

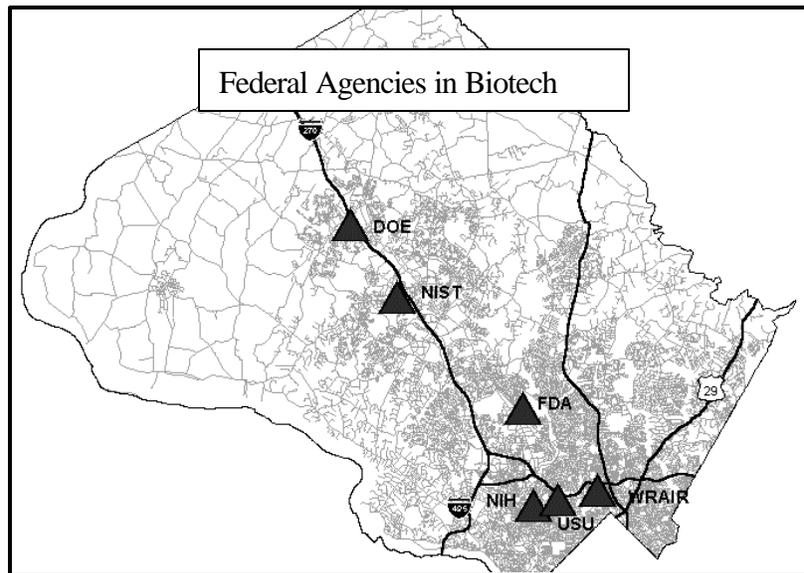
# Montgomery County's Biotechnology Industry

## Institutions in Biotechnology

### Federal Agencies in Biotech Research

The biotechnology industry in Montgomery County was born out of the federal research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), Walter Reed Army Institute of Research (WRAIR), the Uniformed Services University of the Health Sciences (USUHS), and the National Institute of Standards and Technology (NIST). These federal labs provide a critical mass bioscience labor force, including scientists who become entrepreneurs of biotech firms. The federal government has several programs that encourage entrepreneurship by its scientists. The founders of EntreMed and MedImmune came from WRAIR and the founders of The Institute for Genomic Research, Human Genome Sciences, and Celera Genomics came from NIH. One biotech industry observer said that the federal labs are “not so much a magnet as a fountain.” They are a source of labor force, founders, and contracts for new companies.

The U.S. Government supports the largest share of the world's biotechnology research, much of which is performed by NIH. NIH is comprised of 18 institutes including the National Human Genome Research Institute, the National Cancer Institute, and the National Institute of Allergies and Infectious Diseases. The Department of Energy together with NIH is a major sponsor of the international Human Genome Project. In addition, the Walter Reed Army



Institute of Research and the Uniformed Services University of Health Sciences have active vaccine research and therapeutic drug development programs aimed at protecting U.S. armed forces from infectious diseases. The National Institute of Standards and Technology (NIST) in Gaithersburg has a Biotechnology Division whose mission is to advance the commercialization of biotechnology. NIST and the University of Maryland have jointly formed the Center for Advanced Research in Biotechnology (CARB) at the Shady Grove Life Sciences Center.

## Non-Federal Institutions

### Montgomery County and State Government Programs

In addition to the aforementioned federal programs, Montgomery County government created an extensive plan to attract and encourage biotech, a natural target in view of the strong federally supported scientific community in the County. In the early-1980s, the County developed the Shady Grove Life Sciences Center (SGLSC) a 288-acre park owned and operated by the County and specifically zoned for research and development. The County received subdivision approval in 1989 and has sold or leased land to a dozen biotech entities. There are currently no vacant parcels left to sell or lease in the SGLSC.

Recognizing that academic institutions are integral to successful biotech communities, the County donated land in the Life Sciences Center to Johns Hopkins University and the University of Maryland. Hopkins and Maryland received 35 acres and 50 acres, respectively, for their Montgomery County campuses. Furthermore Johns Hopkins' first building and the University of Maryland's Center for Applied Research in Biotechnology (CARB) were built with County funds. Many biotech companies occupy the remaining land parcels or are clustered just outside the park boundary. The biotechnology firms in, or adjacent to, the Life Sciences Center include:

- Atlantic Biolabs, Inc.
- Atto Instruments
- Bioqual, Inc.
- BioReliance
- Biosource Proteomics
- Diagon
- EntreMed, Inc.
- Galenica Pharmaceuticals, Inc.
- GeneDX
- GenoQuest, Inc.
- GlycoTech Corp
- Hemispherx Biopharma, Inc.
- Human Genome Sciences, Inc.
- Large Scale Biology Corporation
- Life Technologies, Inc.
- Neurologic, Inc.
- Otsuka America Pharmaceutical, Inc.
- Panacea Pharmaceuticals, Inc.
- StaphRx, LLC
- Supertechs, Inc.
- Tetracore, LLC
- TherImmune Research Corporation
- The Institute for Genomic Research (TIGR)
- Virion Systems

In January 1999, the County opened the Maryland Technology Development Center (MTDC), a 50,000 square foot incubator for start-up biotech and info tech companies, at the north end of the Life Science Center. MTDC is home to 12 biotech companies and contains 24 outfitted laboratories totaling 18,000 square feet and ranging in size from 400 to 800 square feet.). Since December 1999, MTDC is 100% occupied and as of July 1, 2000, fourteen biotech companies have been wait-listed. The County is currently planning an MTDC expansion of 5,000 square feet.

