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MEMORANDUM OF CALL Previous editions usable

TO: CL

☒ YOU WERE CALLED BY — ☐ YOU WERE VISITED BY —

Joe Alvarez

OF (Organization)

☐ PLEA[redacted]N

P6/b(6)

☐ WILL CALL AGAIN ☐ IS WAITING TO SEE YOU

☒ RETURNED YOUR CALL ☐ WISHES AN APPOINTMENT

MESSAGE

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63-110 NSN 7540-00-634-4018 **STANDARD FORM 63** (Rev. 8-81)
Prescribed by GSA
☆ U.S.G.P.O. 1992 312-070-40024 FPMR (41 CFR) 101-11.6

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May 11, 1993

Carol H. Rasco
Assistant to the President for Domestic Policy
The White House
Washington, D.C. 20500

Dear Carol:

Thanks so very much for taking the time to meet with representatives of the Massachusetts Biotechnology Council last Wednesday. I hope that you found the session as informative as we did.

Needless to say, it was an added pleasure to be able to reintroduce myself to you from those days of Clinton-Dukakis at the NGA. I remember my days as Secretary of Economic Affairs with fondness and nostalgia.

I do hope that you'll feel free to call me for lunch or a drink when you need a brief respite from your important and challenging assignment as Domestic Policy Advisor to the President.

I will be passing on to you additional materials concerning some of the issues discussed at our meeting as soon as they are available.

Again, my thanks and my best wishes as you advance the cause. Give Mark Gearan my regards.

Sincerely,

Joseph D. Alviani
Senior Advisor, Massachusetts
Biotechnology Council

D16461.1

Price controls on new drugs - death
Blow to biotech
Time sensitive

DPC FDA User fees - new people hired?

? Patent issue

DPC NIH

? Ongoing interp. on licensing program
Get products out, reap benefits (big)
to NIH
Relates to Technology Transfer

Coop research
Wyden - bill to chg
rules w/return
NIH/Univ/Drug Cos.

nothing to do Orphan Drug Act
has filled gap where patents don't work

Stock options - currency of the realm

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BIOGEN

May 26, 1993

Ms. Carol Rasco
Assistant to the President
for Domestic Policy
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear Ms. Rasco:

When we met on May 5th as part of the Massachusetts Biotechnology group, you indicated that you would find some additional information on the various subjects we were discussing useful. I have, therefore, enclosed brief summaries describing the industry's viewpoint on NIH CRADAs, Prescription Drug User Fee Act of 1992 and the Orphan Drug Act.

In addition, you may recall that our central subject of discussion with you related to the devastating financial impact that is occurring to biotech companies because of their inability to access funds from Wall Street which is largely being caused by the administration's discussions related to price controls on pharmaceutical products. I've enclosed a very recent Wall Street Journal article describing this situation on a current basis.

In addition, since you mentioned during our discussion your daughter's interest in biotechnology, I have included some information for her on Biogen.

Biogen was founded in 1978 and was one of the first three biotechnology companies in the world. Consequently, we have been able to invest enough money (almost $500 million to date) and have been doing it for a long enough period of time that we have some very successful drugs currently on the market such as alpha interferon and the Hepatitis B vaccine. She will be able to read all about it in the enclosed report.

BIOGEN

I appreciate very much your taking the time to meet with us and demonstrate interest in learning more about the world of biotechnology. All of the best to you in your new position.

Sincerely,

James L. Vincent
Chairman & Chief Executive Officer

jeg

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FEDERAL SUPPORT FOR RESEARCH AND DEVELOPMENT OF PRESCRIPTION DRUGS

NIH CONTRIBUTIONS TO THE BIOTECHNOLOGY INDUSTRY

- NIH basic research programs provide fundamental knowledge about human biological processes. While this information does not apply to any specific products, it is part of the foundation on which companies build when trying to develop new therapeutic products.

- University research projects sponsored by NIH also provide training to thousands of young scientists, whose skills are so necessary to the biotechnology industry's effort to develop breakthrough products.

- NIH works directly with specific companies on specific research projects through Cooperative Research and Development Agreements (CRADAs).

LICENSING ARRANGEMENTS RESPOND TO DUAL CONCERNS ABOUT RECOGNITION OF THE FEDERAL CONTRIBUTION TO RESEARCH AND ABOUT PROVIDING ACCESS TO NEW PRODUCTS FOR NEEDY PATIENTS

- Biotechnology companies are deeply concerned about the "reasonable price" clause contained in NIH CRADAs and are opposed to proposals that would encourage or require NIH to control the prices of drugs on which it collaborates with companies.

  IBA believes that drug price controls are a major disincentive to the wilingness of companies, especially smaller companies, to license technology from, or enter into cooperative research agreements with, NIH. Price control mechanisms would lead to a reduction of the health and economic benefits of federally funded research.

- IBA suggests that instead of attempting to set prices, NIH should license its technology in exchange for upfront cash payments and/or royalties on sales. The precise amounts should be determined by negotiation between the parties, and would vary, based on the stage at which the technology is transferred. However, estimates of the additional aggregate revenues from licensing agreements range up to $1 billion.

- Funds received from licensing could be used to support new research. They could also be used to provide a fund for use by patients who are not otherwise able to afford the product.

- Licensing would preserve incentives for participation in NIH CRADAs, ensure that NIH receives fair market value for its research, and generate funds to provide expanded patient access. Licensing arrangements are preferable to solutions which emphasize price controls, which IBA believes will adversely impact on our industry's ability to attract the equity capital upon which biotech companies rely for much of their R&D funding.

PRESCRIPTION DRUG USER FEE ACT OF 1992

The Prescription Drug User Fee Act of 1992 represents a historic agreement between the federal government and regulated industry. The statute requires drug and biologic companies to pay $350 million in fees over the next five years, these funds to be used exclusively to speed up FDA review of drug and biologic products.

Industry's agreement to pay user fees was conditioned on a number of points, all of which are contained in the legislation as enacted:

- o User fee revenues be used exclusively to speed up review of new drugs and biologics, as well as new indications for approved drugs and biologics, and not for enforcement or other purposes.

- o User fees be additive to current appropriation levels and cannot be used for deficit reduction purposes.

- o User fee revenues will be raised from a combination of three types of fees: application fees for new drugs and biologics (and new indications for approved products), establishment fees, and product fees. One-third of fee revenues will be generated from each of these sources.

- o Small companies (defined as companies with fewer than 500 employees) whose first prescription drugs have not yet been approved by FDA pay one-half of the regular new product application fee. Furthermore, these companies may defer payment for one year.

- o In exchange for a user fee program that will pay for FDA to hire an additional 600 drug/biologic reviewers, FDA agreed to specific performance goals that are referenced in the legislation. FDA's progress toward meeting these goals is the subject of an annual report to Congress.

    - ▸ FDA's five year performance goal is to cut application review time in half. This means reviewing and acting on PLAs, ELAs, and NDAs for priority applications within 6 months after submission (rather than the current 13 months) and for standard applications within 12 months after submission (rather than the current 23 months).

Present Status: While the FY1993 Supplemental Appropriations bill recently approved by a House Appropriations subcommittee includes the funding necessary to trigger the collection of user fees, it does not include any provision for increased staffing. In addition, the Administration's proposed FY1994 budget for FDA requests appropriations that are below the threshold required under the Act. It also will result in a decrease in FDA staffing for drug application review.

All of these issues are of considerable concern to the biotechnology industry. We believe that the statute presents real promise for us to work in partnership with the FDA to provide important new therapies to patients whose livelihoods, quality of life or lives themselves depend on them. We intend to work hard to make that promise a reality.

Proposed Amendments to the Orphan Drug Act

Background on the Orphan Drug Act

- The Orphan Drug Act was enacted to create incentives for companies to invest in developing drugs for rare diseases (defined as diseases affecting fewer than 200,000 U.S. patients). The principal incentive contained in the Act is the reward of seven years of marketing exclusivity for those who pioneer new therapies for rare diseases. This incentive is analogous to the marketing exclusivity system provided under U.S. patent law, although it is much more limited in both scope and duration.

- Orphan drug marketing exclusivity has proven to be an extraordinarily effective incentive. According to a report published in JAMA, during the eight years prior to the Act's enactment, only ten orphan drugs had been approved by FDA. In the eight years following enactment, however, 54 orphan drugs have been approved to treat 60 rare diseases. Between 300 and 400 orphan drugs are either undergoing human clinical trials or are pending FDA review. Orphan drug approvals have increased from 7% of new molecular entities in 1983 to 20% in 1989.

- All but three orphan products approved since the introduction of the Act were sponsored by industry (from a total of 30 companies), of which 81% are for conditions affecting fewer than 50,000 U.S. patients. JAMA reports that annual U.S. sales of more than half of orphan products are less than $1 million. About 83% of orphan drugs sponsored by PMA companies had a lower than average return on investment, while development costs were greater than average for 12%.

- The National Commission on Orphan Diseases, which was established by Congress in 1985, submitted a comprehensive 130-page report and recommendations to Congress in April 1989 calling for increasing the period of marketing exclusivity currently in the Orphan Drug Act.

Background on the U.S. Biotechnology Industry

- The U.S. biotechnology industry is a leader in the development of drugs to treat rare diseases, many of which are life threatening and seriously debilitating. The unique scientific methods of biotechnology -- which focus on the genetic and molecular bases of disease -- make biotechnology companies especially capable of developing safe and effective treatments for rare genetic and metabolic disorders.

- All biotechnology companies that are selling orphan drugs have voluntarily established programs to ensure that no patient is denied a needed drug because of inability to pay. Patients who do not have private health insurance and who are not covered by

Medicare or Medicaid are usually eligible. As many as 10% of the patients receiving some biotech orphan drugs receive the product under these programs. The cost of supplying drugs under these programs lowers the profitability of biotechnology companies but ensures patient access to important new drugs.

- Biotechnology is this Nation's most R&D intensive industry and much of this investment has gone into orphan drug R&D programs. A recent survey by Ernst & Young shows that R&D accounts for 40% of all costs incurred by biotechnology companies. Biopharmaceutical companies currently reinvest an average of 63% of all product sales into research towards tomorrow's products. In 1989, biopharmaceutical companies invested an average of $47,000 per employee into R&D (as compared with $27,000 for traditional pharmaceutical companies). Since the industry's inception in the late 1970s, biotech companies have invested at least $10 billion into long-term R&D programs.

- Many biopharmaceuticals are unpatentable because they consist of synthetic versions of previously isolated human proteins and enzymes. This lack of patent protection makes biotech companies particularly dependent on the limited marketing exclusivity supplied under the Orphan Drug Act. Attacks on the Act will therefore seriously injure the competitiveness of the U.S. biotechnology industry.

- Biotechnology is an industry that can contribute significantly to U.S. economic growth and international competitiveness. Two major reports released this year -- one by the private sector Council on Competitiveness and one by the White House Office of Science and Technology Policy -- labelled biotechnology one of several "critical technologies" that will drive U.S. productivity, economic growth, and competitiveness over the next ten years and perhaps over the next century.

- Currently, the U.S. is the world leader in the research, development, and manufacture of biotechnology products. In 1991, the U.S. biotech industry produced sales of $5.9 billion and some estimates project that biotechnology will be a $50 billion industry by the year 2000.

