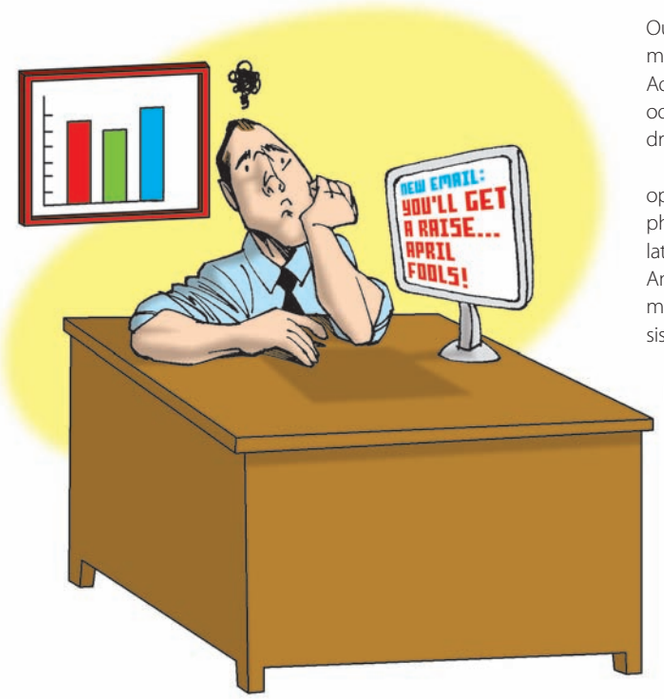

Market for Biochips in Clinical Research **EXPECTED TO EXPAND**


Charanya Ramachandran

There is very little that has changed over the past two decades to convert solid science to a more functional business commodity in the realm of clinical diagnostics, says Frost & Sullivan Research Analyst Charanya Ramachandran.

As biochip technology makes the transition from bench to bedside in the clinical-trial process, improved patient therapies will result, according to a recent report from Frost & Sullivan.

Frost & Sullivan analysts predict that the European market for biochips in clinical research will grow from $14.1 million in 2004 to $65.6 million in 2011, at a compound annual growth rate of 24.6%. Protein chips are expected to have a higher growth potential than DNA chips in clinical research as most drug targets are proteins and post-translational modifications can be avoided.

In the report, European Market for Biochips in Clinical Research Applications, researchers explain that identifying relevant, disease-specific markers holds the key to using biochips in real-time diagnostics in killer diseases, such as cancer and Alzheimer's.

R&D **PRODUCTIVITY IS IMPROVING**

Following years of declining R&D productivity, during which the United States has witnessed a decline in new drug approvals, drug developers are poised to reverse this trend, according to the Tufts Center for the Study of Drug Development (CSDD) Outlook 2006 report. Only 58 new drugs received marketing approval from the U.S. Food and Drug Administration (FDA) during the 2002 to 2004 period. This is a 47% drop from the peak of 110 new drugs in the 1996 to 1998 period.

One key to improving R&D productivity is developers' willingness to use new discovery tools, such as pharmacogenomics, to accelerate the pace of translating basic research into viable drug candidates. Another critical factor is the aggressive management of clinical trials through advanced data analysis and outsourcing.

"As drug development has become more complex and expensive, developers have concentrated their resources on fewer projects," says Kenneth I. Kaitin, director of Tufts CSDD. "This, in turn, has led to fewer new drug approvals in the last few years. Turning this around will require the industry, working with regulators, to embrace strategies and technologies that will enhance development of more complex drugs of high therapeutic value while improving assessments of product safety and effectiveness. It's a tall order, but it can be done."

NEAR-TERM TRENDS IN R&D

- Developers will boost R&D productivity by increasing licensing and outsourcing and codevelopment agreements.
- Use of e-clinical technologies will grow rapidly at investigative sites.
- The FDA will increase its demand for monitoring industry postmarketing commitments, while encouraging drug sponsors to formulate and implement their own risk-management plans.
- Biotech companies developing therapeutic and vaccine products will increasingly seek U.S. fast-track designation to help accelerate clinical-development programs.
- More Rx-to-OTC switches will occur in 2006 as pressure grows on the FDA to allow them.

Source: Tufts Center for the Study of Drug Development, Boston.
For more information, visit csdd.tufts.edu.

Breakthrough Biotech Products **APPROVED IN 2005**

The biotechnology industry ended 2005 with steady financial investments and product deliveries as companies succeeded in introducing novel therapies for patients suffering from some of the most devastating and deadly diseases.

In 2005, the U.S. Food and Drug Administration approved seven recombinant biologics, a number of first-in-class products, and several orphan drugs.

About 45% of all recombinant and monoclonal antibodies cleared for marketing have been approved since 2000, demonstrating a recent growing trend of industry market success, say officials from the Biotechnology Industry Organization (BIO).

In 2005, biotech companies raised about $20.1 billion in public and private financing, compared with $20.8 billion in 2004.