## **Universities**

As previously discussed, Johns Hopkins University and the University of Maryland are both located at the Shady Grove Life Sciences Center (SGLSC) in Montgomery County. Johns Hopkins annually provides over 8,000 students the opportunity to pursue graduate degrees on a part-time basis. Many of the campus' programs focus on areas such as biotechnology and bioinformatics and are designed for biotech professionals, engineers, scientists and lawyers. The University of Maryland in collaboration with the National Institute for Standards and Technology has established the Center for Advanced Research in Biotechnology (CARB), a 120,000 square foot facility with state-of-the-art laboratories for collaborative research among academic, government, and industry scientists. This site also houses the University of Maryland System Shady Grove campus, offering a four-year undergraduate degree. In addition to their own research, these universities have contracted out research to some of the firms covered in the interviews. Biotech workers also take courses offered by the universities in science and business administration fields.

A number of the interviewed firms consulted for local universities. Four companies consulted for Johns Hopkins University and three consulted for the University of Maryland. Two of the firms participating in the survey had CRADAs with Johns Hopkins University or the University of Maryland. The amount of this research was considerably smaller than that funded by the federal government.

## **Howard Hughes Medical Institute**

Another presence elevating the biotechnology industry in Montgomery County is the headquarters of the Howard Hughes Medical Institute (HHMI), one of the most heavily endowed research institutions in the world. Although the Institute's main function is to support medical research, no research is performed at HHMI's Chevy Chase headquarters. The headquarters administers HHMI's programs and has disbursed about \$2.1 billion dollars over the past five years. Locally, the Institute supports 50 students from 35 institutions participating in the HHMI-NIH Research Scholars Program in Bethesda. Outside the County, the Institute supports some 330 investigators at the Institute's 70 laboratories housed at medical centers, teaching hospitals and university campuses. These researchers, together with their support staffs, are HHMI employees and are compensated directly by the Institute.<sup>4</sup>

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<sup>4</sup> Howard Hughes Medical Institute website, [www.hhmi.org](http://www.hhmi.org)

## The Importance of the Biotechnology Industry

A number of years ago John Naisbit, author of *Megatrends*, said that the impact of biotechnology would be bigger than electronics. A biotechnology industry analyst states “In the long run the potential of deciphering the mysteries of biology are probably much bigger and longer lasting than the impact even of the Internet.”<sup>5</sup> “The commercial drug market totals more than \$300 billion a year, and this vast industry is about to be transformed: Biotechnology will create drugs that are like precisely calibrated wrenches—able to unlock diseases we now try to destroy with the equivalent of dynamite or a blowtorch.”<sup>6</sup> The state of development of the biotechnology industry today is comparable to the computer industry in the mid-1970s. In humans the promise is for drugs that mimic the proteins that healthy cells produce to control body processes and even to substitute health-producing genes for ones that cause disease. In agriculture, breakthroughs of similar magnitude are possible.

Montgomery County is one of the most important centers for the biotechnology industry. In size, the County, with its 15,000 biotechnology workers, is second only to the San Francisco area and about tied with the Boston area for the largest number of firms. The large federal health agency labs listed earlier give the County its unique base for biotechnology.

Another aspect of the County’s biotechnology industry is our high concentration of resources in genomics and bioinformatics. The sequencing of the human genome will likely be one of the watershed events of the century and the County’s biotech industry is at the center of this important work. Following the discovery of the full human genomic sequence, the equally important work of discovering the way each gene’s sequence controls processes in the body will take center stage and continue for decades. This field is called bioinformatics and several local companies are active in this field.

## Sequencing the Human Genome

Determining the entire sequence of DNA bases that make up the human genome is one of the most important aspects of biotechnology today. Although, in the past, the locations of many individual genes have been mapped on chromosomes and genetic sequences had been determined for some, having the entire sequence will provide an invaluable resource for researchers. Many genes act by switching other genes on or off. Having the entire sequence will help researchers determine these important interactions.

Two entities were the main competitors for the prize of being the first to publish the entire human genome sequence. Both have major presences in Montgomery County. While the Human Genome Project is a worldwide endeavor, the U.S. Department of Energy and the National Institutes of Health

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5 Colleen Bazdarich, CBS Market Watch, February 25, 2000

6 David Ignatius, “Biotech Bubble,” *Washington Post*, June 28, 2000, page A25

are major sponsors of the project. The National Human Genome Research Institute (NHGRI) at NIH administers the project. The Institute for Genomic Research (TIGR) at Shady Grove, a private nonprofit entity, is one of many organizations worldwide working on the HGP.

In May 1998, a private firm, Celera Genomics of Rockville was founded by Dr. J. Craig Venter, PhD. to challenge the government driven Human Genome Project with a stated goal of mapping the genome several years faster, by the end of 2001. The competition between these two drove the project to a much faster completion than originally planned, culminating in their joint announcement at the White House on June 26, 2000 of the completion of their respective draft human genome sequences.