<u>Sen. Metzenbaum's bill would seriously undermine the Orphan Drug Act</u>

- In the last Congress, Senator Metzenbaum proposed legislation to undermine the incentive for companies to develop orphan drugs. His bill would have imposed a cumulative "sales trigger" that would revoke orphan drug marketing exclusivity when a company's cumulative sales of the drug reach $200 million.

- The "sales trigger" approach seems to assume that revenue and profitability are equivalent. They are not. Seven out of ten drugs on the market do not make money. A Tufts University study shows that the cost of developing the average new drug is $231 million. This figure only covers investment prior to FDA marketing approval. The revenues after approval need to also

cover the sizable manufacturing and marketing expenses associated with actually delivering the drug to patients and continuing investment in working capital, inventory, capital equipment and facilities, continued R&D to support the product, and allowing the company a return on its investment. In fact, very few companies will make profits before surpassing the $200 million "sales trigger."

- If companies cannot profit from orphan drugs, they will not develop them. Imposing a "sales trigger" will strongly discourage orphan drug development because development of drugs for larger markets will yield a greater return on investment at a much lower risk.

- Imposition of a "sales trigger" would undermine the settled expectations of companies who have already undertaken research and development efforts in reasonable reliance on current law. Faced with the economic uncertainty created by a sales trigger, many companies will terminate, or decline to start, promising research on diseases that could eventually lose market exclusivity due to the sales trigger.

- Because many biopharmaceuticals are unpatentable, the orphan drug law offers a company the only meaningful protection available. Enacting a "sales trigger" weakens the principal incentive that companies have to fund research and development into drugs to treat rare diseases. In addition, since biotechnology companies are developing a disproportionate share or orphan drugs, these changes are an indirect attack of the U.S. biotech industry.

- A "sales trigger" would discourage the development of new therapies for certain rare diseases, especially those requiring the chronic administration of a drug. For example, multiple sclerosis (MS) currently afflicts 185,000 Americans. Under current law, MS is an orphan disease. But if a $200,000,000 sales trigger is enacted, then an MS drug costing $1,000 per year per patient would lose its market exclusivity in about a year. Under such circumstances, it is unlikely that any company will pursue a nonpatentable MS drug.

- The Securities and Exchange Commission requires companies to disclose products that materially affect a firm's revenues. Because of this rule, all dedicated biotechnology companies publicly report their orphan drug sales data, while large pharmaceutical companies can maintain this information as a trade secret (since no orphan drug product comprises a substantial part of any large company's sales). As a result, small biotechnology companies are more likely to suffer under a "sales trigger" than are large pharmaceutical companies.

- Many of the orphan drugs produced over the last few years have resulted in innovative technologies being developed. The products are often breakthrough products for serious diseases. This development of new technology is critical for U.S. biotechnology and basic research competitiveness.

ENTERPRISE

Clinton Health Plan Hurts Biotech Firms

By Udayan Gupta
Staff Reporter of The Wall Street Journal

If uncertainty about President Clinton's health-care plan is denting big drug companies' stocks, it is helping to wreak havoc at small biotechnology companies.

Ever since the administration started talking about health-care changes, the fear of price and cost controls has hurt the biotech business. On Wall Street, stock prices of biotech companies have plummeted. Financing has dried up. And plans for expansion, including hiring, new construction and new projects, have been put on hold.

The entire biotechnology industry is under a cloud. But small biotechnology companies are the hardest hit. With no products and no revenue, they need steady access to the capital markets. The drought they now face threatens their plans for research and commercialization—and, for some, their very existence.

Of course, the industry hasn't helped its own cause. Problems with some highly publicized drugs and the industry's inability to come up with new blockbusters have tarnished its image. And a slew of me-too companies backed by venture capitalists have further clouded the competitive picture.

Other Setbacks

Initial public offerings in the first four months of this year fell 63% from the 1992 period to $119.7 million, according to In Vivo, a Norwalk, Conn., industry newsletter. More than a dozen companies, including Triplex Pharmaceutical Corp., GenPharm International Inc. and Tanox Biosystems Inc., have put their stock offerings on hold. Others, such as Viagene Inc., which had postponed previous offerings following other industry setbacks, have simply canceled public financing plans altogether.

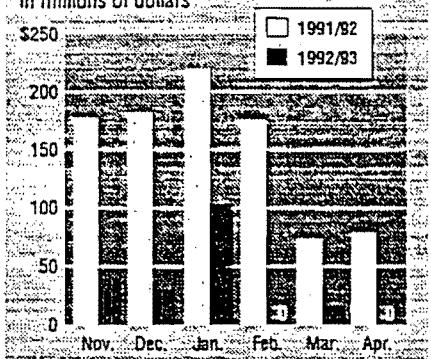
"There's no question in my mind that the Hillary effect has put a nail in the coffin on our ability to raise money," says Robert Abbott, chief executive officer of Viagene in San Diego, referring to the first lady's role as head of the Clinton administration's health-care task force.

Relatively more mature companies have fared little better. Secondary stock offerings declined 11% to $245.7 million. But the biggest casualty was a package of convertible debt that had been expected to bring more than $200 million into the coffers of seven small companies, including Celtrix Pharmaceuticals Inc., CytoTherapeutics Inc., Liposome Technology Inc., Neurogen Corp. and Repligen Corp.

"The uncertainty and speculation surrounding price controls killed the bio-bundle. We hit the market at the wrong time," says Misha Petkevich, a managing director at Robertson Stephens & Co., the San Francisco investment bank that put together the convertible debt package.

Fewer Stock Offerings

Volume of biotechnology initial public offerings following President Clinton's election victory, compared with year-earlier figures, in millions of dollars



Sources: Health Care Strategist, Windhover Information Inc.

Source of Resources

Strategic alliances with big companies have also been affected. Such partnerships, a source of capital and resources such as technology and marketing for smaller companies, dropped to 19 in the first four months of this year from 26 a year earlier, says In Vivo. "The large companies are hunkering down because of the uncertainty. They want to know what's going to happen to the overall environment before they do more outside collaborations," says Ron Henricksen, chief executive of Khepri Pharmaceuticals Inc., Alameda, Calif., and former head of U.S. business development at Eli Lilly & Co.

"Investors already have been disappointed by the poor clinical results of some high-profile companies such as Synergen, Centocor and U.S. Bioscience," says Roger Longman, editor of In Vivo. Now, "a host of disparate and confusing reform proposals, ranging from price controls to a national list of reimbursable drugs, has thrown them for a loop."

"The biggest concern is price controls for new products," says John Kaweske, a Denver manager of Global Health Sciences Fund and Financial Strategic Health Sciences Portfolio. "If price controls are put in place you will not see any further financing of these biotech companies."

The Food and Drug Administration is also contributing to the industry's quandary. "The big FDA signals are that the threshold [for approval] has changed from safety and efficacy to safety, efficacy" and cost effectiveness, says Steven Burrill, head of Ernst & Young's international high technology practice. For most young companies, unfamiliar with the regulatory process, the confusion only adds to the already prohibitively expensive cost of clinical trials, he adds.

But at Viagene, which in March abandoned its $30 million initial public offering, the implication is clear. The company has frozen hiring and drastically slowed its plans for development and diversification.

Five years ago, Viagene received $20 million from venture capitalists to develop drugs based on gene therapy. Last year, it decided to raise $30 million in an initial public offering to accelerate the clinical trials of its most promising drug: a treatment that enhances a patient's "killer T-cell" response to fight viral infections, including HIV, the virus that causes AIDS.

The company filed to go public on April 15, 1992, the same day that Centocor's announcement of problems with its septic-shock drug sent the entire biotech market into a freefall. Viagene tried again to raise money in January, just weeks before Synergen announced that its septic-shock drug Antril performed poorly in clinical tests. The company kept its offering on the backburner, hoping that news and market conditions would improve. But in March, "I reluctantly terminated Viagene's efforts to raise capital through a public offering," Dr. Abbott wrote U.S. Rep. Pete Stark, a California Democrat.

As a result, instead of accelerated testing or diversifying to other diseases, Viagene is cutting back on its clinical trials. In its first study it will work with only four patients instead of 12. It will also cut out a "quick peek" test that helps ascertain the potential impact of the clinical trials. The revised strategy will reduce costs but it will also add six months to the trials.

Conserving Cash

Viagene has also stopped hiring. Between January 1991 and October 1992, the company increased its staff to 107 from 40. But now, with only about $8 million left, it wants to conserve that cash.

The company is discovering that there is no U.S. corporate interest in its activities. A major U.S. vaccine producer cut off talks about a product-development alliance because of the fiscal uncertainty associated with President Clinton's reform, says Dr. Abbott. Viagene still has five collaboration candidates, but three are Japanese

Please Turn to Page B2, Column 5

Uncertainty Over Plan To Alter Health Care Hurts Biotech Firms

Continued From Page B1

pharmaceutical companies and the other two are German.

Other companies are also scrambling for new partners to make up for the paucity of public capital. Vertex Pharmaceuticals Inc. last month signed a collaboration agreement with Japan's Kissei Pharmaceutical Co. to develop the Cambridge company's anti-AIDS compounds. As part of the deal, Kissei will invest $20 million in Vertex's HIV program.

Another Cambridge, Mass., biotech company, Procept Inc., was counting heavily on a $20 million initial public offering to finance clinical tests for its AIDS therapeutic drug. But it has had to put off the offering, says Stanley Erck, chief executive officer. Now it is scrambling to put together an $11 million private financing to stay on course.

But even these private equity markets, traditionally less sensitive to industry upheaval, have become wary. Mr. Kaweske, for example, invested $1 million in Incyte Pharmaceuticals, a Palo Alto, Calif., start-up, at a price "at least 50% lower than six to 12 months ago."

Other venture investors simply won't invest. "We're rejecting deals that three or four years ago we would very seriously consider," says Barry Weinberg, managing partner of CW Ventures, a New York venture-capital firm. No more start-ups with products that are only incrementally different from others, he says. "For companies that don't offer cost-effective solutions, there simply isn't any money."

MedImmune Elects Two of Its Executives Chairman, President

By a WALL STREET JOURNAL *Staff Reporter*

GAITHERSBURG, Md. — MedImmune Inc. said Michael D. Kishbauch was named president and chief operating officer and Wayne Hockmeyer, who was president and chief executive officer, became chairman and chief executive.

The chairmanship and the post of chief operating officer are newly created. The election of Mr. Kishbauch, 44 years old, to the board increases it to six members. Dr. Hockmeyer, 48, founded MedImmune, a developer of therapeutics and vaccines for infectious diseases, in 1988 after serving as vice president of research and development at Praxis Biologics, now a unit of American Cyanamid Co.

Mr. Kishbauch joined MedImmune in December 1992 as executive vice president. Prior to that, he spent 10 years with Ciba-Geigy International in planning, marketing and product management. There, he helped lead the marketing of that company's Habitrol nicotine patch and Volatren, an antiarthritic, MedImmune officials said.

As president and chief operating officer at MedImmune, Mr. Kishbauch will be responsible for sales and marketing, manufacturing, regulatory affairs and quality assurance.

While research and development activities will continue to be focused on infectious diseases and, over the longer term, cancers, Dr. Hockmeyer said he also will evaluate the possibility of licensing products from other manufacturers for sale by MedImmune's 15-person sales force.

