RM Research

11 November 2013

ASX CODE: PAA

Speculative Buy

Proposed Capital Structure

Sector	Healthcare
Share Price	$0.013
Fully Paid Ordinary Shares (m)	1440
Market Cap at Issue Price (m)	$17.28
PAA 52wk Range	$0.007 - $0.016
Approx. Cash (A$m)	$3.0

Directors

Dr Roger Aston	Exec Chairman
Robert Bishop	Exec Director
Prof David Morris	Non-Exec Director
Sam Wright	Non-Exec Director

Analyst

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Share Price Performance

PharmAust Limited

Company Update, Solving the Identity of PPL1 Compound

Pharmaust - An Oncology Focused Company

Recall that in August Pharmaust have completed the acquisition of Pitney Pharmaceuticals Pty Ltd. The acquisition gave Pharmaust a pipeline of oncology products developed within Pitney and the University of NSW (UNSW) in recent years. The new business greatly complements the contract manufacturing business that has been a core asset of Pharmaust since 2003 (i.e. Epichem Pty Ltd). The company has recently completed a heavily oversubscribed placement and then an SPP, raising A$3.5M in total. We believe the company is currently well capitalized to execute its proposed oncology programs.

Pipeline Update

Since completion of its fundraising activities in September/October 2013, Pharmaust has launched into fast tracking its two principal oncology product programs forward by developing clinical and veterinary protocols for application of PPL-1 in cancer and clinical protocols for albendazole for the treatment of cancer associated with asites.

From our recent meeting with the management, we understand that Pharmaust has entered into a second corporate arrangement with a listed overseas corporation for the co-development of PPL-1 for human cancers and identifying improved versions of this compound.

New Patent Filing – PPL1 Mystery Revealed

Through our investigation we discovered that Pitney has recently published a patent on the use of monepantel (an aminoacetonitrile derivative) for the treatment of cancer (*Source: http://patentscope.wipo.int/search/en/WO2013138863*). Aminoacetonitrile derivatives (AADs) are a class of anthelmintics effective against drug-resistant nematodes. Although PAA has not confirmed our investigations, it appears that the only marketed monepantel product is Zolvix®, produced and distributed by Novartis Animal Health (*Source: http://zolvix.com/monepantel/*). Recall that PAA's disclosed lead product is an anthelminthic which is being targeted to the treatment of both veterinary and human cancers.

Near-term Focus on PPL1 Development, New Class of Anticancer Drugs

Our medical literature search showed that monepantel suppresses cancer cell lines (e.g. ovarian, glioma) proliferation and colony formation, while it has no significant effect on normal epithelial cells. According to one publication, monepantel causes G1 cell cycle arrest through down regulation of cycline A, E and Cdk 2 and 4, followed by inhibition of DNA incorporation. We believe that near-term investors will be focusing on PPL1 program development. In our view, the start and completion of the "first in man" study of PPL1 will provide significant upside to the current share price as it will open the doors for potential partnering of PPL1 human cancer applications.

Recommendation

Speculative Buy — We view Pharmaust as one of the most diversified early stage biotechnology companies listed on the ASX. With a strong focus on oncology and an in-licensed compound from top 5 Pharma that represents a new class of anticancer drugs, the company provides significant growth opportunities for investors.

PharmAust - Investment Summary

We view PharmAust as one of the most diversified early stage biotechnology companies listed on the ASX. PharmAust core focus will be on developing its own drug discovery intellectual property in different therapeutic areas (Pitney Pharmaceuticals) which will be supplemented by a business that provides highly specialized medicinal and synthetic chemistry contract services (EpiChem Ltd).

We identify three key reasons that in our view make Pharmaust an attractive investment and will ensure shareholders returns. Company's strategy is to reposition drugs and compounds that were previously approved by regulatory bodies into new indications with a primary focus on oncology. As a result the company expects to avoid much of the time, risk and cost associated with the more traditional new drug discovery and development process.

