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News Headlines Research management[Homepage](#) > [Research management](#) > [Resisting the call...](#)[Email this page](#) | [Print in friendly format](#) | [News by email](#) | [Your comments](#)**Resisting the call for new antibacterials?**

By Dr Matt Wilkinson

30/04/2007 - **While the media calls out for new antibacterials, the majority of large pharmaceutical companies seem disinterested in investing in new treatments, leaving smaller biotechs to pick up the gauntlet.**

Speaking at the SMi Superbugs and Superdrugs conference last week in London, Dr Ursula Theuretzbacher, of the Center for Anti-Infective Agents in Austria, said the key driver for antibiotic research and drug development is the growing problem of bacterial drug resistance.

A recent report published by Kalorama Information entitled '*Anti-Infectives - the World Market, Vol II: Antibacterials*', valued the global antibacterials market in 2006 at \$22.6bn (€16.6bn).

The report highlights that market has suffered nearly a 2 per cent decline since 2004 due to a shift of sales to generic products. However, the report's authors predict that the market will recover and hit \$25.5bn in 2011.

The current advice about the sparing use of antibiotics means that peak sales may not be as high as drug companies would like, but drugs such as [Pfizer's](#) Zyvox (linezolid), which had 2006 sales of \$782m, seem to buck the trend and have almost hit blockbuster status.

Zyvox, launched in 2001, was the first truly new molecular entity to be launched after an innovation gap of several decades and opened a new class of antibiotics - the oxazolidinones.

This was followed by the launch of the lipopeptide Cubicin (daptomycin) by [Cubist](#) in 2003, which the company claims is the most successful intravenous (IV) antibiotic launch, in dollar terms, in US history.

These big sellers may have bigger problems than competing drugs and patent expiry normally faced by drugs - the onset of [antibacterial](#) resistance.

"The most successful antibiotic is one that is not used," said Theuretzbacher.

This was backed up by a graph that showed that as drugs are used with increasing regularity, the incidence of resistance increases. This becomes more pronounced the faster the uptake of the drug is.

This didn't stop GlaxoSmithKline (GSK) developing a new topical antibacterial, [Altabax](#) (retapamulin), a first in a new class of antibacterial treatments known as pleuromutilins.

The transfer of resistance to natural product based drugs has received lots of interest especially after the

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problem of natural antibiotic resistance was highlighted in an article published by Dr Gerard Wright and co-workers in *Science* last year.

In the article the authors found an unprecedented density and concentration of environmental antibiotic resistance with some bacteria being resistant to over 15 of today's commonly used antibiotics.

While the article did not provide evidence for the direct transfer of resistance elements from the soil 'resistome' to pathogenic bacteria, it did highlight a potential problem because bacteria are able to exchange genes through a variety of mechanisms including conjugation, transduction and transformation - as well as being able to evolve the resistance for themselves.

This resistance may mean that the approach of using natural products and their derivatives as antibacterials may be fundamentally flawed as a bacterium somewhere is likely to have developed a natural resistance to the drug and that resistance may just be waiting to be transferred to pathogenic bacteria.

"If doctors do not want to use new antibiotics [for fear of resistance evolving] where is the incentive for pharma to invest in the R&D of new drugs?" asked Theuretzbacher.

However, in spite of this there were many companies at the SMI conference still interested in developing new antibacterials; however many of these were the smaller biotech and pharmaceutical companies.

This shift is mainly due to the estimated sales of niche drugs for specific resistant strains being below the \$200m mark, somewhat lower than the usual cut-off point for big pharma to consider worthwhile.

Another factor is that the uptake of new antibacterial classes is often hindered by doctors saving them for the most resistant bacteria - reducing sales and making 'me-too' drugs more appealing to many manufacturers.

Of the new drug classes discussed at the meetings, Ipsat's P1A drug was the most advanced. It is in Phase II trials as an oral degradation agent - it aims to destroy β -lactamase antibiotics in the gut, before they have time to affect the bacteria there.

The company has shown that exposure of gut proteins to antibiotics leads to the selection of resistant bacteria which can then horizontally transfer the resistance genes to the pathogenic species.

Affinium Pharmaceutical showed results from a potential first-in-class fatty acid synthesis inhibitor, API-1252, for *Staphylococcal* infections.

According to Dr Nachum Kaplan, vice president of microbiology at [Affinium](#), the primary mechanism of action is via the inhibition of the bacterial enoyl-acyl carrier protein (ACP) reductase (FabI) which blocks lipid biosynthesis.

The company presented results showing that the drug has no off-target antibacterial activity which should help reduce the onset of resistance.

The drug has successfully completed Phase 0 microdosing studies which showed that the drug candidate had good bioavailability and a half life that would be amenable to once or twice daily dosing.

Preclinical screens showed that the drug showed good activity against several key resistant strains and that it could be up to 500 times more active than vancomycin and linezolid.

The company is poised to start Phase I studies in humans within the year.

Basel-based Basilea Pharmaceutica has been working on reducing β -lactam antibiotic resistance by looking for drugs that inhibit the resistance mechanism of bacteria against these drugs for use in combination with various β -lactams to allow them to effectively inhibit the cell wall synthesis.

Merck is currently developing [platensimycin](#), which is produced by the fungus-like bacterium *Streptomyces platensis* for use against Methicillin-resistant *Staphylococcus aureus* (MRSA) infections.

Mutabilis are currently developing a range of antivirulence drugs that target bacterial genes that produce virulence factors that block the ability of the host's immune system to kill the bacteria.

Arpida has recently announced the successful completion of Phase 0 microdosing trials for its dihydrofolate reductase (DHFR) inhibitor. DHFR is an enzyme that plays a key role in DNA synthesis and while not first-in-class, the drug is being investigated for inhalation delivery for pneumonia sufferers.

Cumbre Pharmaceuticals is currently investigating a linked combination drug, CBR-2092, for use against the bacterial biofilms that can form on artificial substances inserted into the body - such as hip or knee replacements.

These films are notoriously difficult to treat and often lead to the replacement joint being replaced after extensive antibacterial treatment.

CBR-2092, which comprises of a rifamycin unit linked to a flouroquinolone unit via a stable linker, is currently in Phase I trials.

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