MedImmune began assembling that sales force late last year to handle sales of the company's first product, CytoGam, which is used to prevent cytomegalovirus disease in kidney-transplant patients.

Why health costs are soaring

MARTIN FELDSTEIN
AND KATHLEEN FELDSTEIN

THE UNITED STATES HAS THE HIGHEST-quality health care system in the world. But the nation must now find a way to provide quality care at lower cost and to expand access to the 15 percent of the population without insurance.

Congress will soon receive a Clinton health plan that gives government the central role in health care provision. Before agreeing to more government intervention in the private sector, Congress should first sort out why health care costs have been rising so fast.

There is no disputing that health care costs are absorbing a rapidly increasing share of our national output. Health care spending now amounts to 14 percent of gross domestic product, up from 9 percent in 1980. It is this rapid rise in spending and not dissatisfaction with the quality of health care that is motivating the groundswell of support for health care reform. For the 85 percent of the population that is insured, access to high-quality health care is generally not a problem.

Although rising costs are the biggest problem, there is little understanding of the underlying reason for the rapid rise in costs. Worse, there are many erroneous explanations floating around that make people feel it would be easy to control costs by government regulation. Probably the most common gripe is that doctors are making too much money. This leads to the mistaken view that regulating doctors' fees would bring health costs under control. Doctors are certainly well rewarded for their years of training, basic ability and demanding work. But although the 600,000 practicing doctors earn an average of nearly $200,000 a year, their total income only accounts for about one-seventh of total health spending.

Even if the government could halve all doctors' incomes, total health care spending would fall less than 7 percent. The unfortunate result of regulating doctors' incomes would be that the profession would not continue to attract people of the same ability and dedication.

Another misconception is that the high cost of prescription drugs is a major contributor to soaring health costs. Both President and Mrs. Clinton, in speeches highly critical of pharmaceutical companies, have given the impression that drug companies are gouging the public. Their criticism fell on receptive ears because drugs are often not covered by private insurance plans and drug prices have risen noticeably. But drugs are such a small percentage of the total spending on health that even dramatic reductions in the costs of drugs would hardly make a noticeable dent in the total US medical bill. Spending on drugs amounts to only about 8 percent of total health expenditures and has actually fallen from about 12 percent 20 years ago.

Since more than 40 percent of health care dollars go to hospitals, it might seem that costs are rising because hospitals are benefitting financially at the expense of the patient. But remember that virtually all hospitals are non-profit institutions that typically incur annual operating losses and must depend on charitable contributions to close the gap between revenues and expenditures.

Nor can insurance companies be blamed for making excess profits. Some of the major providers of insurance like Blue Cross and Blue Shield are non-profit while the rest face tough competition that keeps their profits very low. In many cases insurance companies act only as servicers for large companies that choose to take on the actual insurance risk for covering their employees.

Where, then, should we look to explain the explosion in spending on health care? The real moving force behind the excessive spending on health in this country is the tax code incentive to overinsure and then to choose care without regard for cost. Most Americans obtain insurance through their employer, and since employer payments for health insurance are excluded from taxable income, there is a strong incentive for employees to prefer compensation in the form of health insurance.

For a typical couple earning about $40,000 a year, the combined marginal tax rate is now about 50 percent – a 28 percent federal marginal income tax rate, a 15 percent employer-employee payroll tax and state income taxes of about 7 percent. If that couple has to choose between $100 in taxable income and $100 in non-taxable health insurance premiums, they have a strong incentive to choose the insurance, since they would only get to keep $50 of the additional wages as cash.

The net result of the incentive to choose insurance rather than cash is evident: very comprehensive health insurance with low deductibles and low copayments. That leaves health care consumers indifferent about the cost of their medical treatment. That in turn encourages doctors and hospitals to order the most expensive technologies and procedures.

Instead of rushing to a health care plan that will involve detailed government regulation of all health care providers, Congress should look to the root of higher health care costs and harness consumer incentives to contain future cost increases. Limiting the amount of tax-free insurance premiums that any employee can receive should be a central part of any plan to control health care costs.

Martin Feldstein, the former chairman of the Council of Economic Advisers, and his wife Kathleen, who is also an economist, write frequently together on economics.

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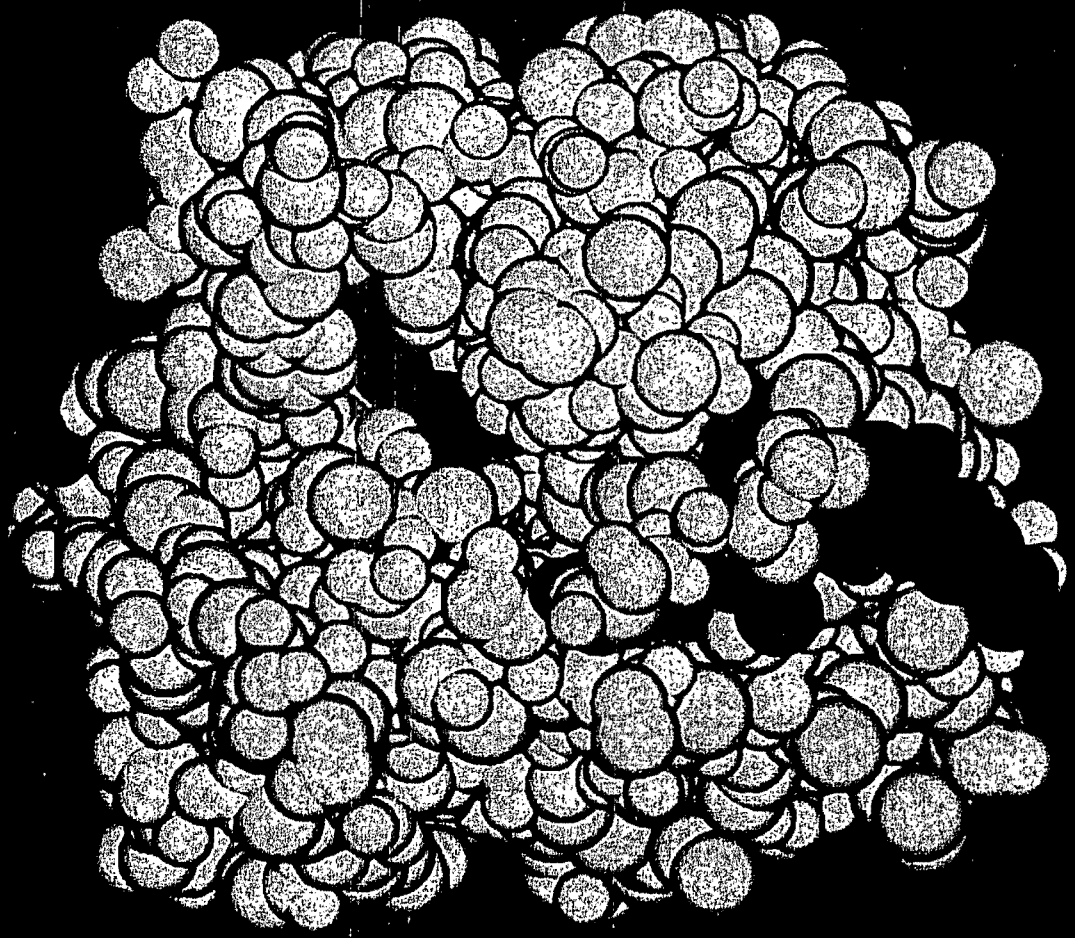

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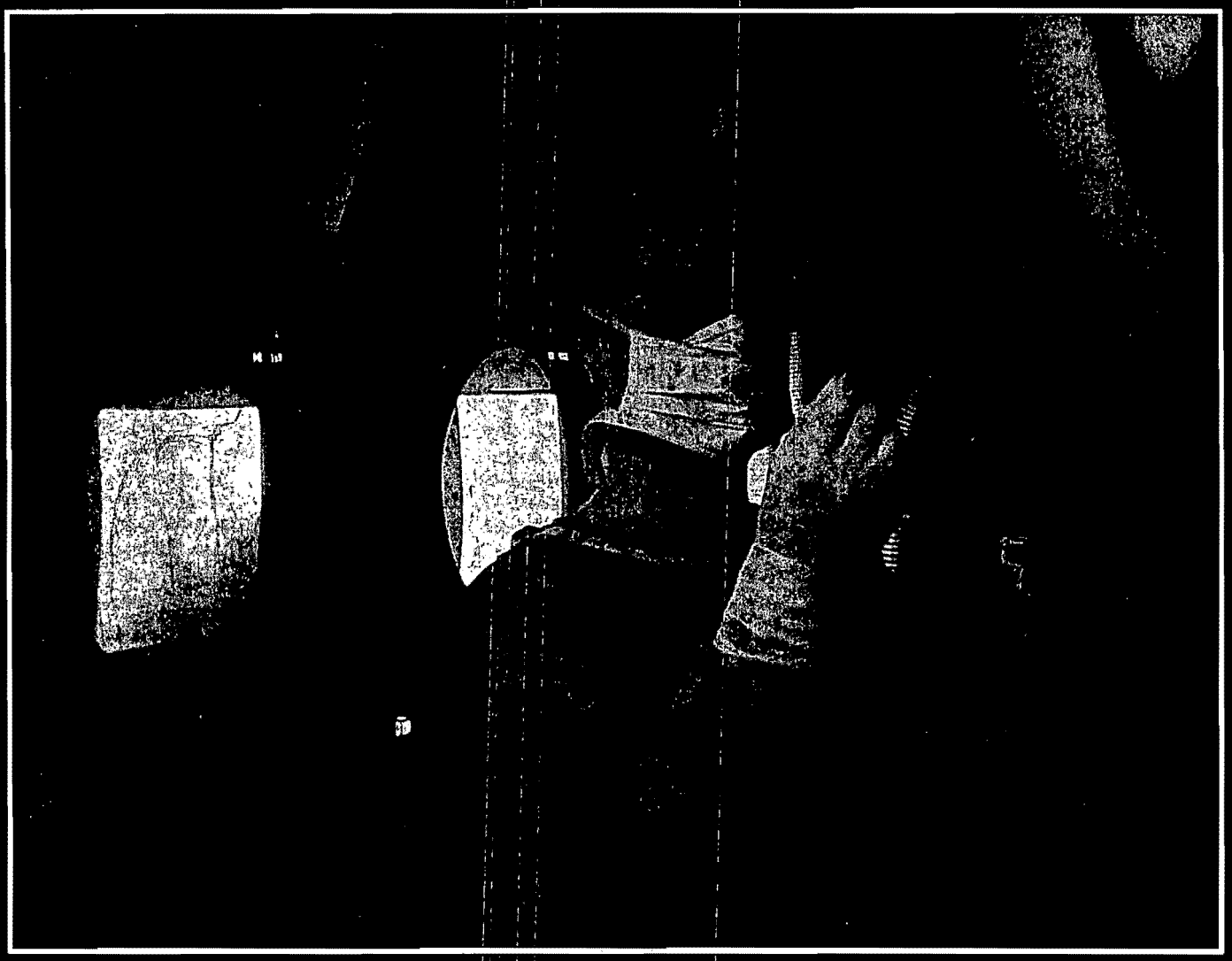
Ideas for Today's Investors



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CORPORATE VISION AND MISSION

Vision

The developments in modern biology in the last three decades have caused a major discontinuity in the rate of change in life science research that establishes for the first time in 35 years the opportunity for major new companies to be built in the pharmaceutical industry. These companies will be based upon new products and therapies that dramatically improve the practice of medicine and the quality of life for patients. Biogen was created to be a corporate and scientific leader in this new opportunity environment.

