

**Investment Brief for
Serotype Identification Technology for
Streptococcus Pneumoniae and Group B
Streptococcus**

**NSW
AREA HEALTH
SERVICES**

Office of Commercialisation

**For further information under a Confidential Disclosure
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Serotype Identification Technology for Streptococcus Pneumoniae and Group B Streptococcus

Summary

Infections caused by pneumococci are a major cause of morbidity and mortality especially among young children and the elderly worldwide. The development of novel diagnostic and therapeutic vaccines is enabled by the identification of all ninety streptococcus pneumoniae and all nine Group B streptococcus serotypes.

The technology was developed under the leadership of Professor Gwendolyn Gilbert, Director, Centre for Infectious Diseases and Microbiology Laboratory Services. It enjoys strong patent protection.

Market

The global market for a Group B Streptococcus vaccine is estimated at over \$US700mill. The market for diagnostic and bacterial resistant probes is estimated at US\$3bill by 2006.

Benefits

Rapid product development of both diagnostics and therapeutics could be undertaken using this serotyping technology to enable the development of superior products to meet the large projected demand for vaccines over the next few years.

The Technology

We have developed a molecular capsular type prediction system for all 90 Streptococcus pneumoniae serotypes and all 9 GBS serotypes, based on a combination of partial sequencing of the respective cps gene clusters and serotype- or serogroup-specific PCR.

Applications

The technology can be used for serotype identification in diagnostic kits, surveillance studies, as well as in vaccine development.

Market

The diagnostic and bacterial resistance genetic probes market is estimated at US\$3 billion by 2006.

In 2002 The US Centers for Disease Control (CDC) introduced new guidelines for universal mandatory testing for GBS on all pregnant women at 37-39 weeks gestation. There is a global move to adopt CDC guidelines.

One commercially available *Streptococcus pneumoniae* vaccine, 7-valent Wyeth vaccine (Prevenar) - 2002 global sales >\$1 Billion.

In development - GlaxoSmithKline, Streptorix - (phase III trials); paediatric, 11 valent conjugate vaccine; *Streptococcus pneumoniae* elderly (phase I trials); adult, 23-valent polysaccharide vaccine.

Global GBS vaccine market is estimated at US\$700 million. No commercially available GBS vaccine. One company is at the stage of Phase II trials (Microscience).

IP Position

Sydney West Area Health Service (SWAHS) has a PCT filed April 13th, 2004 for selected combinations of sequences for identification of all 90 serotypes of *Streptococcus pneumoniae*. National phase applications submitted for GBS serotyping sequences in Japan and USA (March 19th, 2004), Australia, South Africa, and Europe (April 19th, 2004), and China (May 19th, 2004).

Commercialisation

SWAHS is seeking a partner for the manufacture, distribution, and sale of diagnostic kits, microarrays/biochips using our serotype identification technology. The licensee may also take advantage of faster, more robust and cost-effective methodologies recently developed by our scientists, which may be applied for other infections in addition to *Streptococcus pneumoniae* and GBS.