

Overview of the Bio-IT Landscape: Segmenting and Analyzing the Life Sciences Market in 2004

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March, 2004

LSI OPINION

Recent industry analyst reports predict that worldwide pharmaceutical industry revenues will grow at a compound annual growth rate (CAGR) of 8.58% through 2008. Worldwide biotechnology revenues are expected to grow at a compound annual growth rate of 25.96% through 2008 – this large growth rate is not surprising as many biotechnology and biopharmaceutical companies are just now moving products into the marketplace and generating significant revenue for the first time. Life Science Insights estimates that R&D spending within commercial life science companies will grow at a rate of 10.69% CAGR through 2008 for pharmaceutical companies worldwide and 13.8% for biotechnology companies worldwide. To understand the actual scope of this market and its potential for IT and other technology developers, it is necessary to understand technology spending in light of overall R&D costs and develop a model for how spending is broken out by customer segments, applications, and industry drivers.

At Life Science Insights it is our opinion that:

- Total IT spending (R&D and non-R&D) for the combined pharmaceutical and biotechnology industries will grow at a CAGR of 7.01% for the U.S. and 7.51% worldwide through 2008.
- R&D IT spending for the combined pharmaceutical and biotechnology industries will grow at a CAGR of 7.99% for the U.S. and 9.11% worldwide through 2008. R&D growth rates for pharmaceutical companies will be lower than years past for several reasons: pharmaceutical companies continue to merge and consolidate and account for capital depreciation from rapid growth over the last five years; in light of decreasing numbers of blockbuster drugs, the industry as a whole is moving to cut costs; with the increasing bargaining power of buyers of drugs (e.g. Medicare) and the globalization of the market (e.g. discounted drugs from Canada), the industry is moving to cut costs including R&D and R&D IT spending; and pharmaceutical companies will favor R&D alliances with biotechnology companies in lieu of rapidly growing their own in-house R&D programs.
- R&D IT spending for agricultural biotechnology companies will grow at a CAGR of 8.64% within the U.S. and 10.28% worldwide – primarily due to increased R&D spending for the development of GMO products in countries such as India and Australia.
- Industry drivers, such as a desire to decrease the times and costs associated with clinical trials, will drive innovation and technology development within the IT sector.
- Application areas such as biomarker discovery and validation, pharmaco- and toxicogenomics, and systems biology will drive innovation and technology development within the genomic, proteomic, and IT sectors.

In This White Paper

This white paper will look at the evolving life sciences technology and IT markets segmented by customers, applications, and drivers. We also identify some key areas for growth and opportunities for technology developers to play a significant role within the pharmaceutical and biotechnology industries. For more information Life Science Insights has available several reports and multi-client studies including “*The Green Book – IT*” and “*The Green Book – Tools*”, two quantitative reports that size and forecast the IT and tools and platforms markets within the life sciences space; “*Leading Indicators in Life Sciences*” and “*Best Practices in Drug Discovery and Development*”, two multi-client studies focused on benchmarking and identifying best practices used by pharmaceutical and biopharmaceutical companies for data acquisition and integration, target identification and validation, lead compound generation and optimization, and ADMET practices; and our subscription report series “*Life Sciences Market and Technology View*”, “*Drug Discovery Landscape*”, and “*Clinical Trials IT Infrastructure*.”

Segmenting and Sizing the Opportunity

Life science companies continue to embrace enormous technological change. In every area of discovery and development the pharmaceutical organization is forced to absorb techniques only months out of R&D and make decisions on how use to that data as part of their business practices. Even as IT and technology vendors continue to improve the utility of their products and services, they must sell them into a dynamic and highly fragmented marketplace. To compete successfully in this marketplace, vendors will need to:

- Develop a sophisticated understanding of how their products and services fit into the overall drug discovery model,
- Be able to demonstrate how their offerings impact the time and costs associated with life science product discovery and development, and
- Develop a realistic sizing of the market opportunity and forecast how that market will grow over the next five years.

The life sciences market is highly fragmented. Within this market there are many customers, vendors, and applications all focused on improving the productivity of drug discovery organizations. There are a number of ways to segment the market place. For purposes of this white paper we segment the market by:

- Customers
- Applications
- Market Drivers

Segmenting the Market by Customers

For purposes of this white paper, we divide the life science market customer base into three broad segments:

- Academic and Government Labs (non-profits)
- Biotechnology and Biopharmaceutical Companies
- Top 50 Pharmaceutical Companies

There are approximately 6500 academic institutions world wide. Within the U.S. alone there are many large government agencies that support life science research including the NIH, DOE, NSF, DOD, NASA and others. Many of these academic and government institutions support several laboratories engaged in life science research. It is our estimate that these life science institutions have a collective R&D budget of \$49,932 M within the U.S. and \$76,818 M worldwide in 2004. It is our estimate that these institutions will spend a total of \$3,657 M for R&D related IT in the U.S. and \$5,688 M worldwide in 2004. R&D IT includes hardware, software, content and services for life sciences related research and development.