Mission

To build a global based pharmaceutical company based on leadership in creating fundamental change in new drug discovery and development to create, make and market pharmaceuticals.

As we pursue this mission, we will:

- Staff the organization with people possessing both excellence in professional skills and strong values.
- Create an organizational culture that is sensitive to people without compromising excellence in performance standards.
- Lead the company with policies that give equal importance to the needs of our customers, employees and shareholders and conduct ourselves in an ethical and balanced manner with all of our constituencies.

Our incentive for this effort is the opportunity to create value for the medical community and their patients, and we will measure our success in this endeavor by the benefits actually created by our products in the market.

The New York Times

SATURDAY, AUGUST 15, 1992

Seeking Profits It Can Call Its Own

By BARNABY J. FEDER

Special to The New York Times

CAMBRIDGE, Mass. — In the early 1980's, when Wall Street fell head over heels for biotechnology, Genentech, Cetus, Genex and Biogen were the start-up companies that came to be known as the Big Four. Each had ambitious goals, heaps of venture capital, impressive links to blue-chip multinationals, advisory boards packed with renowned scientists and top executives with a flair for pitching their visions.

But only Biogen N.V. has remained independent.

Genentech Inc., the biggest money maker, sold a controlling interest in 1990 to Hoffman-LaRoche, the giant Swiss pharmaceutical company, so it would have the cash to fill a hole in its projections caused by disappointing sales of TPA, its high-priced heart drug. The Cetus Corporation and the Genex Corporation, humbled by strategic failures and financial weakness, were both taken over last year by other biotechnology companies.

Here at Biogen's headquarters in an office tower overlooking the Massachusetts Institute of Technology, the surrounding industrial parks and Boston, executives admit that Biogen could easily have been among the corporate casualties.

"This company was perceived to be dead in 1985, '86, and even into '87," said James L. Vincent, Biogen's blunt-speaking 52-year-old chief executive who presided over the revival of its fortunes.

Looking Beyond Royalties

Today, the question is not whether Biogen will survive but if it can flourish. The company has been slightly profitable for three years in row, having closely geared new investment to profits from its growing stream of royalties from early inventions licensed to big-name drug companies like Schering-Plough and Merck & Company.

Biogen, whose shares are traded over-the-counter, earned $4.5 million on revenues of $69.6 million last year. Nearly 80 percent of the revenues came from royalties.

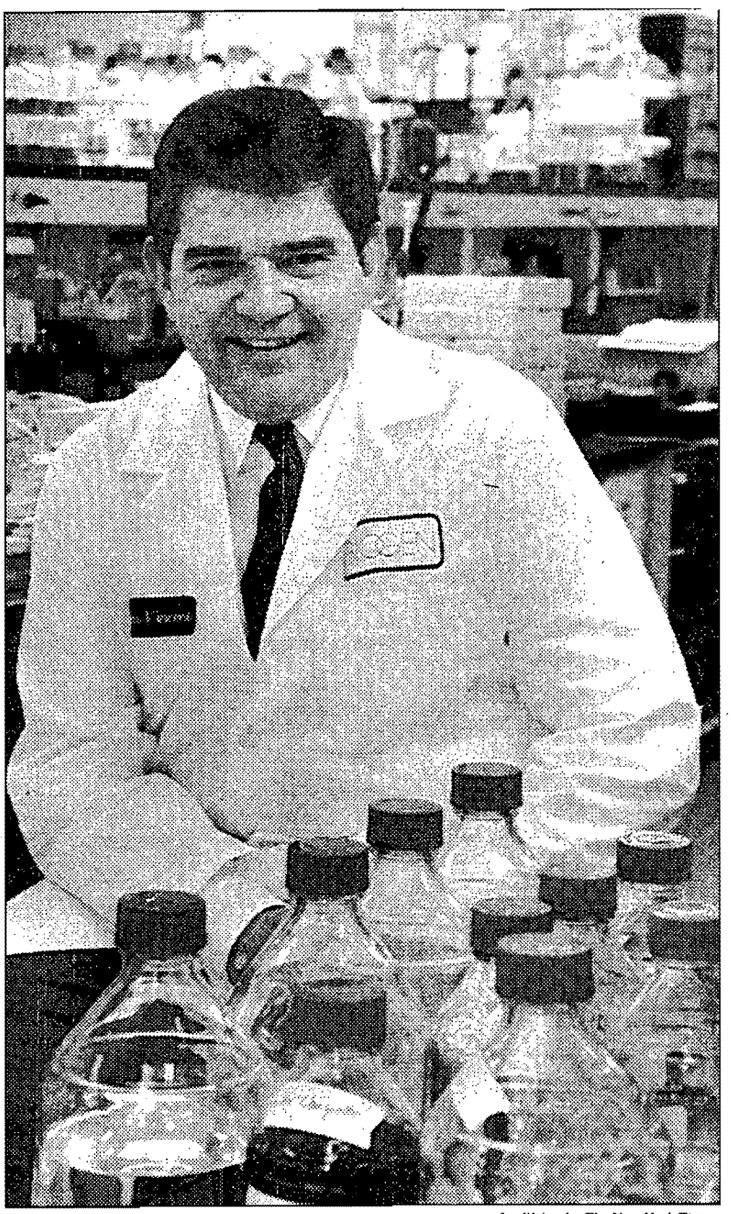
Now Mr. Vincent is steering toward the transition in the mid-1990's when the company plans to begin making and marketing its own products and reaping more of the profits.

"They are one of 6 companies out of 60 I follow that are profitable," said Denise M. Gilbert, a biotechnology analyst with Smith Barney, Harris Upham & Company. "The question on future profits is how much and when."

Betting On a Leech Derivative

The prime candidate to become the first product that Biogen commercializes itself is hirulog, a small molecule that Biogen developed based on a natural blood anti-coagulant produced by leeches. In June, the drug began phase-three clinical trials, the last step needed before it can get Food and Drug Administration approval.

The trials are expected to end in late 1993 or early 1994. So far, hirulog appears to be both safer and more effective than heparin, an anti-coagulant that currently has a $600 million worldwide market. But some industry experts expect the anti-clotting market to separate into a number of niches as understanding of the clotting process grows, raising questions about how big a seller hirulog can become.



Joe Wrinn for The New York Times

James L. Vincent, chief executive of Biogen, in a laboratory at the headquarters of company, one of the original biotechnology "Big Four."

A biotech survivor wants to move beyond royalties to selling products.

Biogen has other potential revenue generators in its pipeline, notably human beta interferon, a potent antiviral compound that it has produced in genetically altered bacteria. Biogen is well along in clinical trials of the substance's safety and effectiveness in treating some forms of chronic hepatitis and is also testing its potential as a treatment for multiple sclerosis.

Biogen is also involved in research on anti-AIDS drugs and drugs that might reduce inflammation without interfering with the body's ability to fight the infections that might have caused the inflammation.

Despite these several pursuits, Biogen is narrowly focused compared with its early days. Like many of the biotech pioneers, Biogen plunged into more research than it could sustain, including biotechnology projects in mining and agriculture as well as a wide range of drugs. In some cases, such as eurythropoietin, a natural hormone that stimulates red blood cell production, the company was among the first to recognize the potential value of finding a way to genetically alter bacteria to produce the product.

But it was also among those that failed to focus enough resources on the challenge. Amgen won the race, despite a late start, and went on to become the biggest biotech success story of the 1980's.

Biogen also paid dearly to pursue a grand international vision. It incorporated in 1978 in Luxembourg and made its headquarters in Geneva, hoping to tap scientific talent and business contacts in Europe as well as in the United States.

The job of running the ungainly enterprise soon fell to Walter H. Gilbert, an outgoing Nobel Prize-winning biologist from Harvard who spent most of his time in the United States. One of Biogen's 10 founding scien-

Independent Biogen Seeks Profits on Its Own Terms

Continued From First Business Page

tists, Mr. Gilbert was unable to stop the growing rivalry between the various arms of the company and unwilling to make it live within its means.

Biogen was "charming but chaotic," according to Linda Webber, a longtime industry analyst now at Paine Webber.

Biogen's stock price hit $23 in 1983, the year the company went public. But Wall Street's patience wore thin with the lack of profits, sending shares down to around $5 by the end of 1984 when Mr. Gilbert abruptly resigned as chief executive.

Arriving 10 months later was Mr. Vincent, a mechanical engineer with an M.B.A. from the Wharton School, who had earned his business spurs helping small operations grow into big ones at Texas Instruments, Abbott Laboratories and the Allied-Signal Corporation. His early efforts at Biogen included rebuilding the patent portfolio by buying back the rights to some inventions and renegotiating others so that the company could more aggressively pursue income from royalties.

Most of the company's European operations, including its prized Swiss-based research group, were sold or closed. Teams were formed to tie research more closely to business development, and administrative functions like accounting were improved.

"The perception had been that everything else would take care of itself if we had good science," Mr. Vincent said.

Mr. Vincent says he also worked hard to replace internal rivalries with team spirit, a task analysts say he has accomplished as much by changing the team as anything else. Mr. Gilbert retains he now part-time job of chairman, but none of the managers who report to Mr. Vincent had their jobs four years ago and many were not even with the company.

But in keeping with Biogen's origins, Mr. Vincent made it clear to the company's scientists that they would not be straitjacketed by his determination to bring costs into line with revenues. Researchers are allowed to devote 20 percent of their time to their own pet projects. One result of that outlet was the invention of hirulog.

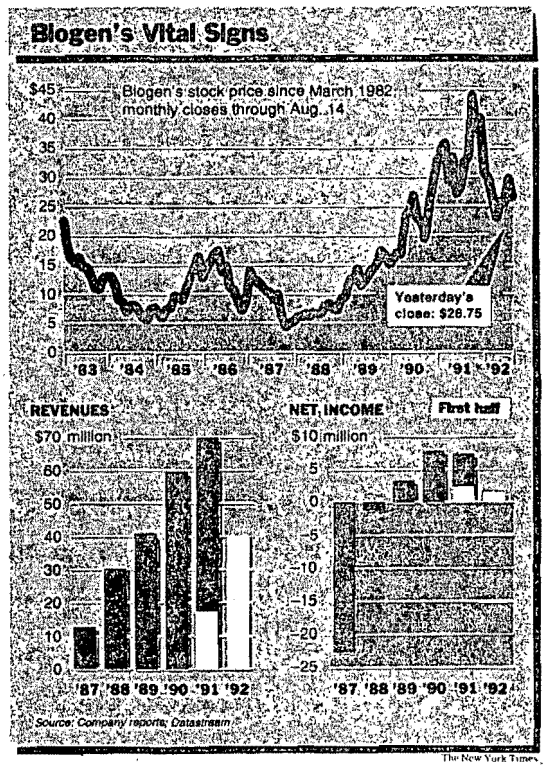
"Hirulog started as 20 percent of my time but it did not take long until it was 150 percent," said John Maraganore, a former AIDS researcher who invented hirulog and now oversees Biogen's entire anti-coagulants program.