Celera Genomics is a subsidiary of Massachusetts based PE Corporation, an outgrowth of Perkin-Elmer and a leading supplier of life science systems and analytical instruments used by the pharmaceutical and biotechnology industries. Perkin-Elmer will retain ownership of about 80 percent of the new company. Celera will combine the rapid gene sequencing of Perkin-Elmer equipment with Dr. J. Craig Venter's genomic expertise to shave several years off the process plus map the genome of the most frequently used test animal in human medicine experiments, the mouse. Celera will follow-up by interpreting the sequence to make it useful to its clients in the pharmaceutical industry. One of the products that Celera will offer exclusively to its paying customers is the mouse genomic sequence arranged in the same order as the human sequence. Celera has also formed a strategic alliance with Compaq Computer Corporation to ensure it has sufficient computer power to handle the billions of fragments of genomic data for sequencing. Celera has the largest concentration of gene sequencing machinery in the world and the largest civilian concentration of computing power. This system uses 700 interconnected 64-bit processors, capable of 1.3 trillion floating point operations a second, and a 50 terabyte (50,000 gigabyte) database growing at 10 terabytes a year. What once took 10 years can now be done in 15 seconds.<sup>7</sup>

The company will derive revenues from its information, primarily as access fees from database customers (e.g., pharmaceutical, biotechnology companies, research institutions) who will retain the rights to any discoveries made using Celera databases. While the sequences themselves will become public knowledge Celera will offer its customers the application of its huge computing power and genetic expertise to sift through the billions of pieces of information in search of promising drug leads. Celera completed its pilot project, the sequencing of the fruit fly genome, in the fall of 1999. Following that success, between September 1999 and April 2000, it finished the basic reading of all the DNA of one human. Now it has completed arranging all the pieces in a draft order.

The Human Genome Project is committed to putting all its results daily in the public domain database GenBank maintained by the National Center for Biotechnology Information at NIH at [www.ncbi.nih.gov](http://www.ncbi.nih.gov). GenBank now holds sequence data on more than seven billion units of DNA from a

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<sup>7</sup> [www.compaq.com/alphaserver/news/celera\\_june00](http://www.compaq.com/alphaserver/news/celera_june00).

variety of species.<sup>8</sup> Its private sector competitor, Celera Genomics, while committed to public release of the entire genome through publication in a scientific journal, is obtaining patents on some of the key sequences and selling access to its data base and tools to its subscribers.

## **Bioinformatics**

With the entire sequence soon to be made public, the next critical phase of determining the roles of genes in the body will accelerate. Several Montgomery County companies are active in the discovery of drug applications from the genomic sequence, part of a field known as bioinformatics. Much of this work will be computer analysis of the data from the human genome. The action, interaction, and expression of genes through the proteins they produce are much more complex phenomena than the straight reading of the genomic sequence. This phase will provide several decades of work for hundreds of biotechnology companies. “One of the most basic operations of bioinformatics involves searching for similarities, or homologies, between a newly sequenced piece of DNA and previously sequenced DNA segments from various organisms. Finding near-matches allows researchers to predict the type of protein the new sequence encodes. This not only yields leads for drug targets early in drug development but also weeds out many targets that would have turned out to be dead ends.”<sup>9</sup> Celera and Human Genome Sciences will apply their great expertise and computer power to be very active in this bioinformatics phase. Other Montgomery County firms including Gene Logic and InforMax are already marketing computer database and software tools to help with this next phase.

Whereas Celera has seen itself primarily as an information company, Human Genome Sciences (HGS) plans to become a global pharmaceutical company developing drugs from the gene sequence up. Gene Logic of Gaithersburg takes an approach between these two, focusing on the expression of genes in diseased tissue to help its subscribers to more easily identify drug development targets. InforMax, located in an office building off Rockville Pike, develops database software to help researchers gather meaning from the overwhelming amount of genetic sequence data.

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<sup>8</sup> Ken Howard, “The Bioinformatics Gold Rush,” *Scientific American*, July 2000 on [www.sciam.com](http://www.sciam.com)

<sup>9</sup> *Ibid.*

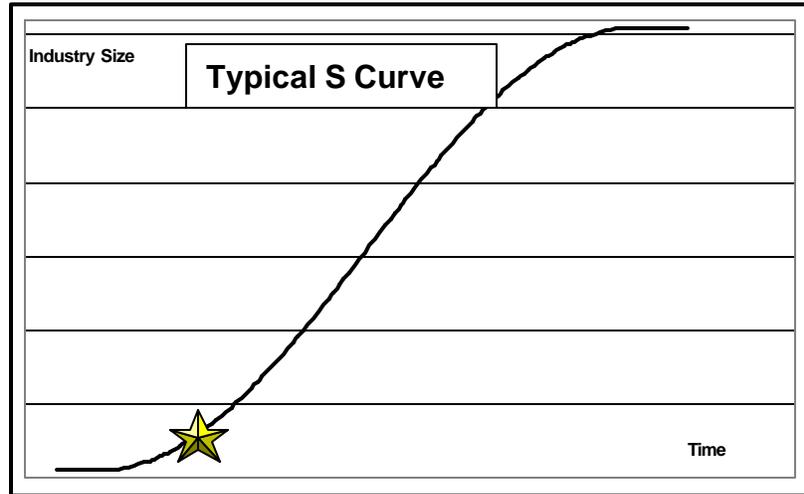
# The Biotechnology Industry is Rapidly Growing

## “S” Curve Growth

Industries, just like biological populations, follow an “S”-shaped growth curve. A typical S-curve growth cycle is illustrated in the schematic graph at the right where the vertical axis represents the size of the industry and the horizontal axis represents time.