Shorter Development Times – company expects that in most cases there will not be a need for an extensive pre-clinical toxicology program. We believe that under these circumstances Pharmaust could move a product from initial work to readiness for regulatory approval within 3-5 years (vs traditionally 7-10 years). Similarly, long-term human safety studies are less likely to be required for drug compounds that have previously been approved by regulatory authorities for other indications, particularly considering the new applications revolve around late stage or terminal cancer therapies;

Lower Development Costs – with the lower requirements for pre-clinical or pilot human safety trials, the cost of taking a repositioned drug through clinical development and approval process should be significantly lower comparing with the cost to develop a new drug;

Higher Probability of Success - since the focus of company's product development is on targeting oncology applications of well established drugs (i.e. anthelmintic drugs) and "piggy backing" on existing programs and data developed by major pharmaceutical companies, we expect that the risk of development failure should be significantly less comparing to new drug development. In addition, the Company will only proceed with such products as long as it has established an intellectual property position in terms of a new method of use.

Our View

While Pharmaust are at an early stage of its business model we believe the ultimate exit strategy for company's product portfolio will be an outlicensing opportunity with large pharmaceutical companies. Given todays uncertainties around the macroeconomic environment and access to capital, we have a positive view on that model as it provides lower risk and capital efficiency. We expect increased appreciation of the company's platform and portfolio over the next 12 months as management continues to execute on the clinical development program.

Near-term Value Drivers

Key milestones identified by PAA in their AGM presentation include:

- Initiation of a trial to treat dogs with cancer with PPL-1;
- IND and phase I trial for PPL-1 in humans;
- Second option/licence agreement for human applications of PPL-1;
- Filing an IND for albendazole in ascites;
- Initiation of Phase II/III trials with albendazole in ascites;
- Grow Epichem sales.

Risks

We believe there are several factors that could affect Pharmaust business, its share price and commercial success of its products given the clinical, regulatory, commercial, manufacturing and intellectual property risks associated with its clinical platforms.

Clinical Risk – We cannot know with any certainty what the outcome of any of the clinical studies of the drugs that are in development by Pharmaust/Pitney. If the Phase II/III studies of the proposed clinical programs were to fail and not show required efficacy profile, or if an intolerable safety concern were to arise, that would have a significant negative impact on Pharmaust share price.

Regulatory Risk – Even if all subsequent clinical trials will be positive, we can not know with any certainty whether or not Pharmaust products will receive regulatory approval in the US or Europe. Without regulatory approval, revenues from the products cannot be generated.

Commercial/Reimbursement Risk — To provide significant top-line contributions to PAA we estimate that the products in development will have premium pricing (above $10K per therapy). Thus the company will be dependent on third-party payers, such as private insurance companies, agreeing to reimburse patients for the costs. If third -party payers and government health administration authorities do not reimburse or limit the amount of reimbursement, sales and revenues from PAAs will be below our and company expectations and could affect share price performance.

Manufacturing Risk - It is a core requirement to have sufficient facilities, materials and staff available to manufacture clinical products according to GMP. If company is unable to secure the infrastructure for manufacturing, train appropriate technicians for these facilities, establish required third party relationships (if outsourced), then continued development and any future commercialization of the products may be delayed.

Intellectual Property Risk – As with other biotechnology companies, failure to obtain new patents or protect issued patents could negatively impact the PAA‘s share price.

Capital Funding Risk - In order to achieve growth and invest in further technology, the company may need additional equity or debt in the future. There is no assurance that the company will be able to raise such funding when it is required.

Company Management

Dr Roger Aston BSc (Hons), Ph.D – Executive Chairman

Dr Aston currently serves as an Executive Chairman of Pharmaust. Roger Aston received his B.Sc. (Hons) Ph.D. degrees from the University of Manchester (1975-1981) after which he joined the Wellcome Foundation (Beckenham, Kent) (now Glaxo SmithKline). He joined Peptech Limited in Australia (1987) (Arana Limited, acquired by Cephalon Inc.), a publicly listed Company on the Australian Stock Exchange. In 1995 he become CEO of the Peptech Group of companies (Arana). During this period, Roger Aston was also CEO of Cambridge Antibody Technology and subsequently a non-Executive Director of this company. In 1999 he joined Cambridge Drug Discovery Limited as their Executive Chairman and later in that year, he joined the UK Government's Defence Evaluation and Research Agency (now QinetiQ Ltd).