Hopeful About Interferon

The current star of the Biogen portfolio is human alpha interferon, an antiviral and anti-cancer protein that the company licensed to Schering-Plough, which markets it worldwide under the name Intron. Schering is currently working to expand the number of cancers that Intron can be used on and to prove its usefulness as a treatment for AIDS in combination with other drugs. Other interferon products are being used to treat cancer and arthritis in Germany and Japan.

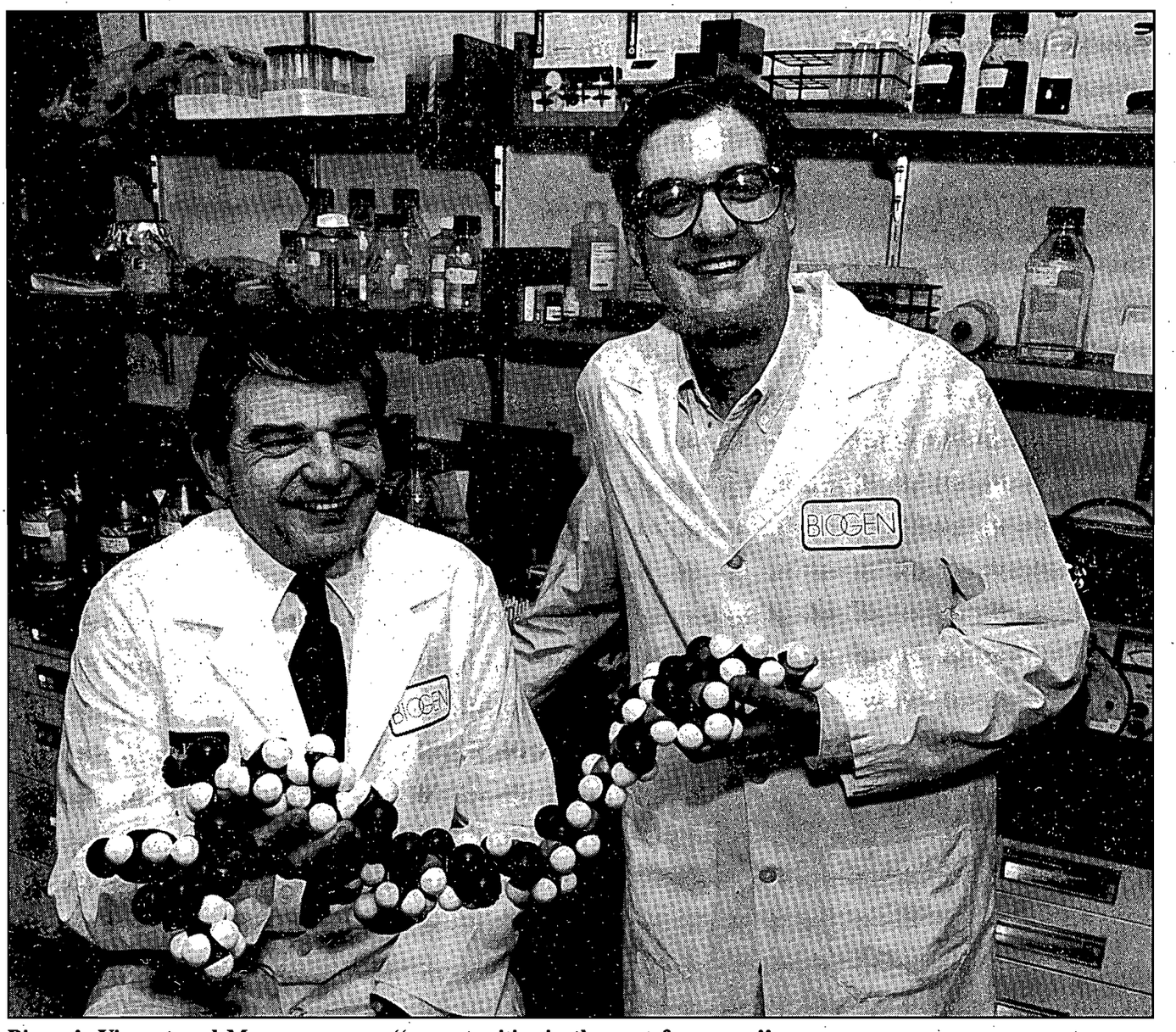
Biogen also earns royalties from its hepatitis antigens — substances that stimulate the production of antibodies to fight hepatitis infections — which are now widely used in hepatitis vaccines and diagnostic kits.

"But the cherry picking days are over," Mr. Vincent said. "The industry started with a group of proteins that had been characterized, and it was clear that if you could make them synthetically you'd do well. Now the choices aren't so obvious."



THE BOSTON GLOBE

TUESDAY, NOVEMBER 17, 1992



Biogen's Vincent and Maraganore see "opportunities in the next few years." GLOBE STAFF PHOTO/FRANK O'BRIEN

BIOGEN BETS ON THE LEECH

Biotech company seeks approval of drug expected to capture a chunk of $500 million market for blood thinners

By Ronald Rosenberg
GLOBE STAFF

Biogen Inc. is preparing to go solo.

Instead of just licensing its products to major pharmaceutical companies and living off the royalties as it has done with vaccines and diagnostics, Biogen is getting set to develop, manufacturer and distribute its first drug — a blood thinner derived from leeches.

This week at the American Heart Association meeting in New Orleans, Biogen scientists are presenting four scientific papers on the test results of hirulog, a drug derived from the anticlotting protein found in the leech. Biogen has developed hirulog as an alternative to heparin — a drug widely used to treat patients with sudden chest pains, clogged arteries, strokes and other cardiovascular problems.

Biogen's clinical studies, based on tests on more than 400 patients, show no deaths, no heart attacks or bleeding complications in any of the test subjects. Unlike some patients treated with heparin, those on hirulog did not need transfusions, the studies showed. Moreover, the company claims, hirulog is easier to administer than heparin, which requires changing dosage levels to be effective.

Hirulog probably won't reach the market until 1995. But having such a highly promising proprietary drug coupled with the successful vaccines and diagnostic products it licensed to Schering-Plough, SmithKline Beecham, Merck & Co. and others will undoubtably cement Biogen's position as one of the nation's biggest — and oldest — independent biotech companies.

With hirulog, Biogen is going after the heparin market that last

BIOGEN, continued on next page

Biogen bets on hirulog

BIOGEN Continued from page 1

year had estimated worldwide sales of about $500 million. In pursuing that market, company officials are reluctant to discuss the potential cost of hirulog to patients, if it is approved by the Food and Drug Administration.

But some Biogen watchers like Karen Firestone, manager of Fidelity Investments' Select Biotech Fund, predict that if the FDA approves hirulog, the drug could generate sales of $100 million in 1996 and $150 million to $200 million in 1997.

Hirulog alone could double Biogen's revenue, she notes. Until then, Biogen is prospering on the strength of its product licenses. This year its drug company partners are expected to have $1 billion in sales from Biogen-derived products, compared to about $600 million last year. And based on a 10 percent royalty rate, Biogen has forecast royalty revenues exceeding $100 million.

In mid-September, Biogen shocked Wall Street when it forecast a 70 percent jump in 1992 earnings and a 40 percent surge in revenues for the year. Moreover, the spike in revenues is expected to continue into the mid-1990s, trailing off just as hirulog enters the market.

But Biogen's royalty revenue could continue to climb if Schering-Plough seeks to use Biogen's alpha interferon, which is marketed as Intron A, to treat other illnesses such as AIDS and other forms of cancer — an expansion that could and add another $1 billion to the alpha interferon market.

"I try to caution people that this spike in royalty revenues will be limited and start to level off by the middle of the decade," said James Vincent, Biogen president.

Last year Biogen reported revenues of $69.6 million last year, which included $56.5 million in product royalties from its pharmaceutical company partners. Since 1986, sales have grown at an annual compound rate of more than 50 percent.

Profits, which last year totaled nearly $7.2 million or 15 cents a share are expected to climb substantially, offset only by the high cost of getting hirulog through lengthy FDA clinical trials.

Not surprisingly, the boom in Biogen's fortunes had a profound effect on the stock. Biogen shares closed yesterday at 44½, up more than 20 points since around Labor Day when its shares were 24.

Even at its current price, some Wall Street analysts claim that Biogen's stock does not reflect the string of forthcoming drugs led by hirulog.

And while Biogen spends substantial sums on large hirulog clinical trials, it is far from having the market locked up. The Cambridge bio-tech company is facing some tough competitors, notably Centecor, Core Therapeutics and Merck, that are also looking to crack the heparin market.

"We believe we have about a year's lead time over them," said John Maraganore, head of biological research at Biogen.

Unlike its rivals which are developing drugs that work with heparin, Biogen's hirulog is designed as an alternative.

Hirulog acts as a direct inhibitor of thrombin — the main enzyme that coagulates blood — and is designed to provide immediate relief to people with severe and sudden chest pains, and to prevent clotting complications after veins are opened up through balloon angioplasty or coronary by-pass surgery. Hirulog is also being evaluated as an alternative to heparin patients following orthopedic surgery.

Others question whether hirulog will be as big a winner as Vincent claims.

"Will hirulog replace heparin? It's still a possibility, but there are others developing new drugs that we're looking at," said Dr. John Bittle of Boston's Brigham and Women's Hospital's cardiovascular division, which also tested Centecor's anticlogging drug and expects to start side-by-side comparisons between hirulog and heparin early next year.

And Fidelity's Firestone expects the price of hirulog, while difficult to compare to heparin because of different dosage levels, would be three times more expensive, but worth it if you can shorten a patient's time in a hospital.

If hirulog is Biogen's future for the mid-to-late 1990s, its continued development will depend on licensed drug royalties.

But until recently, those licences were viewed as giving away Biogen's birthright. And yet, that strategy saved the company from near bankruptcy in the early 1980s.

Formed in 1978 by Walter H. Gilbert, the Nobel prize-winning biologist from Harvard University, Biogen's major problem during its formative years was that it was a charming place to work, but lacked focus, direction and long-term vision. One result was that it was near bankruptcy by the mid-1980s with losses reaching $100 million over a five year period.

To save itself, the young company licensed its early products and technology — a strategy that has proven to be its savior. Jim Vincent, who joined the company as president in 1985, is credited with restructuring the company by modifying some of the licensing agreements, selling its European operations, refocusing the company and improving its management team.

Back in the early 1980s, Biogen along with Genex, Cetus and Genetech were pioneers. Today only Biogen remains independent as Cetus and Genex merged with other biotech companies while the elder statesman of biotech startups, Genentech Inc., is a majority-owned subsidiary of Hoffman-LaRoche.

Indeed, a major reason for Biogen's independence has been the phenomenal success of its licensed drugs. Biogen-developed recombinant alpha interferon compound, was the first new genetically engineered drug to receive market approval.

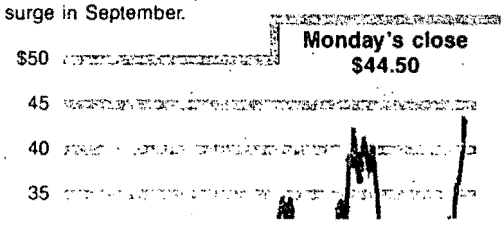
Biogen is also getting a major boost from the success of its hepatitis B vaccines and diagnostics.

