

# COMPANY OVERVIEW



January 2009

## Overcoming microbial resistance in the hospital environment

### Strong and Entrepreneurial Management

Novoxel presently has a team of 50 employees, including 43 scientists with significant experience in anti-infectives research and development. 47 employees are based at the Company's headquarters in Paris, France and 3 in the Company's subsidiary in the United States.

The Company is led by a management team with significant experience and an international track record of success in the global biotech and pharmaceutical sector. A combination of big pharma experience and biotech entrepreneurial dynamism is driving Novoxel towards the goal of becoming the leading European specialty pharmaceutical company in the antibiotics space.



### Infectious Diseases Urgent Medical Need

There is a constant requirement for new antibiotics given that resistance among hospital acquired (nosocomial) and more recently community acquired pathogens is a growing global problem.

Only two new classes of antibiotics have been introduced since 1968 (linezolid in 2000 and daptomycin in 2003). This poor output of antibiotic R&D has prompted the Infectious Disease Society of America (IDSA) to issue a clear warning to US legislators and regulators of the dire consequences to society if no novel agents that address the increasing problem of bacterial resistance are delivered to physicians and patients.

## AN EMERGING SPECIALITY PHARMACEUTICAL COMPANY

Novoxel is an emerging speciality pharmaceutical company with a pipeline of novel anti-infective assets focused on overcoming microbial resistance in the hospital environment. The Company's goal is to become Europe's leading specialty pharmaceutical company in the hospital anti-infectives space.

Novoxel was formed in December 2004 around the anti-infective assets which were spun out from the French pharmaceutical company sanofi-aventis. At present Novoxel's most advanced product (NXL103) has completed Phase II clinical development. The company has another product (NXL104/ceftazidime) in Phase II clinical trials as well as other pre-clinical programmes. The Company's success to-date is based both on its inherited assets, which are the product of many years of significant investment by sanofi-aventis, and its own core expertise in biology, chemistry, pharmacology, microbiology, and clinical development.

Novoxel has built on this antibacterial portfolio, know-how and intellectual property to create one of the leading European biotech companies focused on developing new anti-infectives.

## SIGNIFICANT MARKET POTENTIAL

There is a clear and urgent need for novel drugs that have potent activity against "super bugs". This is due to the ever increasing resistance to marketed antibiotics, with more than 70% of the bacteria that cause infections in hospitals now resistant to at least one antibiotic commonly used to treat them. As a result, two million patients in the United States alone get an infection in a hospital and 90,000 deaths annually are as a result of hospital acquired infections<sup>1</sup>. There is an urgent need for novel antibiotics to confront this medical problem.

Novoxel's products are primarily novel class antibacterials which are specifically designed to tackle the problem of antibiotic resistance in the hospital. The target market for Novoxel's programmes is large, with the global hospital antibiotic market being valued at \$15 bn (IMS 2007).

Further attractions of the antibacterial market that Novoxel is targeting are:

- The limited number of other companies developing novel antibacterials
- The relatively small size of the sales and marketing infrastructure needed to commercialise products in the hospital antibiotic sector.

<sup>1</sup> IDSA / CDC Facts about Antibiotic Resistance 2006

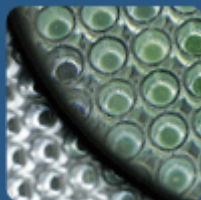
## INNOVATIVE PIPELINE

Novoxel has retained worldwide rights on all products in the pipeline that was originally inherited from sanofi-aventis. In addition, one development programme (NXL105) is a product of Novoxel's internal discovery efforts.

The Company has also added a programme to the inherited pipeline (NXL104/ceftaroline) through a licence agreement with Forest Labs. This represents a significant potential milestone and royalty income for the company.

At present Novoxel has 5 programmes in development and a number of additional programmes in discovery.

### MANAGEMENT



**Iain Buchanan** - C.E.O ex - Vertex, Johnson & Johnson  
**Gordon Waldron** - C.F.O. ex - Syntem; Texas Instruments  
**Carole Sable** - Chief Medical Officer ex - Merck & Co. Inc  
**Kenneth Coleman** - C.S.O. ex - AstraZeneca, SmithKline Beecham  
**Aram Mangasarian** - Business Development V.P. ex - ExonHit  
**Peter Spargo** - Manufacturing & Controls V.P. ex - Pfizer

## MATURE AND DIVERSE PIPELINE

Tackling serious bacterial and fungal infections is a high priority for most countries' health authorities and Novexel is focused on producing innovative products for meeting the specific needs of hospitals:

### Clinical Development

**NXL104/ceftazidime:** NXL104 is a beta-lactamase inhibitor which, in combination with the cephalosporin antibiotic ceftazidime, has demonstrated the potential to treat hospital and community acquired infections that are caused by Gram-negative bacteria resistant to many currently used antibiotics.

