# SNAPSHOT MAY 2010

# AUSTRALIAN LIFE SCIENCE

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## Peptide drugs

Peptide drugs have had a difficult history. From being hailed as the "new systemic antibiotic"[1] in the early 1990's, they fell from favour in a little over a decade, owing to several compromising characteristics. In comparison to some small molecules, for example, they are more expensive to manufacture, more difficult to administer and are eliminated more quickly from the blood stream[2].

Or rather: used to be. Since 2005, there have been many improvements in peptide drug development and thus their many advantages are coming more into focus. In 2007, the peptide drug market grew twice as fast as the overall pharmaceutical market. Around 70 therapeutic peptides are on the market at the moment, with more than 170 in clinical phases of development and at least 400 more in advanced pre-clinical development[3].

Peptides are essentially short strings of amino acids. Many physiologically important substances, such as the hormone insulin, consist of peptides, therefore it seems only natural– in the literal sense of the word– to use this class of molecule pharmaceutically. They can be derived naturally, i.e. from bacterial, plant, or animal products, or manufactured either in microbial fermentation systems or by synthetic production[1].

### Uses of peptide drugs

As peptides are a diverse substance class, their uses are similarly diverse. One of the first peptides used as a drug was insulin for diabetes, as early as the 1920's[2]. In the mean time, other hormones such as calcitonin and vasopressin can also be manufactured synthetically and administered as drugs. These are uses relatively close to the way the human body physiologically uses pep-

1,2 http://pubs.acs.org/cen/business/83/i11/8311bus1.html

[1] http://www.genengnews.com/gen-articles/peptide-drug-discovery-research-reenergized/1564/

[3] http://www.springerlink.com/content/v52445t0p8mu7vt5/

[2] http://en.wikipedia.org/wiki/Insulin

tides, but there are also drugs that diverge more from this path. Fuzeon is a peptide-based drug used to treat HIV[1] and antimicrobial peptide drugs, which would not have to face the issue of resistance that antibiotics currently face, are being developed[2]. The possibilities are endless considering the incredible diversity in structure.

## Advantages of peptide drugs

- **Small size:** Peptides are relatively small compared to their larger antibody and scaffold protein-cousins. This makes the better delivery methods possible and gives them an edge on penetrating tissue[3].
- **Specificity:** Within the body, peptides have the important task of sending messages between cells, something that can only occur error-free if the peptides reach the right target cells. Thus they have been designed to achieve exactly that.
- **Easy optimization:** An important fact for the pharmaceutical industry, peptides are easily optimized[2] to achieve desired pharmacokinetic and other characteristics.
- **Low toxicity**
- **Chemical predictability:** Unlike small molecules, it is easy to predict the way peptides will work when used as a drug[3]. This makes rational drug design much easier, as it is more likely that designed drugs will actually act in the desired way.
- **High potency:** Of certain peptides, only very small doses are needed to achieve the desired effect[4].

## Advances in peptides

In the early days of peptide drugs, they had to be administered intravenously because too much of the drug would be broken down in the bowel before actually reaching the blood stream if taken orally. With more advanced methods of delivery, i.e. as a nasal spray, peptides have be-

[1] http://www.dddmag.com/first-successes-turn-tide-for.aspx

[2] http://pubs.acs.org/cen/business/83/i11/8311bus1.html

[3] http://phylogica.com/media/articles/Investors---Investor-Presentations/Presentation-to-Specialist-Institutional-Biotech-Investors-470/PhylogicalnvestorPresentation.pdf

[1] http://www.genengnews.com/gen-articles/peptide-drug-discovery-research-reenergized/1564/

[2,3] http://pubs.acs.org/cen/business/83/i11/8311bus1.html

come more patient-friendly. This improvement is reflected in sales figures:: After nasal-spray-delivery was developed as an alternative to injection for calcitonin, sales increased more than 30-fold[1].

In addition, manufacturing methods have been improved dramatically. Peptides can now be manufactured through transgenic, recombinant or synthetic methods[2] and it is possible to manufacture them so as to be more stable both inside and outside cells. The cost-of-goods for synthetic manufacture of peptides has also changed considerably in recent years, driven by high volume production of large peptides such as Fuzeon (36 amino acids) and Calcitonin (32 amino acids).

## Phylogica

Phylogica is an ASX-listed company based in Perth, Australia, specializing in a specific class of peptides called Phylomers®, for which it has granted patents worldwide[3]. These are peptides derived naturally from protein fragments that are encoded from biodiverse bacterial genomes. Phylogica has managed to assemble the largest and most structurally diverse library of peptides in the world, making it an ideal resource for larger pharmaceutical companies to screen for drug leads for certain targets.

