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BIOTECH *focus*

ADDRESSING THE NEEDS OF BIOTECHNOLOGY INVESTORS AND PLANTING THE SEEDS FOR A SECURE FUTURE.

Biotechnology this Century's most dynamic force - one positioned to reshape virtually every other Industry it intersects and to redefine our lives

The impact of Modern Biotechnology

The impact of modern biotechnology on the world's economy is becoming increasingly evident, as the past two decades of investments are now resulting in a wide range of new products, processes, and services. Total sales of these new biotechnology-based products in the USA, presently the major market, were approximately \$22 billion in 2003. It is estimated US sales alone will increase by 12% annually over the next decade, leading to total sales of approximately \$35 billion by 2006 (Ernst and Young, 2004).

Biotechnology has been defined by the United States Office of Technology Assessment (OTA, 1991) as any technique that uses living organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses. It is comprised of a continuum of technologies, ranging from traditional biotechnology based on long-established and widely used technologies, such as those used in fermentation, through to modern

biotechnology based on more recent techniques of recombinant DNA technology to enable the genetic manipulation of living organisms, modern immunology as a basis for new diagnostics and vaccines, and new cell and tissue culture techniques for the production of biological products.

Biotechnology is thus not an industry in itself, but a set of enabling technologies that are being applied to research and product development in several existing industries, notably in the pharmaceutical industry, agriculture and food processing, and in the conservation of the environment.



MARKET WATCH

Biotechnology TODAY is currently the most powerful investment sector and therefore has the most potential to create unprecedented wealth. This has created an area of opportunity for qualified investors. There is still a major untapped value in biotech and although it is speculative, the potential rewards can be tremendous.



Evolution of Biotechnology and investment

The evolution of new technologies is breathing new life into Biotechnology stocks. Already the new millennium has seen one of the most lucrative periods in the Biotechnology Industry.

Modern commercial biotechnology originated in the USA in the mid-1970s when the business and scientific community recognized the commercial opportunities arising from the new discoveries in genetics, immunology, and biochemistry. Biotechnology has been described as the first business with enough glamour to persuade eminent scientists that the entrepreneurial spirit and academic respectability are not mutually exclusive (Wyke, 1988). The major reason for the greatly increased role of the private sector in modern biotechnology is that for many of the new technologies the process and/or the product are protectable by patents and other forms of intellectual property rights. Thus a company is able to appropriate many of the benefits of its R&D investments in biotechnology, in contrast to previous public good research in biology, from which an individual or organization could not benefit directly from inventions by the commercialization of the intellectual property involved. This new situation means that powerful new discoveries in biology and genetics are able to be developed into valuable commercial products. In the USA, biotechnology developed as a business initially through the creation of new biotechnology firms, some 400 of which were already established in the USA by the late 1970s. The

characteristics of these start-up companies are that they are small, technology-based enterprises, often established in close association with a university. They are usually dependent on venture capital and equity investments.

They have a strong R&D component and a long lag time to product development. Many of the new biotechnology firms are loss makers, at least initially, and often need to go to the capital market more than once for venture capital and equity investments.

The major companies in the pharmaceutical industry and agribusiness have also progressively utilized biotechnology in their businesses, in order to develop new products, to reduce the costs of production, to improve productivity, or to conserve the environment. The areas where the major companies are investing in biotechnology are in human health care for new diagnostics, drugs, and vaccines; and in agriculture for products such as new biopesticides and novel crop varieties with improved characteristics, such as improved pest resistance, extended shelf life, or better processing quality. Approximately four times as much has been invested in R&D for biotechnology applications for human health care as for

agriculture. Total biotechnology-related R&D expenditure in the USA in 2003 was \$7.0 billion (Ernst and Young, 2003).

“ Total biotechnology related R&D expenditure in the USA in 2003 was \$7.0 billion ”
ERNST AND YOUNG 2003

The major companies became involved in biotechnology through both inhouse R&D and contract R&D with academic institutions and new biotechnology firms, from which the major companies owned or shared any resulting intellectual property. There has also been a significant public sector investment in modern genetics and related biological sciences, through universities and national research institutes, notably in the USA, Japan, Australia, and several European countries through the 1970s and 1980s, building on the discoveries in recombinant DNA technology and immunology of the early 1970s. The biotechnology business evolved differently in the USA and Europe, in that approximately two-thirds of all new biotechnology firms were established initially in the USA. Relatively few were established in Europe, where biotechnology has developed primarily through the major European pharmaceutical, chemical, and food companies, especially those from France, Germany, Switzerland and the UK, that operate globally. Similarly, in Japan, the large Japanese companies are the major investors.

SMARTER INVESTING:
Learn about the coming BOOM in Biotech before is too late!



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Market Size and Trends

In the current market, the average Initial Public Offering (IPO) has raised on the order of \$100 million - easily two or three times more than the average deal seven years ago.