Growth in a new industry accelerates from a long, slow initial growth phase then takes off into rapid growth and eventually decelerates into slow growth again as it nears maturity.

Although it is impossible to tell the eventual size and year 2000 position of the biotech industry on this growth curve, it is clear from the rapid acceleration of



employment, research expenditures, patents and biotech drug approvals that the industry is probably moving from its early innovation phase into its rapid growth phase about this time. The star on the graph indicates this point schematically. This point is probably similar to where the electronics industry was in the mid-1970s, a few years before the introduction of the first personal microcomputers.

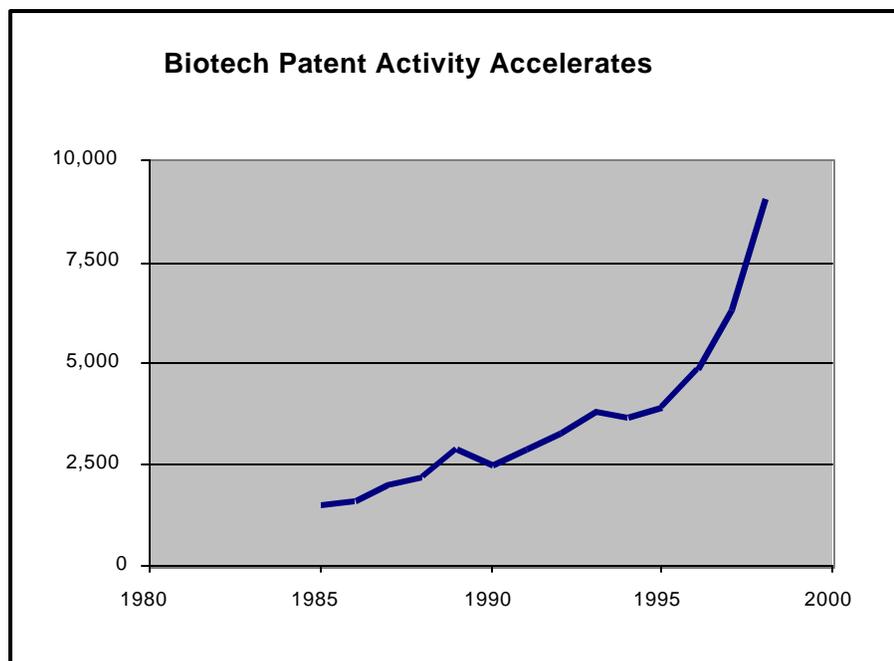
The shift from the slow growth phase into rapid expansion can be seen in the following table showing S-curve employment growth. In this example all phases are of equal length (e.g. years, decades), the employment growth in each phase can be quite different. Phase two starts when the industry already has 1,000 workers. During this phase the employment growth of this hypothetical industry is 9,000 employees. By the third phase, when the industry has entered the rapid expansion mode, the need for additional employees has increased ten-fold to 90,000 workers. This sharp increase in employee growth is dwarfed as the industry enters its fourth phase. There the employment jumps by 400,000 workers. This strong employee need continues in the fifth phase when another 400,000 workers are required. By the sixth phase, the growth declines to 90,000. This sharp shift downward is an indication that the industry has entered the mature growth phase. The seventh phase shows that the industry has nearly reached the peak of its employment and the need for additional workers has leveled off.

<b>Typical “S” Curve Growth of Industry with a Million Jobs</b>			
<b>Equal Periods of Time</b>	<b>Growth as % of Eventual Size</b>	<b>Job Growth in Period</b>	<b>Industry Size</b>
Second	0.9%	9,000	10,000
Third	9.0%	90,000	100,000
Fourth	40.0%	400,000	500,000
Fifth	40.0%	400,000	900,000
Sixth	9.0%	90,000	990,000
Seventh	0.9%	9,000	999,000

The classic S-curve shows the following characteristics derived from the growth patterns of now-mature industries. Growth from 0.1% to 1% of eventual size takes as long as growth from 1% to 10%. Thus the 1% to 10% phase generates ten times as much growth in the same amount of time. This is followed by even more rapid growth, over four times the rate of the previous time period. From 10% to 50% takes this same period of time as the 1% to 10% and reaches the middle of the curve. Growth is now starting to slow and from 50% to 90% takes the same time as the previous periods. Another period of the same length takes the industry from 90% to 99%.

