HAI Treatments
A Challenging Market

Given the attention focused on hospital-acquired infections (HAIs), one would think there would be a thriving market for pharmaceutical products to combat this scourge. And there is a fairly large-sized market – over $8.06 billion earned in 2010 by companies selling pharmaceutical treatments. But it is a market that has seen declines for a variety of reasons, and even as the greatest threats emerge, it may take a few years to recover revenues lost to patent challenges.

Infections contracted in hospitals, also known as nosocomial infections, are the fourth largest killer in the United States. Considering the 40 million hospital admissions each year in the United States, this provides a nosocomial infection rate of 5% of admissions.

Treating hospital-acquired infections has become an increasing focus of healthcare organizations, governments and news outlets. The CDC has reported that about one third of nosocomial infections in the United States are preventable, which represents nearly 700,000 cases. Of these approximately 94,000 are MRSA type. Nearly 100,000 people die each year, of which almost 20,000 are from MRSA infections. Nosocomial infections in the European Union are estimated at 4 million, with approximately 150,000 deaths reported annually. Between 115,000 and 125,000 visits to emergency departments (ED) are reported in the United States each year. 12-13% of these visits result in hospital admissions, or approximately 15,000 each year.

Yet the treatment market remains challenged. The market dropped from $8.25 billion in 2009 and it's expected to fall further as new products barely make up for patent expirations. The top four drugs – Floxin, Zosyn, Zyvox and Avelox all saw a decline in sales.

Treatment of hospital-acquired infections involves the careful selection of antibiotics for the specific infection strain. The increasing concern of antibiotic resistance has added a new dimension to treating HAIs. MRSA infections have recently gained public attention for the increasingly limited treatment options. Many strains of MRSA are resistant to traditional anti-staphylococcal beta-lactam antibiotics, including cephalexin (Keflex). Vancomycin, linezolid,

quinupristin, daptomycin, and tigecycline are all common treatments for MRSA. C. difficile is generally treated with Metronidazole, because of its lower price and comparable efficacy. Treatment for Hospital-Acquired Pneumonia (HAP) is based on factors such as severity of infection, patient-specific risk factors, and total number of days in the hospital before onset. Staph infections that are not antibiotic resistant can be treated in about a month (depending on severity) using antibiotics. Tuberculosis treatment is difficult and requires long courses of multiple antibiotics. The two antibiotics most commonly used are rifampicin and isoniazid.

Estimated Sales of Select Antibacterial Products (2009 vs. 2010)

Product	2009	2010
Floxin/Levaquin/Cravit	$2,687	$2,285
Zosyn	1,230	1,050
Zyvox	1,141	1,176
Avelox/Avalox	1,020	986
Augmentin	1,040	969
Merrem	872	817
Primaxin	689	610
Cubicin	538	625
Biaxin/Biaxin XL	590	515
Cipro/Ciproxan	461	348
Zithromax/Zmax	430	415
Omnicef	350	330
Rocephin	283	299
Ceftin	300	270
Tygacil	295	324
Invanz	293	362

Only a few products (highlighted in blue) showed revenue growth between 2009 and 2010. Some of the drop in sales has been offset by sales of the newer products on the market such as the antibiotic Cubicin. Indeed, this drug and a few others, including Tygacil and Invanz, earned less revenue but saw growth last year and should continue to see growth. Cubicin was launched in the U.S. in November 2003, following its approval for the treatment of certain complicated skin and skin structure infections, or cSSSI, and for S. aureus bloodstream infections (bacteremia), caused by methicillinsusceptible and methicillin-resistant isolates. The product has also been approved in the E.U. for complicated skin and soft tissue infections, or cSSTI, where the presence of

susceptible Gram-positive bacteria is confirmed or suspected, and for RIE due to S. aureus bacteremia and S. aureus bacteremia associated with RIE or cSSTI. Cubicin has been approved in around 71 countries outside of the U.S. as of early 2011.

Long term, this drug will face competition as well. In February 2009, Cubist received a letter from TEVA Pharmaceutical Industries concerning TEVA's application for a generic version of the active ingredient (daptomycin) in Cubicin. TEVA is a global leader in generic products. Following a legal battle, Cubist and TEVA reached an agreement in 2011 allowing TEVA to launch its generic daptomycin in the U.S. in June 2018, if Cubist obtains a 6 month extension of marketing exclusivity from the FDA granting a pediatric exclusivity. If a pediatric extension is not granted by the FDA, Teva may launch its generic in December, 2017. Cubist has a patent that it was working to enforce which expires in 2019.

By 2015, the hospital-acquired infection treatment market will show some signs of increases once again, reaching $8.5 billion, for growth of 1% over 2010. Growth is based on some new market entries, although few, continued demand for products focusing on hospital-acquired infections such as Cubicin, and growing unit sales overall.

Only a handful of top brand products remain in the antibiotic market when compared to the number of generic products available. In most product segments there is a leading product and in some there are two or three. For example, in the cephalosporin market few products remain leaders due to a growing number of generic options. Three products are considered top brand products in the cephalosporin market, including Abbott Laboratories' Omnicef, GlaxoSmithKline's Ceftin, and Roche's Rocephin. In the carbapenem segment, the newest segment in the antibiotic market, three products dominate sales: Primaxin, Merrem, and Invanx. These are all large players in the hospital-acquired infection treatment segment.

Constant innovation is required. Over the years, there have been over one hundred antibiotics introduced and most are no longer in use. There continues to be an expanding unmet need in the area of hospital-acquired infection treatment with a short supply of new treatments coming to market. Pipelines continue to show less than adequate response to the growing need for effective therapies. Of the FDA's yearly approvals, just 3% are for antibiotics, despite this well publicized healthcare problem.

Kalorama Information

Hospital-Acquired Infections: Diagnostic Markets and Testing Developments, Treatments, Key Competitors and Trends

A hospital-acquired infection (HAI) is a new infection that develops in a patient during hospitalization. It is usually defined as an infection that is identified at least forty-eight to seventy-two hours following admission, so infections incubating, but not clinically apparent, at admission are excluded. This type of infection is also known as a nosocomial infection (or more generically a healthcare-associated infection).

The industry has responded with a variety of testing and treatment products. This report, *Hospital-Acquired Infections: Diagnostic Markets and Testing Developments, Treatments, Key Competitors and Trends,* presents the market opportunities for testing such infections and the role of treatment. The following market data is provided in this report:

- **Market for HAI Diagnostics**

- **Forecast for HAI Diagnostics to 2015**

- **HAI Tests on the Market**

- **Market for Diagnostics by Infection Type (C. Diff., MRSA, Pneumonia, Other)**

- **Molecular HAI Market vs. Conventional HAI Market, Present and in 2015**

- **Geographic Breakdown of Testing (U.S., Europe, Asia, ROW)**

- **New Hospital Infection Product Testing Products in the Market**

- **Company Profiles**

- **HAI Treatment Products on the Market**

- **HAI Antibiotic Market Size and Forecast**

This report primarily focuses on bacterial nosocomial infections with some mention of viral infections. The major consideration is given to bacterial nosocomial infections because a) they are the most frequent type of infections spread in the hospital setting, and b) the practical aspects of diagnosis and therapy are more meaningful based both on medical considerations and on market considerations.

The analysis presented in this report is based on data from a combination of company, government, industry, institutional and private sources. It includes information from extensive literature reviews and discussions with experts in the field, including microbiologists, pathologists, hospital authorities, research scientists, business development managers and marketing managers.

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