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Peplin's commercial potential validated in key deal with US specialty pharmaceutical firm

December 18 – Peplin Biotech is a Brisbane based biotech company focused on developing treatments for various cancers, including melanoma, breast cancer and pancreatic cancer, and skin lesions. The company's origins date back to 1997, building on the research of Dr James Aylward. It recently achieved a new level of investment credibility when it struck a deal with US specialist pharmaceutical firm Allergan.

The Allergan Deal

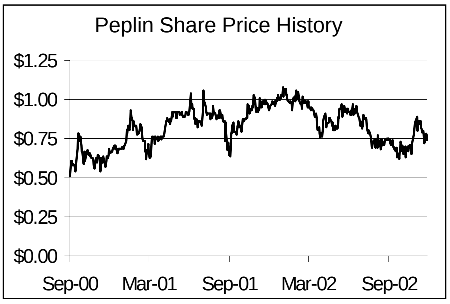
On November 27, 2002, Peplin announced that Allergan, based in Irvine, California, had licensed the rights to Peplin's lead compound, PEP005, for the topical and intra-lesional treatment of skin and eye conditions, for the geographic regions of North and South America. (The areas of the European Union, Australia and Asia were not subject to the license.) Allergan paid an up-front fee of $1.85 million. Peplin stands to gain up to $40.7 million in milestone payments. A royalty rate due on successful initiation of sales remains undisclosed. All regulatory and clinical development costs will be covered by Allergan.

Allergan is virtually unknown as a dermatology company in Australia but has a high profile in the US through its ownership of two leading dermatology products, Botox and Tazorac. Allergan's Botox (based on Botulinum Toxin) is used in the treatment of blepharospasm (the uncontrollable contraction of the eyelid muscles which can force the eye closed and result in functional blindness) and strabismus (misalignment of the eyes).

Botox has now been developed as a novel treatment for skin wrinkles. Botox Cosmetic costs patients a reported US$500 to US$775 per each six monthly treatment. The cosmetic version is designed to relax wrinkle-causing muscles on the brow. This muscular relaxation smooths the deep, sustained lines on the brow caused by aging.

Tazorac is topical retinoid indicated for the treatment of plaque psoriasis and acne.

Allergan is a US$7.6 billion company with 5,000 employees worldwide. It was founded in 1948, acquired by Smithkline in 1980 but spun-out again in 1989. It recorded sales of US$1.6 billion in 2001, up from US$762 million in 1991. The company divested its ophthalmic surgical and contact lens business this year. Botox accounted for US$310 million worth of sales in 2001, an increase of 29% from 2000.



Price (19/12/02):	74 cents
Capitalisation:	$45 million
Cash:	$6.5 million
Speculative Buy - Class B	

Analysis

Why did Allergan choose Peplin's compound as a 'next generation' topical treatment for skin diseases?

Allergan is acutely aware of competitive pressures in its business. Its thriving Botox franchise came under threat when a rival product entered the market in 2001. Although Allergan has retained a 90% market share, sales have been tempered by the rival product in 2002.

Allergan attends to discovery and product development through in-house research programs. However, every pharmaceutical company's R&D programs have limita-

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tions. The in-licensing of potential products is a practical approach to overcoming these limitations.

PEP005 offers to Allergan a novel (by origin and mode of action) dermatology product with a number of attractive features. The compound should be applicable to the full range of non-melanocytic skin cancers. PEP005 should permit much less painful procedures, perhaps no scarring and skin discoloration and increased patient compliance. And potentially PEP005 is, in contrast to many cancer chemotherapies, unlikely to cause damage to DNA or suppress the immune system. PEP005 appears to meet the demand from the marketplace that is seeking a treatment that delivers better aesthetics and less pain.

Allergan's interest in PEP005 is also conditioned by its understanding of the potential market for new therapies, citing strong growth trends in incidence of skin cancers and the increasing prevalence of skin cancers at younger ages.

