## Oncology Market Expected to Post **DOUBLE-DIGIT GROWTH IN NEXT FIVE YEARS**

Despite upcoming patent expirations on a number of top-selling oncology drugs, analysts at Cutting Edge Information (CEI) forecast that the oncology market will grow from $57 billion in 2007 to more than $90 billion in 2013, as companies answer patent expirations with increased R&D investment in the category.

> By 2013, nine drug companies are expected to hit sales of more than $4 billion from their oncology portfolios.

The CEI report, Oncology Market Forecast to 2013, examines the oncology portfolios and pipelines at the top 14 companies in oncology. It analyzes the current market value of each company's oncology products, as well as the company's forecasted positioning in 2013.

The report projects that while Roche will continue to hold around 28% of the oncology market, other top companies will slowly reap the rewards of current development. By 2013, nine drug companies are expected to hit sales of more than $4 billion from their oncology portfolios.

"Companies across the industry are investing hundreds of millions of dollars in oncology R&D and licensing," says Eric Bolesh, research team leader at Cutting Edge Research. "This area will be increasingly dominant in the next five to 10 years."

CEI's report examines more than 130 drugs and provides market analysis on multiple levels, including individual drug profiles, oncology indication market outlook, and company profiles.

## Antibiotics Class in **DIRE NEED OF EFFECTIVE NEXT-GENERATION COMPOUNDS**

Many experts consider the emergence and spread of antibiotic resistance to be one of the chief public health threats of the 21st century. While most resistant microbes continue to emerge in the hospital setting, problems are spreading outside of the hospital environment as well. Despite this growing threat, the industry's antibiotics pipeline contains few late-stage candidates capable of combating the emergence and spread of novel, drug-resistant bacterial strains.

Insight Pharma Reports' Antibiotic R&D: Resolving the Paradox between Unmet Medical Need and Commercial Incentive explores the interrelated factors leading to the current crisis in antibiotic research and development. The report also examines the key scientific challenges to antibiotic drug discovery, as well as the economic and regulatory realities of antibiotic R&D and factors driving the field forward. It includes interviews with experts from companies engaged in both early and late-stage antibiotic research and development, including companies that have a marketed product.

Additionally, it provides an analysis of results from a recent survey relating to the research, development, and commercialization of antibacterial agents, and notes some of the more promising late-stage products with novel mechanisms of action.

Despite the widespread view that antibiotic R&D is too great an economic risk to become involved in, there is lucrative potential in antibiotic commercialization, as exhibited by the only two new classes of antibiotics introduced over the past 30 years: the oxazolidinones class of synthetic antibiotic compounds, and the naturally derived cyclic lipopeptides. Cubist Pharmaceuticals' Cubicin (daptomycin), the first of the cyclic lipopeptides to gain U.S. market approval, is currently the fastest-growing product in the antibiotic class, with 2007 sales surging 53% to $290.4 million.

The first oxazolidinone to win U.S. Food and Drug Administration approval, Pfizer's Zyvox (linezolid), is second only to Cubicin in terms of growth, with sales totaling about $944 million in 2007, a 21% increase from year-earlier results. Zyvox was approved in 2000, while Cubicin won FDA clearance in 2003.

But realization of the antibiotic category's therapeutic and financial promise will require a shift away from the blockbuster model toward niche-market products, the report notes. From a scientific standpoint, combating resistance will require the discovery and development of new antibiotics with novel potential to inhibit bacterial growth, reproduction, and resistance. In addition to combinations of antibacterial and antibiotic agents, companies are investigating entirely different antibacterial approaches, such as phage enzyme therapy and innate defense regulation, and looking to the natural world for more complex bioactive molecules that would be less likely to induce resistance than small-molecule inhibitors.

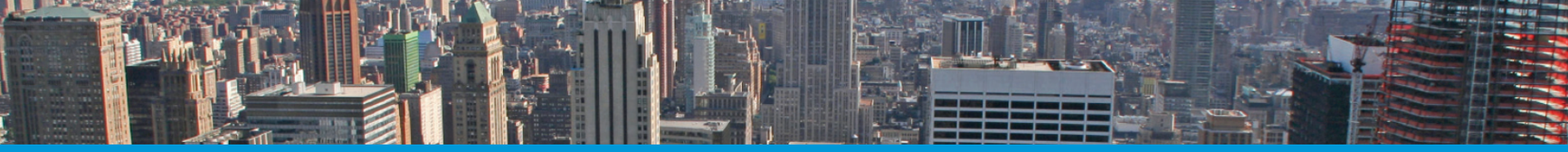
Other than resistance, one of the greatest challenges many antibiotic companies currently face is the need for more regulatory clarity regarding drug-approval standards. In the survey included in the antibiotics report, when asked what the greatest challenge to antibiotic development is, the greatest proportion of respondents (44.4%) indicated, "The emergence of resistance during clinical development."

The next most popular answer, at 25.9% of respondents, was, "Lack of clear regulatory guidelines." Without clear approval standards, the already-significant risk associated with investing in a product already considered risky becomes impossibly large.