Beyond hirulog and Biogen's licensed products is the possibility of acquiring technologies and developed drugs from smaller biotech companies, noted Vincent.

"We're looking at all our options," he said. "There will be lots of opportunities in the next few years."

Stock price rises

Biogen forecast a 70 percent jump in 1992 earnings, which led to a stock price surge in September.



Back to the Future: Biotech Product Sales 1983-1993

The art of predicting which products will make it and when is a lot more difficult than we used to think

ARTHUR KLAUSNER

10 CELEBRATING A DECADE OF EXCELLENCE

With Amgen (Thousand Oaks, CA) likely to record close to a billion dollars in revenue for 1992 on the strength of a pair of blockbuster drugs, the days of wondering whether actual, marketable products would ever emerge from the new science of applied molecular biology seem far behind us. It's well worth remembering, however, that when *Bio/Technology* was launching its inaugural issue just ten years ago this month, the human insulin engineered by Genentech (S. San Francisco, CA) and marketed by Eli Lilly (Indianapolis, IN) was the only biotech-derived therapeutic on the market. In the decade that followed, more than a dozen rDNA products have been approved in the U.S., and total annual sales in this country now top $2 billion (see Table 1).

The "big four"

This is not to imply that the past ten years have been a casual stroll through the lab by any means. Back when *Bio/Technology* was first trying to figure out what it wanted to be when it grew up, the "Big Four" of the toddling biotech "industry" were Genentech, Cetus (Emeryville, CA), Biogen (Cambridge, MA), and Genex (Paris, France). Biogen and Genex dropped off this prestigious list early on as a result of business difficulties, while Genentech and Cetus eventually decided that there were more important things in life than being a free-standing company. Today's "Big Four" of independent biotech concerns would include the following:

- Amgen (which had been written off by many as virtually dead around 1985 and doesn't seem to have made a single mistake since then);
- Chiron (Emeryville, CA) (which acquired neighboring Cetus as part of its impressive rise toward the top);
- Synergen (Boulder, CO) (mostly on the strength of its interleukin-1 receptor antagonist, Antril, which has completed Phase III clinical trials—and whose status is keeping stockpickers across the biotech industry holding their collective breath); and
- Biogen (which has made a spectacular recovery under the leadership of Jim Vincent and now has the enviable responsibility of cashing more than $100 million worth of royalty checks each year).

Back in the early 1980s, however, not only was it difficult to pick the winning companies, but even figuring out what *products* might be blockbusters was no simple task. Early articles in *Bio/Technology* touted tissue plasminogen activators (t-PA) for blood clot disorders (June, 1983), described an experimental enzyme therapy for a rare and little-known genetic disorder called Gaucher's disease (November, 1983), and even put alpha-interferon on trial (March, 1984). All of these products are on the market today.

Biodog or superdrug?

Yet it was more than determining which products would work; even if eventual FDA approval was taken as a given for a particular product, estimates of total sales potential could vary all over the map. Take, for example, the drugs in the early Genentech product portfolio. Alpha-interferon was initially (and very naïvely) hailed as biotech's prototypical superdrug. When this lymphokine's development didn't set new clinical land-speed records, however, it languished for several years in biotech's doghouse. Today, with alpha-interferon boasting worldwide sales of over half-a-billion dollars [via the combination of Schering-Plough (Union, NJ) and Hoffmann-La Roche (Nutley, NJ)], one would be hard-pressed to call this drug a dog. Similarly, human growth hormone (hGH) was originally panned as having just a $40 million U.S. market potential (unless it became widely sold to parents dreaming of being supported in their aging years by basketball-star offspring). Nevertheless, through short-stature applications alone, hGH now generates over half-a-billion dollars in annual worldwide sales. Finally, there is t-PA. Not too long ago, this clot-dissolving agent was supposed to be Genentech's billion-dollar blockbuster. Current an-

Biogen has made a spectacular recovery under the leadership of Jim Vincent and now has the enviable responsibility of cashing more than $100 million worth of royalty checks each year.

Arthur Klausner is director of research at Domain Associates (Princeton, NJ), a venture capital firm specializing in early-stage life sciences investments. From 1983-1988, prior to finding honest employment he toiled as an editor at Bio/Technology.

nual (though declining) sales of close to $200 million in the U.S. can't be considered peanuts, but t-PA certainly didn't become the caviar that high-paid market analysts thought they had ordered from biotech's tempting menu.

Turning to other companies and products, remember when Teena Lerner (then a biotech analyst for L.F. Rothschild; now a biotech analyst for Lehman Brothers) was almost laughed off Wall Street for predicting that Amgen's erythropoietin (EPO) had a greater than billion-dollar sales potential? Say hello to EPO, biotech's first billion-dollar drug. In another case, Genzyme's Ceredase, the enzyme replacement for victims of Gaucher's disease (U.S. population 2000-3000), was widely regarded as nothing more than a concept-proving niche product. But now that the price of this drug may range from $58,000 to $546,000 per patient per year (according to figures from the U.S. Office of Technology Assessment), Ceredase quickly becomes the only player in a potential $100-million "niche."

These success stories, however, do not mean that biotech products have uniformly exceeded expectations. Cetus bet its future on interleukin-2, and although this product is now on the market it is not clear whether IL-2 will ever attain substantial sales. And don't forget the hype that surrounded tumor necrosis factor versus cancer, superoxide dismutase against ischemia-associated damage, and recombinant growth factors for wound healing. Further, while highly touted monoclonal antibodies have succeeded in revolutionizing the diagnostics industry and have begun to impact imaging as well, these "magic bullets" have thus far missed the mark in therapeutics.

A new playing field

Clearly, biotech's playing field has changed greatly over the past ten years. Perhaps nowhere was this transformation more evident than at January's Eleventh Annual Hambrecht & Quist Life Sciences Extravaganza in San Francisco. No longer did presenting companies use the majority of their precious 25 minutes of fame to expound on the virtues of their "enabling technology platforms." Instead, for example, Chiron CEO Ed Penhoet spent the first 10 minutes of his speech defending the pharmaceutical industry — that's right, the *pharmaceutical* industry — and its aggressive pricing practices that have come under so much fire of late. Importantly, the majority of other speakers for so-called second- and third-tier companies succeeded in making comparable transitions from the technical lexicon of the 1980s (rDNA, GM-CSF, MAb) to biotech's modernized, product-oriented version of alphabet soup (IND, NDA, PLA). Can the days of PE ratios, ROI, and EBIT be far away?

So, what does the future hold? Data churned out annually by the Pharmaceutical Manufacturers Association (Washington, D.C.) indicate that biotech products are literally clogging up the FDA pipeline. (If only Genex's ill-fated microbial drain cleaner could have worked on *this* kind of log-jam. . . .). As a result of all this clinical progress, publicly traded biotech companies are beginning to be valued less on science-based "hopes and dreams" and more on the timely accomplishment of commercially oriented milestones.

	1987		1992		1997	
	U.S.	*World*	*U.S.*	*World*	*U.S.*	*World*
Alpha-interferon	14	55	135	565	290	1020
Beta-interferon	—	5	—	20	10	35
CD4	—	—	—	—	30	45
Centoxin/E5 MAbs	—	—	55	75	115	220
Erythropoietin	—	—	600	1225	910	1845
Factor VIII	10	10	140	235	270	445
Gamma interferon	—	—	15	25	35	45
G-CSF	—	—	295	405	550	870
GM-CSF	—	—	50	70	155	305
Hepatitis B vaccine 50	100	105	260	105	275	
Human growth hormone	95	130	270	575	225	660
Human insulin	65	175	245	625	405	1035
Interleukin-2	—	—	5	20	30	50
Orthoclone OKT3	5	10	55	90	95	160
T-PA	55	60	180	230	85	120
TOTAL	**294**	**545**	**2150**	**4420**	**3310**	**7130**

Source: Robin Rodgers, Decision Resources, Inc. (April, 1992). Note that these figures were derived prior to the difficulties encountered by Centoxin.

TABLE 1. Estimated sales of selected biopharmaceutical products (in U.S. $ millions).

Surely this is a more mundane state of affairs than the previous ability to obtain lofty valuations based solely on far-off visions of technological wizardry. But in the long run, the winning biopharmaceutical companies will be the dull, plodding firms that succeed in putting actual products into the hands of practicing physicians to be administered to real patients. Suddenly, "boring" doesn't sound so bad after all.

Reprinted from:

THE WALL STREET TRANSCRIPT

"The Information Center for Business and Finance"

Volume CXVIII Number 8
Published Monday

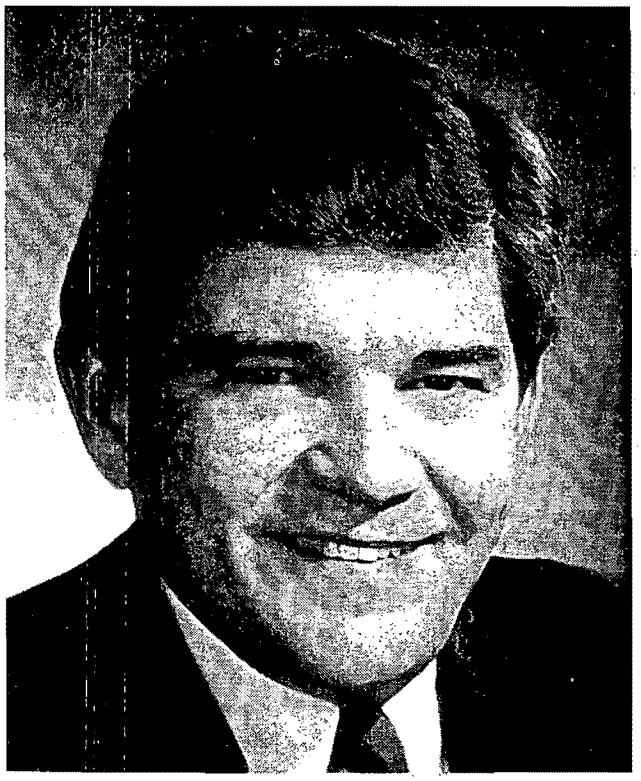
99 Wall Street, New York, N.Y. 10005— Voice (212) 952-7400; Fax (212) 668-9842; (212) 668-9858; (212) 490-3258
Second Class Postage Paid at New York, N.Y. (ISSN0043-0102)

November 23, 1992
Page 107,669-107,760
Single Issue $175.00

CEO Confidential

Biotechnology

BIOGEN INC. (BGEN)



SILVER: James L. Vincent, Chairman & CEO, Biogen Inc.

James L. Vincent, Chairman and Chief Executive Officer of **Biogen**, headquartered in Boston, Massachusetts, is our silver honoree as the experts tell us.

Characterized as a judicious executive, the CEO has demonstrated a keen understanding of the substance and culture of this company. That understanding is clearly reflected in a strategy that capitalizes on **Biogen**'s strengths, focusing this company's experience and expertise on selective fields. **BGEN**'s portfolio may not be one of the largest, but it is one of the most promising and becoming one of the most comprehensive in some very intriguing areas. Revenues have made powerful advances, as strong sales have produced substantial royalties, and are expected to continue the climb as proprietary products reach the market over the next several years.