## Evidence of Rapid Growth

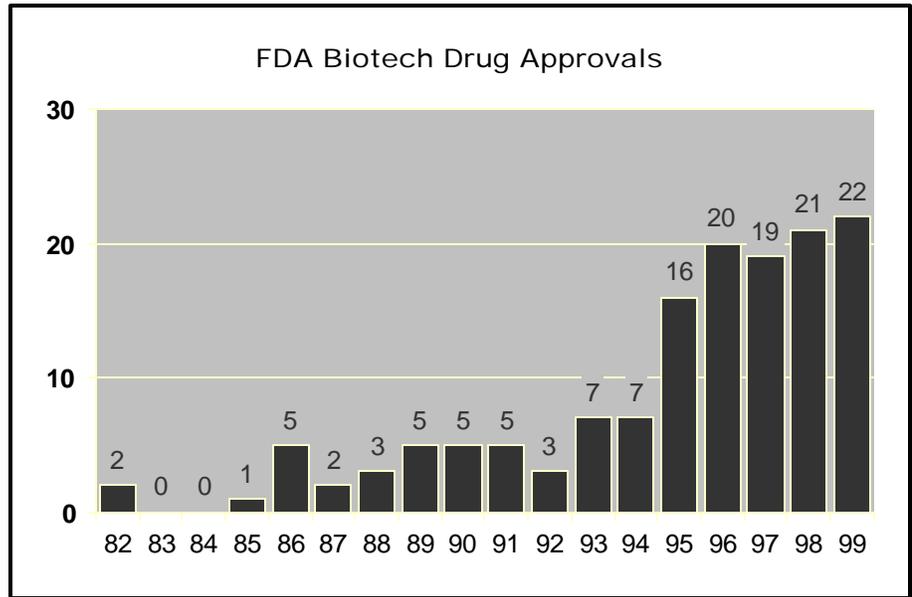
Evidence for the acceleration of biotech’s growth abounds. Patents for biotechnology innovations have increased about six-fold, from about 1,500 in 1985 to over 9,000 in 1998. Another indicator of the acceleration in the biotech industry is the number of FDA approvals of biotech drugs over the past 18 years. Approvals represent the successful conclusion of a development process that



takes about ten years. Therefore the effects of recent sequencing of the human genome have yet to show up in these numbers. Still there has been a dramatic increase in approvals based on earlier biotechnology drug targeting innovations. Looking ahead, 350 biotech drugs are now in clinical trials.

These will result in many more approvals in the next several years. The public domain availability of the complete human genome sequence should dramatically increase the flow emerging from the approval pipeline ten years hence.

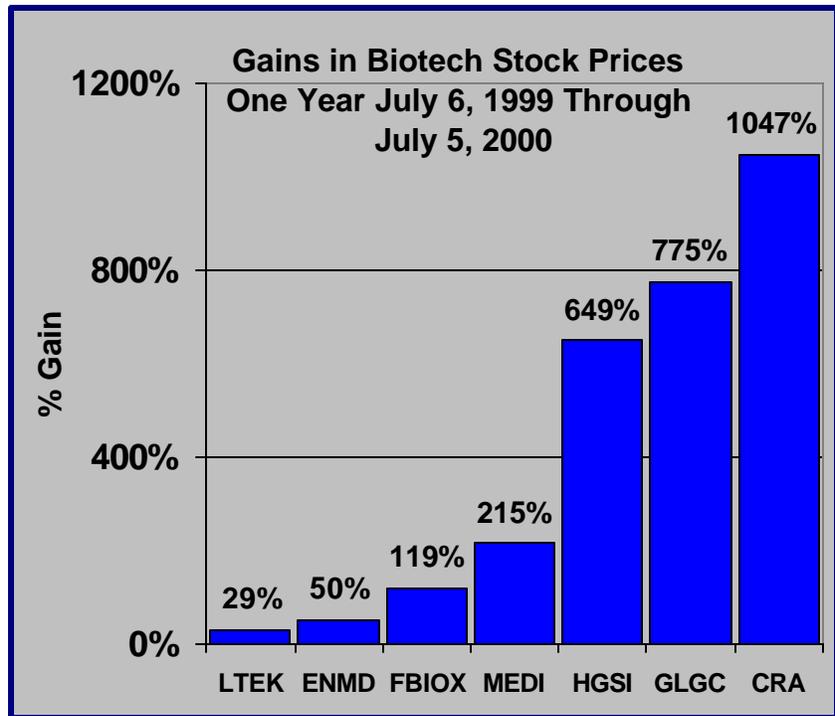
Nationally, the market for processes and products coming from medical biotechnology is expected to grow dramatically. The Consulting Resources Corporation estimated the 1996 revenues and



the anticipated 2006 revenues to the two major categories of human medical biotechnology, therapeutics and diagnostics. The market for human therapeutic biotechnology products will grow from \$7.6 billion in revenues in 1996 to more than \$24 billion in 2006, an average annual growth rate of 13 percent. The human diagnostics biotechnology product sector is expected to grow at an average annual rate of 9 percent from \$1.8 billion in 1996 to approximately \$4 billion in 2006.<sup>10</sup> Additional biotechnology revenues come from the expanding agricultural market. Agricultural biotechnology products are expected to increase from \$295 million in 1996 to \$1.74 billion by 2006, with applications ranging from food crops with enhanced pest resistance to improved methods of food preservation. The total industry may expand much faster than these estimates based on final product revenues. The lengthy drug approval process will generate a lag in the growth of final product revenues but eventually the breakthroughs we are seeing now in gene sequencing and interpretation of gene interactions will dramatically swell the volume of approved products.

<sup>10</sup> U.S. Department of Commerce, Office of Technology Policy. The U.S. Biotechnology Industry, Meeting the Challenge: U.S. Industry Faces the 21st Century, (Washington, D.C., July 1997), p. 10-12.