A recent E&Y report calculates that there are over 4000 public and private biotechnology companies worldwide (*Beyond Borders – The Global Biotechnology Report 2003*). These companies range in size from publicly held biopharmaceutical giants, such as Genentech and Amgen, to private companies with less than 10 employees currently seeking venture capital. Clearly, these companies have different R&D spending. At Life Science Insights we estimate the total R&D spend for public and private biotechnology companies worldwide will be \$35,173 M for 2004 with \$25,453 M being spent within the U.S. It is our estimate that these companies will spend a total of \$2,545 M within the U.S. for R&D related IT and \$3,517 M worldwide for R&D related IT in 2004. R&D IT includes hardware, software, content and services for life sciences related research and development.

For purposes of this white paper, we size the pharmaceutical market at 50 companies based on revenue. We estimate the total R&D dollars spent by these 50 companies will be \$54,409 M for the U.S. in 2004 and \$68,787 M worldwide. Of that R&D budget, we believe \$3,809 M will be spent in the U.S. on R&D related IT and \$4,815 M will be spent on R&D related IT worldwide in 2004. R&D IT includes hardware, software, content and services for life sciences related research and development. Obviously, the total IT opportunity within the life sciences is higher than just the R&D related IT spending. It is our estimate that R&D IT spending accounts for 29.71% of the total IT spend within the pharmaceutical and biopharmaceutical space for 2004.

Segmenting the Market by Application

Within the *gestalt* of drug discovery, development, optimization, and pre-clinical and clinical trials there are several types of technology applications used. Within the discovery segment alone there are many techniques and methods that fall within the realm of genomics, proteomics, and bioinformatics. Many companies have developed innovative solutions for understanding molecular biology processes and are using that information to drive the discovery of therapeutic compounds and diagnostics. Technologies such as DNA sequencing, gene and protein expression profiling, and gene silencing through siRNA have become part of the mainstream work of biologists within the drug discovery industries. Many vendors have attempted to capture value from these technologies and it is important to realistically size the market opportunity when raising capital and selling to the life science community.

We discuss a few of those application market size estimates here:

- We define **genomics** applications to include techniques such as amplification, sequencing and genotyping, and RNA expression analysis. We size the market for genomics tools and services at \$2,700 M in 2002 and growing to \$3,600 M in 2004.

- **Proteomics** includes such areas as discovery and functional proteomics to include techniques such as high-throughput screening. We estimate the size of that market for 2002 at \$2,000 M growing to \$2,900 M in 2004.
- **Cell analysis** involves techniques such as microscopy, flow cytometry and high-content screening. In 2002, we estimate that market opportunity was \$3,700 M growing to \$5,100 M in 2004.
- **In vitro diagnostics** involves techniques such as nucleic acid testing and diagnostic immunoassays. While we estimate the total market opportunity for diagnostics in 2002 was \$20,000 M, the market for diagnostics that focus on DNA, RNA, and protein measurement was approximately \$11,000 M in 2002 growing to about \$15,800 M in 2004. We expect certain disruptive technologies could significantly alter the molecular diagnostics landscape over the next decade which would radically increase the growth rate of this important area.

Obviously, the acceptance and utility of many of these applications drive IT spending in order to acquire, analyze, and integrate the disparate kinds of data generated by these technologies. Table 1 shows some of the application areas we believe will have an impact on the IT markets within the life sciences over the next 7 years.

TABLE 1

Life Science applications and their impact on IT. The second column gives the year that we believe that application will gain full acceptance within the life science community. For level of impact on IT spending **L** = low, **M** = medium, **H** = high.