**A SAMPLING OF LATE-STAGE ANTIBACTERIAL PRODUCT CANDIDATES**

| Company | Product | Drug class | Current status |
|---|---|---|---|
| Advanced Life Sciences | Cethromycin | Ketolide | Completed Phase III trials; preparing for NDA submission |
| Arpida | Iclaprim | Dihydrofolate reductase inhibitor | NDA almost complete as of Feb. 2008 |
| Basilea and Johnson & Johnson | Ceftobiprole | Cephalosporin | Received approvable letter in March 2008 |
| Cerexa | Ceftaroline | Cephalosporin | Phase III trials |
| Oscient | Ramoplanin | Glycopeptide | Received a special protocol assessment for Phase III clinical trial |

Source: Insight Pharma Reports, Needham, Mass. For more information, visit insightpharmareports.com.



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6. Flomax is the No. 1 branded BPH medicine prescribed by urologists (since 1999)

Source: Best Practices LLC, Chapel Hill, N.C.
For more information, visit best-in-class.com.

## **KEYS TO FLOMAX'S SUCCESS** Include Increased Communication, Disease Awareness

According to a case study from Best Practices, Boehringer Ingelheim deployed many basic tactics plus some innovative marketing to help its benign prostatic hyperplasia (BPH) therapy, Flomax (tamsulosin), become the top player in its market, including carving out a niche for Flomax as a BPH-specific drug and motivating a large untapped patient pool through multiple communication tactics.

Best Practices' Flomax Case Study: Evolving Disease State Awareness to Succeed with New Method of Action reviews the strategy and tactics used by Boehringer Ingelheim to differentiate Flomax from other BPH medicines and to boost disease awareness to expand the product's market.

The study offers insights into methods for differentiating a product and creating effective communication tactics to boost awareness and sales of a new product.

One way in which Boehringer Ingelheim expanded the market for Flomax was by leveraging market research to identify untreated populations and motivate untreated patients through communications to their families. The company also expedited change in the market for BPH by providing superior tools that supported physician diagnosis and patient self-diagnosis.

Boehringer Ingelheim also increased awareness of BPH by sponsoring awareness events and Website health guides through U.S. prostate patient advocacy groups. In the United Kingdom, the company established a Men's Health Matters organization to provide unbranded educational materials in support of Flomax's U.K. launch.

The Flomax study is one in a series of six case study analogs recently published to the Best Practices Database. The case studies review various aspects of product launch, providing unique perspectives for understanding the strategies and tactics used by top biopharmaceutical companies to address commercial issues surrounding their products.

## Regulatory Executives are Migrating to **ELECTRONIC CTD SUBMISSIONS**

About three-quarters (75%) of regulatory affairs leaders surveyed are using submission publishing software, similar to 2007 (67%), and almost one-third (31%) of those respondents not currently using software are very likely to implement submission publishing software into their process.

These are some early results of a recent survey by the scientific business of Thomson Reuters. Its 2008 Liquent Regulatory Affairs Trends Survey attracted respondents from across the globe representing small, medium, and large pharmaceutical companies and provides a unique insight into emerging and future trends in regulatory product management usage and adoption.

Other findings include:

• Almost all (92%) of the survey respondents make regulatory submissions, a slight increase from 2007 (90%); current use of paper and electronic submissions has remained the same since 2007.

• As in 2007, the SAFE initiative has not yet taken hold in most companies surveyed: only 2% of respondents are currently addressing it. But there has been a significant increase in the percentage of companies that are currently using technology to support the FDA Gateway, up to 19% this year, from 9% in 2007.

• 30% of respondents do not outsource any of their regulatory operations.

• Printing (28%) was the regulatory operation outsourced the most by respondents.

• Eight in 10 (83%) of respondents intend to migrate to the eCTD, with 20% of these reporting they will migrate within the next year.

"This year's survey has once again attracted respondents from across the breadth of the global life-sciences industry, with large as well as small to medium-sized companies participating," says Jim Nichols, Liquent's VP of product strategy and marketing, who launched this worldwide initiative in 2003. "We're particularly excited to see a significant increase in the numbers of contract research organizations (CROs) replying to our survey, further diversifying the population sample."

Now in its sixth year, this survey has become a benchmark of global regulatory submission trends offering timely insights into how pharmaceutical regulatory professionals use technology today and how they plan to harness technology in the future.

There were 137 regulatory affairs professionals working in life-sciences companies across the globe who participated in this survey. The survey concentrates on four key areas: technology usage trends, including both submission publishing software and other desktop software document management system usage, regulatory outsourcing trends; and regulatory trends, including use or future use of the electronic common technical document (eCTD).

The demographic makeup of the respondent population is similar to previous years with almost one-third working in large pharmaceutical companies (32%) and more than a third working in small to medium companies (36%). Another 10% of respondents work for biotechnology companies. There were significantly more respondents from CROs in 2008 (10%) than in 2007 (4%). In addition, 68% of those surveyed are from the United States and the majority of the remaining respondents are from Europe, with France (4%), Switzerland (4%), the United Kingdom (3%) and Germany (3%) the most highly represented.

### Follow up

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