Another indicator of the growth potential of the biotech industry is the sharp increase in market capitalization represented by increases in stock values. These increases represent increased availability of capital to fuel the growth of this young industry. Over the past year capital valuations have increased enormously as investors have recognized that the growth potential for this industry is blossoming. It should be noted that these values represent the market after a substantial correction in the market that removed over half of the early-March values of the highest-flying stocks. Six Montgomery County companies and one industry mutual fund are represented in this graph:



- LTEK – Life Technologies
- ENMD – EntreMed
- FBIOX – Fidelity Select Biotechnology (as a proxy for the national industry)
- MEDI – MedImmune
- HGSI – Human Genome Sciences
- GLGC – Gene Logic
- CRA – Celera Genomics

The stocks in this sector are extremely volatile and the results shown above do not predict future results. Even Life Technologies’ 29 percent growth is an impressive annual growth rate.

## Critical Mass Attracts Supporting Industries

As the County’s biotechnology industry continues to grow, it has gained the critical mass necessary to attract non-bioscience companies that specialize in supporting the biotech industry.

Several firms in the real estate industry now specialize in building, leasing and equipping buildings for biotech users. These include Scheer Partners, Alexandria Real Estate Equities, and W. M. Rickman Construction Company. Scheer Partners offers a comprehensive range of service to its clients including leasing, arranging financing, and acquiring, installing and maintaining equipment. Whereas some real estate firms seem to shy away from dealing with the complexities of providing equipped

buildings for biotech clients, Scheer Partners finds opportunities in helping biotech companies deal with these challenges. As the industry matures, more firms will embrace these opportunities. Alexandria Real Estate is a Real Estate Investment Trust specializing in biotech properties. They now own 21 buildings in Montgomery County totaling over 1.2 million square feet and have proposed two more, totaling 149,000 square feet. They purchased three buildings at Northfield Business Park in Gaithersburg in July 2000. Their buildings house some of the prominent County companies including MedImmune, Gene Logic and Digene. W.M. Rickman Construction Co. is involved in developing, owning, leasing and managing buildings including those for many biotech companies. Rickman is involved in 26 buildings in the County, totaling over one million square feet, primarily in the East Gude Drive and Shady Grove areas. Prominent companies located in Rickman buildings include EntreMed, Diagon, and SRA Life Sciences.

The legal profession has a growing awareness of the potential business to be generated by biotech firms and several law firms are setting up new offices in the I-270 corridor to be close to these clients. These firms handle FDA regulation, licensing, intellectual property, finance, and database access deals.<sup>11</sup>

Most of the venture capital firms serving the biotechnology industry are presently operating out of other areas such as California or Boston but their presence here is expanding.<sup>12</sup>

## **Implications of Rapid Growth for Montgomery County**

Rapid growth of the biotechnology industry over the next few decades has implications for the County.

- Biotech research jobs fit well with the County's highly educated and well paid labor force. These workers are attracted by and contribute to our traditionally high quality of life.
- Rapid growth will mean that the search for appropriate space, particularly specialized wet lab space, will continue to be a challenge for the industry.
- The expensively equipped laboratory buildings used by many biotech firms will contribute to the County's real and personal property tax bases.

The 15,000 biotechnology jobs comprise less than three percent of total jobs currently in the County. But if the rapid growth phase were to result in a hypothetical ten percent annual growth for two decades this share would grow dramatically, from 2.8 percent of jobs now to 15 percent in 2020.

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<sup>11</sup> Taitana Boncompagni, "Chasing the Biotech Balloon," *Legal Times*, February 28, 2000

<sup>12</sup> Patricia L. Larrabee, Director Biotechnology Services Group, Scheer Partners Inc., interview March 22, 2000

What are the implications of this growth? With growth at ten percent per year biotech employment would grow from about 15,000 in 2000 to about 100,000 in 2020. Where would it go? The December 1999 pipeline of jobs for approved subdivisions indicates that there is currently transportation capacity to serve new buildings housing about 139,000 added jobs in the County. Beyond the pipeline capacity, there is enough vacant land and redevelopable land in the CBDs to accommodate about 144,000 additional jobs. This capacity will be competed for by all industries in the County and not all of it will end up as biotech. If biotech were to grow by 85,000 jobs in the next two decades it would use up about 25 million square feet or about one-third of future capacity. Hence there is ample total development capacity for biotech in Montgomery County. Also some of the biotech growth can be expected to move into existing buildings as other industries vacate space.

The County will be able to continue to accommodate the community's need for corporate headquarters and R & D lab space. However, as the County's companies are granted FDA approvals and bring products to the market, manufacturing facilities will be of paramount importance. Recognizing that the County may be unable to accommodate the massive land needs associated with manufacturing, the County is proactively developing policies with other Maryland Counties to keep future biotech manufacturing in the State. Two biotech companies headquartered in Montgomery County, Life Technologies and MedImmune, currently have manufacturing facilities in Frederick County. Montgomery County officials were instrumental in locating the facilities in Frederick.

