1.03	February 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.25	$0.42	December 2007
Cogstate	$0.27	$0.13	November 2007
Sirtex Medical	$3.02	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.34	$0.66	September 2007
Starpharma Holdings	$0.33	$0.37	August 2007
Pharmaxis	$2.62	$3.15	August 2007
Universal Biosensors	$1.06	$1.23	June 2007
Biota Holdings	$1.37	$1.55	March 2007
Probiotec	$1.85	$1.12	February 2007
Peplin Inc	$0.63	$0.83	January 2007
Arana Therapeutics	$1.39	$1.31	October 2006
Chemgenex Pharma.	$0.63	$0.38	June 2006
Cytopia	$0.09	$0.46	June 2005
Acrux	$1.22	$0.83	November 2004
Alchemia	$0.37	$0.67	May 2004

Portfolio Changes – 12 June 2009

IN:
No changes

OUT:
No changes

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: Phylogica, Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$320**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:	$550	2-3 email addresses
	$750	4-5 email addresses
	$950	6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9671 3633

I enclose a cheque for **$** made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card **$** MasterCard ☐ Visa ☐

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph ( ) _____

Emails _____

_____

_____