Application	When	Level of Impact	How
Ultra-High-Throughput Sequencing	2012	H	Processing speed, storage
High-Content Screening	2004	M - H	Image processing, storage, standards
Microscopy	2004	L	Image processing, storage, standards
Expression	2004	L - M	Data management
High-Throughput Screening	2004	L	Data management
Systems Biology	2005	H	Processing speed, data bases, data integration
Target Validation	2004	L	Processing speed, integration
Biomarker Discovery and Validation	2006	H	Data storage and management, standards
Clinical Trial Data Management	2004	H	Data storage and management, security, compliance
Pharmaco and Toxicogenomics	2006	M	Data management, integration
Personalized Medicine	2008	H	Data processing, security, compliance
Drug Manufacturing	2004	M	CRM and ERP applications

Segmenting the Market by Drivers

One obvious driver in estimating the market opportunity for technology solutions in the life sciences is the current cost of drug discovery and development. The oft-quoted Tuft's study estimates the time and cost of drug discovery and development at 10.9 years and \$802 M for the year 2003. Clearly, any technology, lab or IT based, that can demonstrably lower costs and reduce development times will be welcomed by the industry. There are a number of pain points that can be targeted by technology and IT vendors. Two that we will mention briefly in this paper include reducing the cost and time of clinical trials, and enabling personalized medicine.

It has been estimated that the clinical trial segment of the drug development process can account for as much as 56% of total costs. Clearly, reducing this cost is critical to lowering the overall R&D costs associated with therapeutic development. There are many aspects of clinical trial management and clinical trial data management that can benefit from automation. Studies have shown that simply automating data capture can reduce the cost of clinical trials by 10% (~\$56 M). The cost of querying paper data from a trial can be as high as \$400,000 per query as opposed to \$20,000 for a trial that used electronic data capture (eDC).

At Life Science Insights we segment the clinical trial process into three broad segments, each with an obvious opportunity for IT solution providers:

- Clinical Trial Development and Initiation
- Clinical Trial Management
- Study Completion and Regulatory Filing

For more detailed information please see our 2004 taxonomy *Clinical Study Conduct and Management*. A second key driver covered by Life Science Insights is a push towards personalized medicine. Simply defined, we believe personalized medicine is the ability for a healthcare provider to get the right treatment to the right patient at the right time. Technologies that will enable personalized medicine include biomarker discovery and validation, pharmacogenomics and toxicogenomics, systems biology, and molecular diagnostics and theranostics. As our knowledge of the human genome improves and researchers are better able to link genomics discoveries with basic biological processes, physicians and healthcare providers will be able to segment clinical trials by patient population, identify risk factors for certain patient groups, stage diseases more precisely, and prescribe the right therapy at the most optimum point in the cycle of disease.

IT providers will play a key role in enabling this important field of medicine. IT and technology vendors have an opportunity to play a leadership role in creating data standards and methods for data integration. Solution providers can also form key relationships with regulatory agencies to provide them with technologies that otherwise might be unavailable due to cost. Many informatics vendors currently provide training to the FDA free of charge in order to assure that discoveries made using their technologies can gain regulatory acceptance and agency reviewers and pharmaceutical researchers will reach similar conclusions when reviewing their data.

Conclusions

We believe that the life sciences, especially drug discovery, development, and pre-clinical and clinical testing, offer many attractive growth opportunities for technology vendors and IT vendors in particular. While the overall IT CAGR within the U.S. is about 4.4% through 2007 (Source: *IDC Black Book*), life science R&D spending will drive R&D related IT spending growth at a higher rate. However, there are a number of issues that must be considered:

- The life science market is highly fragmented. Technology vendors should understand how their products and services address the needs of specific customers, how these products and services fit within the scope of other technology applications, and how they are impacted by market drivers.
- Market dynamics are unique for individual applications. 2004 dynamics are very different from 1999-2001 and are even different from 2002-2003. There are many macro and micro economic factors at play including merger and acquisition activity, intellectual property issues, regulatory and insurance issues, and international political and economic climates.
- To drive maximal commercial success, vendors need to address specific biological questions and issues.
- Technology continues to be “discovery” driven rather than “hypothesis” driven. Applications of technology tend to be “hypothesis” driven rather than “discovery” driven.
- Current market conditions combine to create significant opportunities and risks.

Recommendations for IT and Technology Vendors

There is no stronger recommendation we can make than for vendors to gain a complete understanding of the marketplace and current market conditions. Towards this end, we recommend that IT and other technology developers and providers:

- Build an understanding of the specific requirements for life science IT infrastructure and applications. Understand that a “killer app” might not exist and definitely does not exist for industry-wide implementation of a given technology.
- Develop a clear and detailed understanding of the space and where your company fits in. The life sciences are a collection of complex and rapidly evolving fields.
- Create an organization and culture that has the ability to recognize opportunities and move very fast to address them.
- Keep looking for life science applications of non-life science technologies.
- Make partnerships with specialized vendors and thought leaders in key areas of the life science space.

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