## **Biotech Firms Here Are Diverse and Interconnected**

Industries that contribute to an area's healthy economic growth have two important characteristics. They export goods and services out of the area and they have many connections with other entities within the area. Exports are important because they bring funds into the economy. The interconnections among the exporting firms themselves and with other area firms and institutions create a robustness that is absent when firms only export and don't interact. The biotechnology industry in the County exhibits both of these positive characteristics. The diversity of products and services offered by the approximately 200 biotechnology firms here contribute to the degree of interconnection by fostering sales and collaboration between companies. The extensive web of interconnections is discussed in this section. The firms we surveyed have connections with the federal research agencies, educational institutions, and each other.

## **The Silicon Valley Electronics Industry as a Model for the Biotech Industry**

The electronics industry in Silicon Valley, southeast of San Francisco has an open style of industrial organization characterized by an extensive web of connections among firms, workers and institutions. This industrial organization offers many advantages to rapidly growing, leading edge technology industries. This style involves extensive informal and formal contacts among firms; employees

move frequently and easily among firms. This style contrasts sharply with a closed, vertically integrated style practiced by electronics firms outside of Boston. The open style is credited in large measure for the success of Silicon Valley firms compared to a lesser performance by the Massachusetts firms. The biotechnology industry of the early 21<sup>st</sup> century shares many characteristics with the electronics industry of the 1970s and 1980s. Its technology is rapidly evolving and cutting edge. Among other aspects of the Silicon Valley culture is a cooperative win-win relationship with local and state governments.<sup>13</sup> The industry works with government to support physical infrastructure and educational programs needed to foster industry growth. In contrast the Boston area industry fought local government spending and emphasized tax cuts. The culture of the biotech industry in Montgomery County seems to share the interconnected trait with the California electronics industry. There are many types of connections among firms and also with local federal and educational institutions.

## **Federal Connections**

### **The Federal Role in Encouraging Research**

Federal research agencies have been able to support the formation of private firms through the Federal Technology Transfer Act of 1986, which allowed companies for the first time to form partnerships with NIH and other government agencies. One vehicle for this relationship is known as a Cooperative Research and Development Agreement (CRADA). Under these agreements, NIH, or another agency, supports outside research projects that they approve. The ability to form these relationships encouraged many employees of government labs to start their own companies. The founders of some of the firms participating in interviews for this report had been researchers at NIH or Walter Reed Army Institute of Research. The NIH, which is the primary vehicle for U.S. Government funding of biomedical research, is comprised of 18 separate institutes employing nearly 10,000 scientists. The Walter Reed Army Institute of Research is the Department of Defense's lead agency for infectious disease research.

Five of the 35 interviewed firms (see Appendix I) had Cooperative Research and Development Agreements with NIH, Walter Reed or the Uniformed Services University. Genetic Therapy, Inc. of Gaithersburg was the first company to share research with NIH under the 1986 Federal Technology Transfer Act. A team of researchers at the NIH, the institution is considered the birthplace of gene therapy, discovered that retroviruses (viruses based on RNA rather than DNA) could be used as vectors to carry desired genes into target tissues. In 1995, this team at NIH was awarded a patent on this basic technique for gene therapy. This patent is one of many that have been licensed under a CRADA to Genetic Therapy. The most prominent examples of this process involve former NIH scientist, Dr. J. Craig Venter and Harvard professor Dr. William Haseltine. Venter licensed a new gene sequencing technology he developed while at NIH to start a new not-for-profit company, The Institute

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<sup>13</sup> Annalee Saxenian, *Regional Advantage: Culture and Competition in Silicon Valley and Route 128*, Harvard University Press, 1996.

for Genomic Research (TIGR). Haseltine founded a related for-profit company, Human Genome Sciences, Inc. to help commercialize the new technology. Both of these companies are located in the Shady Grove area of Rockville. Genetic Therapy, TIGR and Human Genome Sciences are all represented in this survey.

The federal government also has several other funding programs that encourage private companies to engage in innovative research. These include the Small Business Innovative Research (SBIR) Program, the Small Business Technology Transfer (SBTTR) Program, and the Advanced Technology Program (ATP). The last program, which is administered by the Department of Commerce, seeks to identify and fund research programs with great potential benefits but whose high risks and costs would discourage private sector investment. Some of the biotechnology firms in Montgomery County have participated in these federal programs.

### **Contract Research with Federal Agencies**

Eighteen of the 35 firms interviewed, about one-half of the total, have performed some contract research for NIH. This research generally does not account for more than one-half of an individual firm's business, and many of them rely less on this source as they add clients over the years. The National Cancer Institute (Bethesda) is relatively active in this area, judging by survey results. Other federal agencies that use biotech firms for contract research include the National Science Foundation, the Food and Drug Administration, and the Center for Disease Control.

The Food and Drug Administration (FDA) controls the availability of drugs to the general public by way of the lengthy process through which new candidate drugs are developed, tested, and approved. All new drugs go through this process and therefore all companies seeking to introduce new drugs to the market have extensive contacts with FDA. The FDA is currently located in Rockville and will be moving to White Oak over the coming decade.

In addition to these programs for funding and technology transfer, the federal bioscience agencies also foster the industry by holding seminars and conferences which encourage interaction among scientists. The location of these agencies in the County encourages participation by the local biotech industry.