Overall, the FDA has approved 38 new biotech and biotech-related products and expanded labels. Among the highlights are three diabetes and cancer therapies, including Novo Nordisk's Levemir, for treatment of diabetes mellitus, and Onyx's and Bayer's Nevaxar, for the treatment of advanced renal cell carcinoma.

"Investors have recognized biotech's value; in the last six years as the industry has matured, biotech and biopharmaceutical firms have raised more than $120 billion in financing, the majority of which is used for the purposes of research and development," says Jim Greenwood, president and CEO of BIO.

Biotech companies last year raised about $20.1 billion in public and private financing, compared with $20.8 billion the previous year. Financings in 2004 and 2005 top all annual figures from the previous decade, with the exception of the year 2000, when the industry raised a record $38 billion following completion of the draft sequence of the human genome.

Synthetic Biology Will **SHAPE THE FUTURE OF LIFE SCIENCES**

Thanks to early successes in synthetic DNA and antibody-based applications, as well as significant attention and investment from the research community, synthetic biology is likely to play a large role in shaping the future of the life sciences.


Richard Fisler

It appears that this industry is poised for rapid growth, says Richard Fisler, Director of Beachhead LLC.

Synthetic Biology, A New Paradigm for Biological Discovery, a report from Beachhead LLC, suggests that synthetic biology products and technologies could be among the fastest growing segments of the life-sciences market. Although the research market is currently $600 million, the potential for growth in the next 10 years is projected to expand this market to more than $3.5 billion.

Synthetic biology is a field of research in which experts from different fields of

study — such as biochemists, molecular biologists, engineers, and organic chemists — take existing biological pieces, transform them into micromachines, and create artificial systems that mimic the properties of living systems.

Beachhead's report illustrates that new drug applications discovered through synthetic biology have streamlined the pharmaceutical industry's ability to deliver new therapeutic agents.

Clinical Drug Research **BOOMING IN CHINA**

With its vast patient population, broad disease profile, and expansive scientific talent, China is quickly becoming one of the most important countries in the world for clinical pharmaceutical research. While most of the world's leading drug makers are already including China in their research plans to some degree, the Chinese government is making systemic improvements that will encourage future growth in the number and scope of clinical drug trials and will further enhance the nation's standing as a hotbed of research activity.

By 2010, China is predicted to be the fifth-largest pharmaceutical market in the world.

These findings are included in a new Kline & Co. report, China Clinical Research: Key Success Factors for Global Pharmaceutical Companies. The report is part of the Kline Advisory Service: China Healthcare, a series of 50 syndicated reports offering insights on key developments and issues that are shaping the current and future direction of the Chinese healthcare market.

At the end of 2004, there were already more than 250 trials in progress, all sponsored by multinational companies. This is an increase of about 25% since 2002. By 2010, China is predicted to be the fifth-largest pharmaceutical market in the world, according to Kline analysts.

"Because the Chinese population is mostly concentrated in metropolitan areas that include formerly state-run hospitals, this provides for a large pool of potential patients with ready access to high-quality hospitals that qualify as clinical study centers," says Wenli Ding, a healthcare consultant in Kline's Shanghai office. "Conversely, there are also significant numbers of the rural poor, or patients who otherwise do not have access to medical care, who often seek out clinical trials as a way to obtain treatment. In fact, this is one area where the State Food & Drug Administration is working to develop and implement ethics policies and practices."

Another report in Kline's China Healthcare series suggests that while stem-cell research continues to be a hotly debated issue in many Western countries, companies should look to China for lucrative opportunities in this breakthrough area.

The report, Licensing Strategies and Opportunities in the China Pharma/Biotech Industry, highlights the growing opportunities for Western companies to partner with the Chinese for licensing, strategic partnerships, joint ventures, and technology transfer, particularly in the areas of gene therapy, stem-cell research, infectious diseases, and traditional Chinese medicine.

Because Chinese culture has fewer objections to the use of embryonic stem cells and the government does not oppose funding this research for academic, educational, or therapeutic purposes, Kline's analysts say China could be the first country to conduct human stem-cell trials. This presents a significant opportunity for Western companies that are interested in this potentially lucrative sector of the biotech industry.

Earlier Meetings with FDA **MAKE PROCESS MORE EFFICIENT**

According to a report from the U.S. Food and Drug Administration, 52% of companies that held milestone meetings with the FDA at the end of Phase II trials received approval during the product's first round of FDA reviews. But only 29% of sponsors that did not have consultation meetings in this phase gained approval during the first review cycle for their product.

The report, entitled Independent Evaluation of FDA's First Cycle Review Performance — Retrospective Analysis, also noted a positive link between a first-cycle approval and an earlier consultation before the application is even submitted. Of 58 products with these types of meetings, almost half received first-cycle approval.

52% of companies that held milestone meetings with the FDA at the end of Phase II trials received approval during the product's first round of FDA reviews.

Most products with multiple cycles had major deficiencies identified in one or two areas. Deficiencies in safety assessment were the most common reason for the FDA requesting additional cycles, followed by efficacy and chemistry/manufacturing related issues.