In the 2000's there has been a new wave of investment in biotechnology as the first suite of novel products have come to market successfully. Total industry sales in the USA were approximately \$9.1 billion in 2003, an increase of 21% over the previous year. The estimated sales for 2004 were \$9.8 billion. It is estimated that these sales were for human therapeutics (75%), human diagnostics (17%), agriculture (3%), specialties (3%), and non-medical diagnostics (2%). An annual average growth rate of 12% is anticipated over the next decade, leading to a market of approximately \$31.4 billion in the USA alone by 2006.

Pharmaceutical industry

The early biotechnology-based products have been mainly human therapeutics. Product sales in 1996 were expected to reach \$7.8 billion. There are presently 50 products on the market in the USA. These are mainly products for gene therapy and new vaccines. There are approximately 284 potential new pharmaceuticals in clinical trials in the USA, 40% of which are being tested for cancer treatments and 10% being tested against AIDS/HIV (PHARMA, 2004). Biotechnology is now an integral part of new drug development. It is estimated that by the year 2006, 85% of all new pharmaceuticals will be produced as the result of using biotechnology in both the R&D and production processes.

New diagnostics is an area where new biotechnology companies developing products for niche markets have been especially successful. Diagnostic monoclonal antibodies are being

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used in drug testing, cancer detection, pregnancy and fertility testing, and the diagnosis of infectious diseases such as AIDS and herpes. Sales of human diagnostics are expected to be \$1.75 billion in 2003 and grow at least 9% annually.

Agriculture and food processing

Biotechnology now has increasing commercial applications in agriculture and food processing. There are at least 15 new products on the market, with the first recent releases of new varieties of crop plants with novel traits (e.g. cotton with insect resistance, potatoes with disease and insect resistance, and tomatoes with extended storage life; canola with herbicide resistance).

“Total industry sales in the USA were approximately \$9.1 billion in 2003, an increase of 21% over the previous year”

In 2003, it was estimated that there were approximately 0.6 million ha of novel crop varieties grown in the USA. Other products on the market include new diagnostics for plant and animal diseases, biopesticides, and vaccines to prevent animal diseases. Annual sales of the novel agricultural biotechnology products were estimated to be \$310 million in 2004, with a rapid annual growth rate of 20% predicted over the next decade as the many new products in the pipeline come to market. In the agriculture and food sector, it is recognized that the products of biotechnology will be delivered mainly through seed. The time to commercial release of some products has been delayed by the lengthy and controversial regulatory processes in the USA and the European Union, due to public perceptions of possible risk from the release of genetically engineered organisms into the environment.



The regulatory system in the USA and Canada is being streamlined but the EU system continues to be time-consuming and controversial.

Environmental biotechnology

Biotechnology techniques, based on the use of microorganisms, can be used to clean up hazardous waste sites, to degrade industrial waste, to clean up oil spills and to rehabilitate mining sites. While long-standing problems in industrial countries, these environmental problems are also emerging in the newly industrialized countries and new, biologically based solutions are being sought. Environmental biotechnology is a growing segment of the market, with sales forecast to grow from \$250 million in 2005 to up to \$620 million by the year 2007.

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The next STEP Biotech is HOT

The top 50 biotechs have rocketed 87% since August. Learn about undervalued companies set to Explode to the Upside But most investors are missing out. Here's how you can get the inside secrets to making money in this fast paced market.

The time is right for biotech investing as healthcare spending is set to double over the next 10 years from \$1.7 trillion in 2003 to \$3.4 trillion in 2013. Prescription drug spending will lead the increase.

... continued from page 3

Biotechnology also offers the possibility of more environmentally sustainable agricultural production, for example by the use of novel biological agents rather than pesticides to control plant pests and weeds, an advantage both to the environment and to the consumer. There are several new biopesticides emerging, with potential for use in integrated pest management systems in a range of crops where pesticide use is presently excessive and damaging to human health and the environment (Waage, 2003).

Production and marketing

The novel products arising from biotechnology have been taken to market mainly by the major pharmaceutical companies

and by the agrochemical and seed companies. Many of the technologies were developed either by public sector laboratories or by new biotechnology firms. These technologies have either been licensed to the major firms or the latter have acquired new firms with promising technologies. The major companies have three advantages: (1) a global distribution and marketing network; (2) sufficient cash flow to acquire new firms with their intellectual property; and (3) the funds to continue to invest a proportion of their profits in R&D to develop the next generation of novel products. This trend towards mergers and acquisitions is particularly evident in agriculture, where much of the enabling technology, intellectual property, patents, knowledge, and investment in the commercial use of agricultural biotechnology now lie with a small number of multinational companies.

There is a rich pipeline of innovative biotechnology-derived drugs on the horizon with more than 370 biotech drug candidates and vaccines currently in late-stage human trials.

The biotech industry has proven that it can deliver new innovative drugs as well as powerful sales and earnings growth. In 2003 Amgen announced product sales double from 2001 levels growing to \$7.8 billion. Genentech projects a minimum 20% EPS growth year-over-year through 2010.

Prepare yourself now, the time is ripe. In the process, you'll build a legacy of lasting wealth -- safely and securely -- just like the richest families in America.



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