Vincent's leadership and direction have had a dramatic impact on this company, as **Biogen** emerges a dynamic, disciplined organization.

Born in 1939 in Johnstown, Pennsylvania, the CEO is a graduate of Duke and Wharton.

The CEO's perspective most impressed one Wall Streeter, "Strategically he's one of the most thoughtful CEOs. He never has the knee-jerk reaction to any of **Biogen**'s products. He's very focused, in terms of which products are going to develop. So, **Biogen** hasn't run off into hundreds of different areas, even though it has some $100 million worth of royalty income coming in this year. I think he's built a really excellent management team. And, he's strengthened the scientific effort at **Biogen**. Remember, this company had many problems a few years back. I think he's really had to rebuild that company.

"As to the pipeline, hirulog is in Phase III. Beta-interferon is just entering Phase III. Those are in late-stage clinical trials and are very interesting developments. But it will be a royalty play, obviously, for the next two or three years as those studies will take at least another year to finish then filing and 18 months at the FDA."

Another **Biogen** supporter reports, "Vincent at **Biogen** has done a great job. **Biogen**'s royalty strategy has paid off handsomely. The company is developing its own drugs, proprietary products. He's just managed this business extremely well. **Biogen** has earnings now. This company's success was achieved by Jim Vincent."

This team is determined to call its shots, maintains an industry expert, "**Biogen** has not bowed to the demands for reporting a higher bottom line. Rather, this team is investing in the future, and maintains a single-minded focused on specific products. **Biogen** did get quite lucky with two of its licensed products, which are generating good royalties.

Biogen is at a very exciting stage, asserts a buy sider, "**Biogen**'s royalty stream has increased substantially over the last six months. The company's income has increased substantially because of substantially higher sales of alpha-interferon for the treatment of hepatitis and sales of hepatitis-B vaccine, particularly in the U.S. **Biogen** gets royalties on both of those products.

"The more important issue, however, is that **Biogen** is getting closer to commercializing two proprietary products. This is a second phase, the new **Biogen**. Both products are in Phase III trials, middle-phase retrials, and are likely to be filed for approval some time next year. So, **Biogen** is getting closer to the market with its own products."

This is one tough contender, concludes a long time follower of the group. "He's non-promotional, he gets things done. He has managed to strike some of the best royalty arrangements in the biotech industry. Vincent has kept **Biogen** self-financing for the past several years. A single-minded, very touch executive."

Opinion

Protecting our new frontier

JAMES L. VINCENT

ONE REASON FOR THE CURRENT overemphasis on the bad news in the private sector is a failure to recognize that, for two decades, American industry has been undergoing a profound change. We are shifting away from the large, company-driven economy we have all grown up with to a world of economic growth fueled by entrepreneurial-driven small and mid-sized companies. If we remain too closely focused on the ups and downs of our Fortune 500 companies – and then extend their problems arbitrarily across the board – we are putting a falsely negative spin on the entire business picture in this country today. We are missing the exciting new frontier in business in which America is leading the world.

This frontier is dominated by small and mid-sized companies, many of them in high-technology areas. Consider some of the important new industries creating jobs and changing our lives: seniconductors, lasers, worldwide broadcasting with CNN, cellular telephones, computer software, telecommunications with MCA, diagnostic medicine. Then there are computers in general, with recent explosions in PCs, workstations and laptops. And, of course, there's biotechnology. There is a common thread in this list – we in the United States have been fundamental in creating these industries and creating the changing industrial climate.

The biopharmaceutical industry is a very good example of this dynamic and chaotic cauldron. It is an industry with tremendous potential, only now beginning to be realized. It is a particularly good model of this new order of industry, especially in the way it reflects a growing dynamism in the partnership among US industry, government and academe. Many of its lessons and examples can be applied across the entire spectrum of technology-based industries.

It has been only 15 years since the commercial phase of this industry started. Since then, more than 1,000 biotechnology companies have been founded in the United States alone – nearly double the number of just five years ago. More than 200 are public companies, with a market capitalization of more than $45 billion. Fifteen biopharmaceutical drugs have received US Food and Drug Administration approval; an additional 135 medicines and vaccines are currently in clinicl trials – up to 70 percent from two years ago.

There are two key reasons for this industry's jumpstart success. First, biotechnology builds on traditional American strengths and values. Second, it has capitalized on a dynamic relationship among academe, government and industry, which are working together in creative new ways.

By breaking down some of the divisions between academe and industry, we have assured our ability not only to conceptualize new technologies, but to bring them to market. Route 128 today, for example, is a monument to MIT's activities in this regard.

The government is clearly the second important leg in this triangle. The federal government makes an extraordinary contribution to scientific research in this country, both in its own laboratories and in support of extramural research. In 1990, for example, the National Institutes of Health alone invested more than $860 million in its own research labs and in excess of $6 billion to support grants and contracts. Almost $3 billion of this applied to research in biotechnology.

The government also plays a vital role in stimulating a healthy economic climate and in providing a regulatory environment that protects the American public without crippling American industry.

The private sector is the third leg. It is often criticized for its emphasis on short-term gain, but the investment community has made significant long-term commitment to the biopharmaceutical industry, where the payback is often eight to ten years away.

We now face a critical question: How do we make sure America's leadership continues? There are many people in technology-related fields who worry that the United States will become a "technology colony" for the rest of the world, losing competitiveness as we export the basic technologies that will build other economies at the expense of our own.

We can – and will – retain our global leadership position if we remember that technology-based industries change fast because they're growing fast and need the kind of support from society and our government that encourages this growth instead of stifling it.

Excerpted from a speech by James L. Vincent, president and chief executive officer of Biogen Inc., one of the state's largest biotechnology companies. He delivered the speech Feb. 12 at MIT's Technology Initiatives conference.

BIOGEN 1992 ANNUAL REPORT

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Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

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TELECOPIER COVER SHEET

Direct Dial Number
(202) 434-7350

TO: Ms. Rosalyn Kelly

DATE: May 3, 1993

FROM: Judy Doyle

Telecopy Number: (202) 456-2878

Business Telephone: (202) 456-2216

Attorney No.: 600

Client/Matter No.: 03783.013

We are sending a total of 2 pages, including this cover sheet. We are transmitting on a Xerox 7021. If you do not receive the indicated pages, please call us at 202/434-7300, as soon as possible so that we may check it for you. For your information, our automatic 24-hour incoming telecopy phone number is 202/434-7400.

As per our conversation, I am sending a list of participants for the meeting scheduled for 10:00 am on May 5, 1993, with Ms. Rasco.

Time Transmitted: _____

By: _____

MBC PARTICIPANTS

MAY 5, 1993

NAME	TITLE	COMPANY	DOB
Garen Bohlin	Executive Vice President	Genetics Institute, Inc.	P6/b(6)
Janice Bourque	Administrative Director	Massachusetts Biotechnology Council	
David Castaldi	President & CEO	BioSurface Technology	
Peter Feinstein	President	Feinstein Partners, Inc.	
Marc Goldberg	President	Massachusetts Biotechnology Research Institute	
Richard Pops	President & CEO	Alkermes, Inc.	
Ramesh Ratan	Senior Vice President, Administration & CFO	Repligen Corporation	
Gabriel Schmergel	President & CEO	Genetics Institute, Inc.	
Mark Skaletsky	President & CEO	GelTex, Inc.	
Sandford Smith	President & CEO	Repligen Corporation	
Alison Taunton-Rigby	Senior Vice President, Biotherapeutics	Genzyme Corporation	
James Vincent	Chairman and CEO	Biogen	
Joseph D. Alviani		Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.	
J. Edward Fox		Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C.	

D16208.1

Roz
Call them to set up 30-45 min. meeting on requested day.
CLR

MBC

Massachusetts Biotechnology Council, Inc.

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(617) 577-8198
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April 3, 1993

Ms. Carol Rasco
Office of Domestic Policy
The White House
Washington, D.C. 20500

Dear Ms. Rasco:

On May 5, representatives of the Massachusetts Biotechnology Council and its member companies will be in Washington holding its 1993 Washington retreat. The purpose of this letter is to request a meeting with you during the morning hours of that day to discuss issues of national interest confronting the biotechnology industry.

Formed in 1985, the Massachusetts Biotechnology Council currently represents over 70 commercial companies as well as over 50 public and private entities involved in biotechnology that are on the cutting edge of scientific and technological development in this country. As one of the nation's premier centers for academic research and development, Massachusetts and the surrounding area have been able to create a large segment of the biotechnology industry through the innovative and cooperative efforts of both government and the private sector. A key component of the MBC's mission is to foster dialogue and understanding between the biotechnology industry and government policymakers. It is with this goal in mind that the MBC and representatives of its member companies will be making the trip to Washington on May 5th. I am certain that you will find this opportunity to exchange views with representatives of the MBC to be a time well spent.

We will be contacting your office in the next few days in order to arrange for such a meeting that will be convenient to your schedule. For your information we have enclosed a brochure providing a brief description of the MBC and its objectives. If you have any questions or would like any further information, please contact our Washington representative, Ed Fox, at (202) 434-7317. We look forward to meeting with you on May 5th.

Sincerely,

Marc Goldberg

Marc Goldberg
President, Massachusetts
Biotechnology Research Institute
Chairman of the 1993 Washington
Retreat

Enclosure

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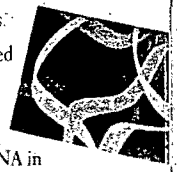
Why Massachusetts?



It is not by chance that Massachusetts is now a world center of biotechnology. The Commonwealth has always attracted emerging industries because its many universities house leading researchers who early on recognized the value of new technologies. These institutions have made great human capital investments in basic biological research ever since the role of DNA in encoding proteins was discovered by Watson and Crick in the 1950s. The power of this rich academic environment and related cultural wealth is perhaps the single most important factor stimulating the growth and development of the biotechnology industry in this state.

Other factors have also spurred industry growth. For example, Massachusetts has in place a full spectrum of financial and legal support services needed by rapidly growing, innovative industries. This unique combination of circumstances in Massachusetts has produced an increasing number of biotechnology start-ups in the state in recent years.

Biotechnology in Massachusetts has grown in three ways:

- The establishment of new companies.
- The maturation of existing companies, several of which are moving from research and development into manufacturing and marketing.
- Expansion by out-of-state pharmaceutical companies into Massachusetts-based biotechnology.

The Massachusetts biotechnology industry will continue to expand as the list of products grows, the number of companies increases, and the technology encompasses more and more industries.

Cover Image: The atomic structure of FKBP, an important immune system protein, as determined by protein NMR spectroscopy and X-ray crystallography.
Courtesy of Vertex Pharmaceuticals Incorporated
Cambridge, Massachusetts

Design courtesy of Gröh & Co., Inc.
Cambridge, Massachusetts

Printing courtesy of R.R. Donnelley & Sons
Boston, Massachusetts

Massachusetts Biotechnology Council, Inc.
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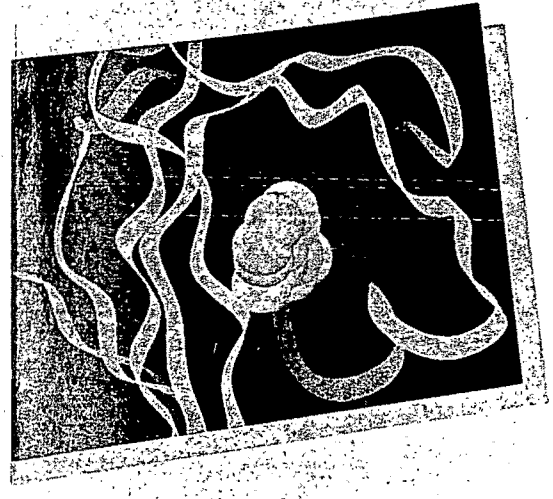
The Massachusetts Biotechnology Council, Inc.