### **Connections with Educational Institutions**

Many of the firms we surveyed have varied connections with the higher education institutions in the County. The two universities and the community college with campuses in the Shady Grove area contribute to the technical and scientific education of area biotech employees. The universities also engage in research activities at Shady Grove and contract with local biotech firms to conduct research on a contract basis.

Employees of seven of the surveyed firms took courses at Johns Hopkins University or the University of Maryland. Johns Hopkins offers a popular MBA program geared toward scientific staff. Some local companies subsidize tuition for their employees. None of the participants in the interviews indicated that their employees took courses at Montgomery College. Staff at two of the companies also taught courses at the local universities.

Several of the 35 firms participating in the survey have either formal or informal intern programs with universities in the area. Four firms used interns from either Johns Hopkins or the University of Maryland. Another three firms used interns from Montgomery College. Many of these interns were used as lab assistants. All of these firms expressed satisfaction with the performance of their interns. In fact, many had eventually added these workers to their permanent staffs. Three companies had hired students from both the University of Maryland and Johns Hopkins. Three other firms had hired students from Montgomery College.

## **Connections with Other Firms**

There are many ways that biotechnology firms in Montgomery County interact among themselves and with nearby institutions. The picture that emerges is of a complex web of ties that encourages the biotechnology industry to continue to grow in this County and region. Just as residents form many linkages that foster cohesion, through shared activities and facilities, within their communities, the community of biotechnology firms and institutions interrelate in many ways.

Three firms in the survey had CRADA agreements with other firms. In addition, 10 of the 35 biotech firms participating in the interviews had consulting contracts with each other. Firms often find it more economical to farm out R & D involving expensive cutting edge procedures to other companies than to attempt to develop the techniques in-house. Intracel of Rockville consulted for three other interviewed firms.

## **Supplier-Buyer**

The most common relationship was of a supplier-buyer nature. Several companies participating in the survey purchase lab supplies from Life Technologies, Inc. (Rockville). This company manufactures and supplies more than 3,000 products (e.g., enzymes, cell culture media) that are used to perform hundreds of routine molecular and cell biology experiments involving the manipulation of genetic material and the study of how genes grow, differentiate and function. The company offers technical expertise, technology licensing, research services, and large-scale production services.

Most companies covered in the survey did not obtain a majority of their lab supplies from local firms, however. There are no mass-market local manufacturers of heavy lab equipment. Many firms obtain office products (computers, copy machines, etc.) from local vendors or distributors. In addition, some of the small and medium-sized firms have computer support contracts with local firms. The larger

ones tend to have their own computer service staffs.

## **Collaboration**

The interviews revealed that some firms form partnerships among themselves for product development or bidding on contracts. While most relationships did not extend beyond performing contract research or tests, six of the interviewed firms collaborated with each other for the purpose of product development. All of these firms were fairly large and well established. One of the earliest and most successful collaborations occurred between TIGR and Human Genome Sciences, as noted above. Collaboration was more common between biotechnology firms and large pharmaceutical companies. Pharmaceutical companies often look to biotech for new information and technologies to help them develop new drugs. One smaller firm did express an interest in entering into joint development agreements with other firms as it matures. In addition, only two firms had submitted joint bids with other firms for government or university contracts.

On June 13, 2000 Gene Logic of Gaithersburg and Life Technologies, Inc. of Rockville “announced their collaboration to fully sequence and patent the large number of human disease and predictive toxicology genes identified using Gene Logic’s GeneExpress™ 2000 Suite of Databases.”<sup>14</sup> The companies expect to complete sequencing and filing patents on the approximately five percent of human genes that offer the most promising gateways for new medicines against major diseases. As genes are identified they will be isolated by Life Technologies and sequenced and patented by Gene Logic. Subscribers will be able to purchase clones of these sequences. Life Technologies is a major supplier to the biotechnology industry around the world.

The relatively small degree of partnering between biotech firms could be explained by the industry’s early stage of development. A primary motivation for partnering is to develop a source of capital for product development projects. Historically, pharmaceutical companies supply that necessary capital to small companies to tide them over during the long commercialization process. Few biotech companies have been in existence long enough to have acquired the financial resources that would be required to subsidize a smaller partner over an extended period of time.

## **Informal Relationships with Government, Educational, & Professional Associations**

Nearly all the participants in the survey are members of the High Technology Council of Maryland, a professional association catering to the needs of high tech industries. The organization sponsors programs to promote the development of the industry in the state (e.g., student internships, legislative lobbying) and provides education and networking opportunities (e.g., seminars) for the staffs

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<sup>14</sup> Yahoo.com/prnews, June 13, 2000.

of member firms. Another popular networking opportunity is the frequent seminars and conferences sponsored by NIH. The monthly “coffee house” colloquiums sponsored by Johns Hopkins University at their Montgomery County Campus in the SGLSC were also popular with employees of some of the surveyed firms. The University of Maryland Shady Grove Campus also sponsors seminars that were attended by staff at the surveyed firms.

A few surveyed firms mentioned contacts, of a less structured nature, that result from individual employees seeking out their counterparts at other firms. Very few firms participating in the survey attempted to foster communications and contacts between their own employees and those of other firms in the industry. Such contacts are facilitated by seminars and less formal meetings such as the monthly coffee house colloquium at Johns Hopkins. More restaurants and athletic clubs near Shady Grove and other biotech clusters may also help.