In 2001 Dr Aston Co-founded pSivida Limited (ASX:PVA, NASDAQ:PSDV). During his career, Roger Aston has been closely involved in start-up companies and major pharmaceutical companies. He has had a 'hands on' role in company restructuring, improving effectiveness and productivity in both small and significant businesses (up to 200 personnel). Aspects of his experience include FDA and EU product registration, clinical trials, global licensing agreements, fundraising through private placements, preparation of prospects for a public offering, and a network of contacts.

Dr Aston has also held Directorships/Chairmanships with Clinuvel Limited (ASX:CUV), HalcyGen Limited (now Mayne Pharma Group) (ASX:MYX), Ascent Pharma Health Limited (ASX:APH) recently acquired by Watson Inc, Neurodiscovery Limited (now Oncosil Medical) (ASX:OSL), Biolife Science Limited (acquired by Imugene Limited) (ASX:IMU) and Cynata Incorporated (now Cynata Therapeutics Limited) (ASX:CYP).

During 2007 and 2008, Dr Aston was a member of the AusIndustry Biological Committee advising the Industry Research and Development Board. More recently, Dr Aston was Executive Chairman of Mayne Pharma Group (acquisition of Mayne by Halcygen) from 2009 to 2011 and until recently Feb 12, CEO of Mayne Pharma Group. Dr Aston is currently a director of Regeneus Ltd (ASX:RGS), IDT Limited (ASX:IDT) and is a Chairman of Immuron Limited (ASX:IMC).

Robert Bishop - Executive Director

Robert has 30 years experience in corporate finance and equity capital markets having worked extensively in London and Sydney, first as a lawyer at Linklaters & Paines and Allen, Allen & Hemsley; and then as a stockbroker and investment banker at Ord Minnett, Robert Fleming and, since 1998, at his Sydney based corporate finance business, First Capital Markets. He has extensive experience in the areas of stock market flotation's, licensing and compliance work.

Professor David Morris MB, ChB, FRCS. MD. PhD, FRACS - – Non-Executive Director

Professor Morris is the Head of Department of Surgery, Faculty of Medicine at St George's Hospital Sydney, University of NSW. Professor Morris is Academic Surgeon and Head of UNSW Department for greater than 20 years with almost 700 peer review publications. Professor Morris has maintained a basic cancer research laboratory for over 20 years and has a demonstrable successful track record in commercializing outcomes of research. Currently. Professor Morris is an active surgical oncologist concentrating on metastatic diseases of liver, lung and peritoneum.

Company Management (*continued*)

Mr Sam Wright – Non-Executive Director & Company Secretary

Sam Wright is experienced in the administration of ASX listed companies, corporate governance and corporate finance. He joined the Company as the Financial Controller in September 2006, was appointed as the Company Secretary in August 2007, and was appointed as a Director in October 2008.

Mr Wright has over fifteen years experience in the pharmaceutical, biotech and healthcare industry and is a member of the Australian Institute of Company Directors, the Financial Services Institute of Australasia, and the Chartered Secretaries of Australia.

Mr Wright is currently Company Secretary of ASX listed companies, Buxton Resources Limited, Cove Resources Limited and Structural Monitoring Systems plc. He is also Company Secretary for unlisted public company, Tropiglas Technologies Limited.

He is the director of Perth-based corporate advisory firm Straight Lines Consultancy, specialising in the provision of corporate services to public companies.

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RM Research Recommendation Categories

Care has been taken to define the level of risk to return associated with a particular company.
Our recommendation ranking system is as follows:

Buy	Companies with 'Buy' recommendations have been cash flow positive for some time and have a moderate to low risk profile. We expect these to outperform the broader market.
Speculative Buy	We forecast strong earnings growth or value creation that may achieve a return well above that of the broader market. These companies also carry a higher than normal level of risk.
Hold	A sound well managed company that may achieve market performance or less, perhaps due to an overvalued share price, broader sector issues, or internal challenges.
Sell	Risk is high and upside low or very difficult to determine. We expect a strong underperformance relative to the market and see better opportunities elsewhere.

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