Is the deal skewed in favour of Allergan?
The deal sweetener, the up-front payment of $1.85 million, is modest because PEP005 has yet to be proven at the level of human clinical trials. However, the deal can be construed to be heavily in Peplin's favour from a non-monetary point of view. Allergan was one of ten potential partners considered by Peplin. Allergan's capabilities in the specialty area of dermatology, and its market visibility brought about from success with Botox, *represents a significant reduction in risks associated with 'path to market'* for Peplin. The company has partnered with an experienced and mature pharmaceutical company willing to adopt a new technology. A substantial portion of this 'new technology' risk has now been shouldered by Allergan, and this is a plus for shareholders of Peplin. The fact that various geographic regions have not been included in the deal also allows for further upside for Peplin.

There is also the advantage of dealing with a specialty pharmaceutical group such as Allergan rather than one of the major pharmaceutical companies. Both types of companies have established distribution networks but the importance of the project to Allergan means it will likely receive strong attention by the company and the chance of the program being delayed or de-prioritised is lower.

What other benefits have accrued to Peplin?
The Allergan deal will put Peplin on the radar screens of many other pharmaceutical and biotech companies and investors in the life sciences. The company's ability to attract further funding (when required) should be improved and the prospects for a cornerstone investment from an institutional investor or biotech fund has now increased.

From a balance sheet position, Peplin now has about $6.5 million in cash. It expects to make a loss for 2002/03 in the vicinity of $3.5-$4 million.

Burrill & Company

An enabling factor in Peplin's tie up with Allergan was Peplin's hiring of US life sciences investment bank Burrill & Company. Burrills was hired to assist in the establishment of such deals, and their specialist knowledge of the pharmaceutical and biotech industries appears to have been a key factor in this deal.

Peplin's patent position

When *Bioshares* assessed Peplin Biotech in edition number 5 (March quarter 2001), we expressed concern with the company's patent position. The company has made significant progress in enhancing and developing its intellectual property position. Peplin's primary patent "Anti-cancer compounds" [Filing date: 19.8.98] has been granted in the USA. Divisionals have been filed on this patent both in Australia and the USA, with divisionals accepted here in Australia and but are pending in the USA. This patent family describes the application of compounds derived from the Euphorbiaceae plant family to treat cancers, including melanoma and squamous cell carcinomas.

The company has filed other patents to encompass additional therapeutic applications of compounds derived from the Euphorbiaceae plant family and the company now possesses seven patent families.

Portfolio

The company has expanded its portfolio of compounds under investigation. Peplin has three Euphorbiaceae derived compounds in development, has in-licensed a compound (for pancreatic cancer) from local sources and has in-licensed 10 compounds from the National Cancer Institute in the US.

Risks

Peplin is by no means a low risk investment and faces many competitive challenges, especially where it intends to occupy space in systemic cancer drug development. *Bioshares* believes that the road ahead for Peplin in developing drugs to treat pancreatic, breast or other cancers will be resource intensive with a lesser chance of commercial success (relative to topical applications). The company has many development hurdles to overcome in all potential product areas, although these hurdles are standard for drug development companies. Systemic toxicity studies are always a key threshold and the determination of a preferred route of administration for systemic cancers will be a challenge.

Peplin's PEP005 faces specific competition from existing medical procedures, such as cryotherapy and procedures entering the market such as photodynamic therapy. However, these therapies do have drawbacks including pain and scarring.

Future Developments

Peplin has still to complete a number of pre-clinical obligations for PEP005 in 2003, although it estimates its pre-clinical tasks are 75% complete. Once this is achieved, by mid-2003, the company will invest significantly in its systemic drug program. Allergan is aiming to achieve FDA approval in 3-4 years time.

Recommendation

Following the announcement of the deal with Allergan, *Bioshares* now rates Peplin Biotech as a **Speculative Buy Class B**. The company is soundly focussed on the business of biotech. The company has made encouraging progress in many areas since *Bioshares* first covered the company in 2001. This is a reflection of its capable board and management. The licensing deal with Allergan presents convincing confirmation of the commercial potential of the firm.

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