But consulting with the FDA does not always prevent the need for multiple review cycles. According to the independent study, which was conducted by consulting firm Booz Allen Hamilton, even when major issues with an application are identified by the FDA in milestone meetings, sponsors do not always adequately address them prior to submission of the application. In fact, 71% of applications where key issues were identified by the FDA during presubmission meetings were not adequately resolved by the sponsor by the time of first action.

"These meetings have become one of the most valuable aspects of the drug development process," says Acting FDA Commissioner Andrew von Eschenbach, M.D.

NEWS SIGNS OF LIFE Among Pharmaceutical Stocks

Standard & Poor's Equity Research Services forecasts pharmaceutical profits to rise modestly this year, helped by improved new product flows, Medicare Part D, continued cost streamlining, and a rosier picture for litigation issues. Based on these improving conditions, Standard & Poor's has raised its fundamental outlook for large pharmaceutical firms to positive from neutral.


Herman Saftlas

Despite near-term uncertainties over pricing and patent expirations, we think pharmaceuticals remains one of the healthiest and widest-margin U.S. industries, says Herman Saftlas, Senior Equity Analyst for Pharmaceuticals at Standard & Poor's.

"We see longer-term prospects enhanced by demographic growth in the elderly (accounting for about 33% of industry sales) and by a healthy number of products in the pipeline, including new therapeutic products from discoveries in genomics and biotechnology," says Herman Saftlas, Standard & Poor's senior equity analyst for pharmaceuticals. "In our view, merger cost economies and synergies should also bolster profits at many companies. In addition, many pharmas also offer what we see as attractive price-to-earnings ratios and dividend yields."

Standard & Poor's Equity Research also views the prospects for the generic/specialty pharmaceutical segment remaining favorable.

"We see a large number of blockbuster drugs losing patent protection over the next few years, providing significant opportunities for this sector," Mr. Saftlas adds. "We also think the new Medicare drug plan will be especially beneficial for generic firms."

Legislation Uncertainty **SLOWS ADOPTION OF PHARMACEUTICAL RFID TRACKING**

No more than about 10 medications are expected to receive large-scale tagging for RFID tracking in 2006, according to a study from ABI Research. This stands in contrast to the optimism early last year, when evidence suggested an almost 3.5-fold increase in life-sciences RFID transponder shipments between 2005 and 2006.

ABI Research analysts attribute the slowdown to cost, a retreat from the excitement of early market hype, and a desire to execute small-scale pilots before committing to full deployments.

Analysts suggest that another factor inhibiting

growth in this market is the "on hold" status of the U.S. Prescription Drug Marketing Act (PDMA). This legislation requires drug manufacturers to prove they have processes in place to prevent the diversion of drugs. This encompasses the idea of "pedigree," or the ability to trace a shipment's "chain of custody" at all stages, from manufacturing to delivery.

Certain states, such as Florida and California, have passed their own pedigree laws, and the FDA has set a target for widespread use of drug-shipment tracking.

But analysts say it's clear that the FDA's RFID expectations will not be met, as many companies plan to use bar codes to satisfy state pedigree laws. Also, the market could slow even more if state pedigree laws are pushed back.

Pharma Looks to **FIND AND DEVELOP NEW TALENT**

As baby-boomers retire, the skill sets and experience levels of a high-performing workforce are diminished.

Additionally, prospective employees are growing in diversity, and their needs are changing the ways corporations think about recruitment.

In light of those changes, companies are finding new ways to attract top talent, according to a new study from Best Practices LLC.

HIRING TOP TALENT

- The most effective people for building relationships with universities are high-profile employees with connections from their own educational background or leadership status in professional or minority groups.
- Companies can reduce costs and improve programs if strategic and tactical advisory committees are employed to help foster a shared ownership of recruiting programs.
- Companies that use automated requisition templates to ensure high-quality postings report less rework and faster cycle times for requisition approvals, ultimately impacting time-to-fill performance.
- At 86% of benchmarked companies, MBA graduates are direct hires and start their positions without going through a rotational program or career counseling.

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

Market Entrance **PLAYS MAJOR ROLE IN COMMERCIAL SPENDING LEVELS**

Entering a market occupied by established competition can cost 51% more than establishing a whole new market, according to Oncology Brand Commercialization, a report by Cutting Edge Information. Follow-on and me-too drugs spend an average of $31.5 million more on activities such as market research, competitive intelligence studies, and building campaigns against existing competition than first-to-market drugs. Follow-on oncology brands especially devote significant funds to diminishing the market share of established brands.

But some brand managers believe follow-on and me-too drugs have the upper hand in some aspects of marketing because thought leaders already have been educated on the drug class and mode of action by the first-to-market drug. According to Cutting Edge, first-to-market brand teams on average spend 127% more to educate specialists during launch than follow-on brands.

"Cancer drugs, unlike mass-market products for conditions such as high cholesterol or arthritis, require careful marketing that educates specialists," says Eric Bolesh, project team leader at Cutting Edge. "An oncology brand's position entering the market plays a major role in allocating resources."

Follow up

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