**NXL103** is a novel oral streptogramin which has potent *in vitro* activity against aetiologies of skin and skin structure infections including the important pathogen MRSA (methicillin resistant *Staphylococcus aureus*). It also has activity against the major respiratory pathogens including penicillin, macrolide and quinolone resistant strains.

## PRECLINICAL DEVELOPMENT

**NXL201** (aminocandin) is a member of echinocandin class of antifungal agents. These are fungicidal with a novel mode of action, and the first new class of antifungals to be introduced in nearly half a century. NXL201 is being developed as an injectable antifungal agent for the hospital market as a first line therapy against invasive fungal infections.

**NXL105** is a product of Novexel's own discovery efforts with the potential to fill the unmet medical need for treatment of multi drug resistant *P. aeruginosa* (Gram-negative), a difficult to treat hospital pathogen.

**NXL104/ceftaroline.** Cefataroline is a novel, bactericidal injectable broad spectrum cephalosporin being developed by Forest Labs as a therapeutic agent for the treatment of Gram-positive pathogens including methicillin resistant *Staphylococcus aureus* (MRSA), and multi-drug resistant *Streptococcus pneumoniae* (MDRSP), as well as common Gram-negative organisms. The NXL104/ceftaroline combination programme is being driven by Forest who have licensed the rights to use NXL104 in combination with ceftaroline for North America.

Compound	Indication	Pre-Clinical	Phase I	Phase II	Phase III
NXL103	Skin & Skin Structure infections (including MRSA), Respiratory Tract infections				
NXL104/Ceftazidime	Gram-negative infections				
NXL201	Invasive Fungal infections				
NXL105	Pseudomonas infections (including multi-drug resistant strains)				
NXL104/Ceftaroline (Partnered with Forest Labs Inc. for North American territories)	Gram-negative and Gram-positive infections				

## THE DEVELOPMENT OF NOVEXEL

2008	<ul style="list-style-type: none"> <li>January – Novexel announces a licensing agreement with Forest Laboratories for NXL104 solely in combination with the cephalosporin antibacterial ceftaroline for North America for €75 million</li> <li>June – Novexel announces that it will discontinue its development of NXL101</li> <li>October – Novexel announces positive Phase II clinical results with NXL103 in a 300 patient Community Acquired Pneumonia trial</li> <li>November – Novexel announces the initiation of the NXL104 Phase II trial in complicated Urinary Tract Infections (cUTI)</li> </ul>
2007	<ul style="list-style-type: none"> <li>January – Novexel raises €50 million in a Series B fundraising</li> <li>November – NXL103 goes into Phase II development</li> <li>December – Novexel nominates NXL105 for preclinical development</li> </ul>
2006	<ul style="list-style-type: none"> <li>September – NXL101 goes into clinical development for the treatment of bacterial infections including MRSA</li> <li>December – Novexel and Indevus sign agreement over the out-licensing of NXL201, an echinocandin anti-fungal agent</li> <li>December - NXL104 enters Phase I</li> </ul>
2005	<ul style="list-style-type: none"> <li>October - Phase I Trial of NXL103 commences</li> </ul>
2004	<ul style="list-style-type: none"> <li>December - Novexel is formed as a spinout of Aventis Pharma, a subsidiary of sanofi-aventis</li> </ul>

## COMMERCIALISATION STRATEGY

Novexel intends to build on its discovery and global clinical development expertise with the mid-term objective of adding a speciality sales capability. This sales effort would cover the key European hospital markets, allowing Novexel to become a fully integrated regional pharmaceutical company focused on antibiotics.

The Company plans to enter into partnerships to develop and commercialize its hospital antibiotics outside Europe. It also plans to out-license products which have the potential to be used to treat community infections in all markets of the globe.

## SIGNIFICANT PARTNERSHIPS

Forest Labs. - In January 2008 Novexel signed an agreement with American Pharmaceutical company Forest Labs. This agreement covered the development and commercialisation of NXL104, Novexel's beta-lactamase inhibitor, solely in combination with the cephalosporin antibiotic, ceftaroline for the North American markets. In return Novexel has received a €75 million up front payment and could receive a further €75 million in development milestones. Once the combination is approved Novexel will receive low double-digit royalties based on the sales of the product.

Novexel has retained the worldwide rights for its own combination product: NXL104/ceftazidime

## SOLID FINANCIAL BACKING

In addition to the revenue arising from the Forest licensing agreement, Novexel has raised a total of €90 million, of which it has currently drawn down €70 million, from a group of international life science investors including:

- Atlas Venture
- Sofinnova
- Abingworth
- 3i
- Novo A/S
- Edmond de Rothschild Investment Partners
- Goldman Sachs
- NeoMed
- Daiwa SMBC Capital Co., Ltd.
- BIT (AXA Framlington Investment Managers)

sanofi-aventis currently holds approximately 15% (fully diluted) of Novexel shares. These shares were granted in exchange for the assets, including anti-infectives programs and IP that it provided to Novexel when the company was formed.

### FOR FURTHER INFORMATION

Gordon Waldron - CFO

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