Some of the advantages of Phylomers are:

- **high specificity**: Phylomers can be chosen to bind very specifically to the desired target, reducing the risk of unwanted side effects
- **high affinity**: only very small concentrations of Phylomers are needed to reach their target, due to high target affinities (low nanomolar to picomolar Kd)

- **high hit-rates against diverse target classes**: Due to the richness of different structures in Phylomer libraries, Phylogica has been able to obtain better hit-rates against a variety of targets, yielding a better quantity as well as quality of candidate drug

[1] http://phylogica.com/media/articles/Investors---Investor-Presentations/Presentation-to-Specialist-Institutional-Biotech-Investors-470/PhylogicaInvestorPresentation.pdf

[2] http://pubs.acs.org/cen/business/83/i11/8311bus1.html

[3] the following information is largely from the following website: http://phylogica.com/media/articles/Investors---Investor-Presentations/Presentation-to-Specialist-Institutional-Biotech-Investors-470/PhylogicaInvestorPresentation.pdf

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- **intracellular targeting**: most biologics target only proteins outside the cell because they are not able to penetrate the cell membrane, while most proteins inside the body are actually enclosed within this barrier. Phylomers have been shown to reach these intracellular proteins.
- **stability**: As Phylomers are derived from bacteria often living in extreme environments such as geysers and volcanoes, they are preselected by evolution for characteristics such as thermal stability. Additionally, they can be modified to exhibit desired pharmacokinetic behaviors for example through PEGylation.
- **Potential for patient-friendly delivery**: Phylomers can be delivered intranasally, which provides major advantages in compliance, driving an increased market share for Phylogica's pharmaceutical partners.

Phylogica's Phylomer library has been screened for several targets, such as CD40L, GM-CSF and TNFR, all known anti-inflammatory targets. Phylomers against intracellular targets in the AP1 pathway have also been shown to be effective in protecting cells from cell damage after a stroke. Additionally, Phylomers have been identified which are active as antimicrobials on multi-resistant pathogens ("killer bugs") which are important in hospital-acquired infections.

Phylogica has partnered with Aegis Therapeutics LLC to make it possible to deliver Phylomers via the Intravail technology as a nasal spray. It has recently entered the commercialization phase: In December Phylogica announced a major deal with pharma giant Roche to screen the Phylomer library for intracellular targets, and it is currently finalizing deals with other pharmaceutical and biotech companies. Based on its pending deal-flow, Phylogica has reasonable prospects of achieving cash-flow sustainability as early as next year.

Considering many of the larger pharmaceutical companies are having trouble finding ways to refill their pipeline and are outsourcing more and more of the earlier stages of drug development, namely drug discovery, Phylogica and other small biotech companies are well-placed to fill their demand.

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# Company Fact Sheets

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## Phylogica



Source, Comdirect, Exchange Sydney

## Ratios

| | |
|---|---|
| Symbol: | PYC |
| Homepage: | www.phylogica.com |
| Market capitalisation (31. May) | 18,86 mio. AUD |
| 52W High | 0,14 |
| 52W Low | 0,046 |
| Price % Chg 4-Wk/52Wk: | -11,11/+14,29 |
| Government grant income 08/09: | 1,273,780 AUD |
| Commercial income 08/09: | 1,162 AUD |
| Loss before income tax08/09: | 4,490,920 AUD |

Source: comdirect, Phylogica Annual Report 2009

## Field of activity

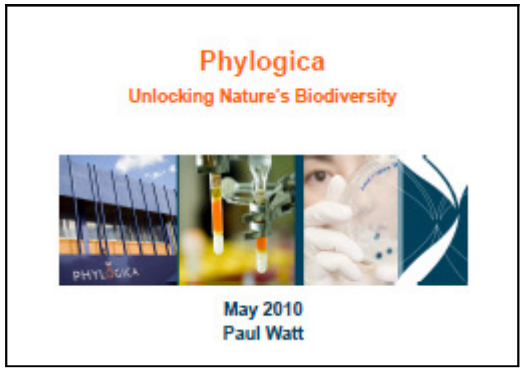
Phylogica has discovered and developed a unique proprietary class of targeted peptide therapeutics (Phylomer® peptides). These peptides exhibit competitive therapeutic, manufacturing, and commercial advantages over other more traditional targeted biologics such as proteins, monoclonal antibodies and most current therapeutic peptides. The hit to target ratios from Phylomer® libraries are high and the proportion of hits which are functional, is also very high.

## Company Highlights

- ◊ Unique drug discovery resource for pharmaceutical industry
- ◊ Technology is fully validated, scalable and optimized for commercialization
- ◊ Broad patent protection for entire class of drugs
- ◊ Initiated commercialization phase, several late-stage deal negotiations
- ◊ Strategy for near-term cash-sustainability, driven by fee-for-service drug discovery
- ◊ Objective to secure an increasing share of down-stream value through co-development

Source: Phylogica

## Download Company Presentation

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## Latest News

- ◊ **19 May 2010: Rodman and Renshaw Global Healthcare Conference Presentation**

  http://www.asx.com.au/asxpdf/20100519/pdf/31qdt6fx77vdc8.pdf

- ◊ **18 May 2010: Frankfurt Stock Exchange Listing**

  http://www.asx.com.au/asxpdf/20100518/pdf/31qd5zmrkjvw48.pdf

- ◊ **30 April 2010: Appendix 4C - quarterly**

  http://www.asx.com.au/asxpdf/20100430/pdf/31q2ngwzlrv0f2.pdf