Biotechnology: A Mean

Biotechnology is the commercial applic
It engages advanced new techniques and
simply part of an age-old practice of usi
to benefit the human race. Biological pro
been used for centuries to make prod
and, more recently, drugs such as penicil
However, traditional biotechnology, a pro
involving years of genetic selection to ach
A dramatic advancement occurred in th
scientists first directly modified the gene
terial cells that controls the production o
manipulated that genetic information to
specifically desired proteins and other s
breakthrough made it possible to develop
in quantities beyond the means of conve
techniques. Currently, biotechnology en
applications in commerce and industry
agriculture and chemicals.

Although scientists around the world a
nology research, only a few places have l
commercial development. Massachusetts
Massachusetts biotechnology companies
understanding of biology to develop, ma
market a wide range of products, includi

- therapeutic drugs
- diagnostic tests
- vaccines
- drug delivery systems
- artificial organs and tissues
- genetic disease screens
- agricultural products
- food in
- veterin
- industr
- and ma

Goals of the Massachusetts Biotechnology Council

The Massachusetts Biotechnology Council is a statewide trade association representing biotechnology companies in Massachusetts, as well as other groups inside and outside the state with an interest in servicing or promoting biotechnology. The MBC is committed to helping communities, local and state governments and regulatory agencies understand biotechnology, its realized and potential contributions to society, the impetus it gives the economy, and the needs of the industry.

The specific objectives of the MBC are:

- To advance common goals and concerns of member companies.
- To promote the social and economic benefits of the biotechnology industry in Massachusetts.
- To help build and maintain a suitable business climate in the state.
- To assist in the development of a realistic and coherent federal, state and municipal regulatory environment.
- To develop and support training programs to help foster a strong base of present and future workers for biotechnology.
- To help the public make informed decisions about issues concerning biotechnology through educational and informational activities.

MBC Public Affairs Activities

The MBC has become an influential voice in setting public policy that stimulates the growth of the general economy in Massachusetts. The MBC also plays an important role in industry specific and allied issues. MBC influence reaches beyond Massachusetts' borders, as it is increasingly considered the leading advocate for biotechnology in the Northeast.

The MBC's agenda for enhancing the state's overall business and fiscal climates has served both public and private interests. For example, the Council has helped attract innovative employers to the state by helping secure significant improvements in the state's tax structure and regulatory environment. At the request of the Governor, the MBC participated in a Task Force on Biotechnology and Pharmaceutical Development, which proposed numerous actionable steps to ensure the continued growth of the state's economy.

Education And Training

In order to grow, biotechnology companies need an educated and skilled work force. The MBC has demonstrated its commitment to education by formally launching an Education and Training Initiative whose director reports to the MBC Board of Directors. This initiative has been undertaken in conjunction with another non-profit biotechnology organization, the Worcester-based Massachusetts Biotechnology Research Institute (MBRI).

This joint initiative has three principal goals:

- To become the focal point for bioscience education activities statewide and to be a resource for teachers, community leaders, parents and interested citizens who want to understand this industry more fully.
- To train current and future workers for the industry by helping to establish continuing education programs, certificate programs and full-degree programs at the state's public and private two- and four-year colleges.
- To support life science education for teachers and students in grades K-12 statewide. The MBC and MBRI work with school systems to train teachers in the biosciences, to pair teachers and schools with individual biotechnology companies, and to assure that quality bioscience materials and information are available to interested educators.

MBC Membership

Full MBC members are corporations in Massachusetts that are developing and, in some cases, manufacturing or marketing a broad spectrum of products using biotechnology. Human health care products predominate. Many members are pursuing drugs to treat major diseases such as cancer, blood disorders, cardiovascular diseases, neurological disorders and autoimmune diseases. Others are developing vaccines and drug therapies to help combat AIDS. A number are committed to developing and manufacturing diagnostic tests for use in the home, laboratory, or doctor's office. Still others are creating skin replacements and blood substitutes.

Beyond health care, members are using biotechnology methods to increase crop yields, grow plants that are resistant to certain pests and to plant disease, and produce nutritional food ingredients. Finally, many members are in allied fields such as manufacturing or distributing equipment and other tools to aid in biotechnology research, scale-up and manufacturing processes.

Among the currently marketed products created by member companies are a treatment for Gaucher disease (a genetic enzyme deficiency disorder), alpha interferon for the treatment of certain cancers and viral diseases, a service for providing skin grafts to burn patients, and tests for food contaminations.

The MBC also includes associate members, which represent other public and private institutions that support or service the industry but are not directly involved in developing or producing biotechnology products, as well as companies outside the state that share a long-term interest in the industry's success in Massachusetts.

The MBC frequently sponsors informational seminars of interest to members and non-members alike. The MBC Annual Meeting is held each spring to bring together members of industry, government and academia for discussions on the business and science of biotechnology.

The Bioline, the MBC's quarterly ne all members, as well as educators, stu and interested citizens.

MBC Structure

The Board of Directors, comprised executives, oversees the Council's acti set policy, and assures that MBC obje pursued and met.

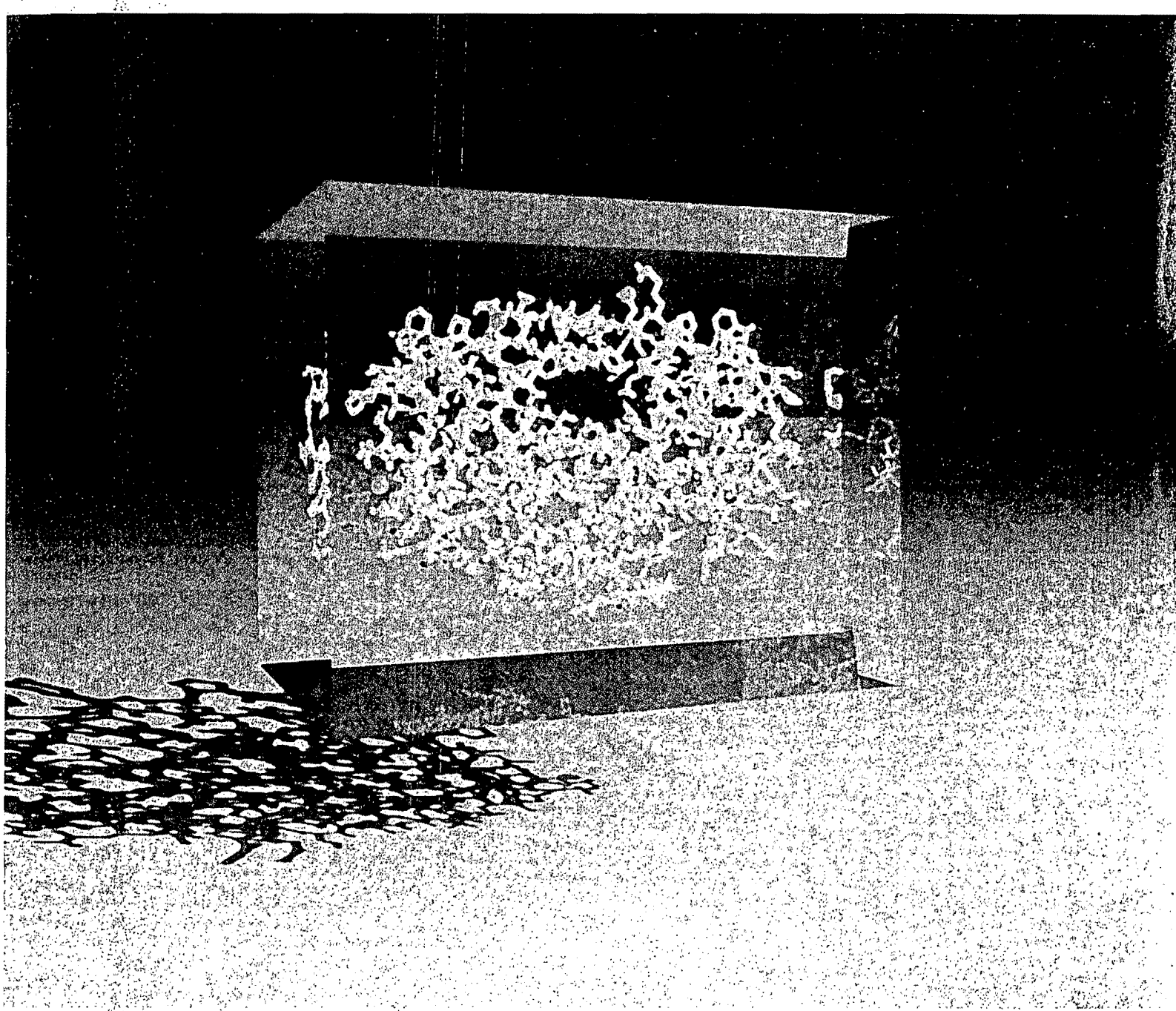
Many of the day-to-day accomplishi been achieved through the MBC's eig communications, community relation information systems, purchasing, safe sports. They are comprised of volunte of managerial responsibilities at mem member organizations. This highly el with an active MBC Board of Directo of the Council's breadth and success.

Where We Are Today

Since the MBC was founded in 198 significantly to include more than 10 member organizations. The MBC no organizations in Massachusetts that a technology or that strongly support it achieved a significant presence in the and political communities since its fo new companies and products brought continues to grow, the MBC's ongoin to communicate and advance the inte Massachusetts industry.

M B C

MASSACHUSETTS BIOTECHNOLOGY COUNCIL



MBC 1993 Annual Conference

April 28 and 29

MBC/NESMA TRADE EXPOSITION

World Trade Center

Boston, Massachusetts

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EDUCATION INITIATIVE

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COMMITTEES

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ACTIVE COMMITTEE MEMBERS

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A Quarterly Publication of the Massachusetts Biotechnology Council

THE BIOLINE

VOLUME 6, NO. 1 SPRING 1993

COMMONWEALTH'S EMERGING TECHNOLOGY FUND SIGNED INTO LAW

Fund to Back $200 Million in Private Debt Financing for Massachusetts Company Expansion

by Jeanine Kelly

The Massachusetts Legislature has passed the Emerging Technology Fund component of the Economic Development Bill, sending a strong message to companies in Massachusetts and elsewhere that the Commonwealth is committed to creating a business climate friendly to emerging technologies. The $15 million provided by the fund, together with another $30 million-plus in moral obligation capacity, enables the Commonwealth to provide loan guarantees that can generate as much as $200 million in total financing from the private banking sector. The fund will be used as a credit enhancement vehicle in which the Commonwealth will guarantee approximately 20 to 25 percent of the total value of a company's financing package.

Garen Bohlin, President of the MBC, commented, "The Emerging Technology Fund addresses one of the most critical needs of Massachusetts'

Continued on page 5

INSIDE

MBC ANNUAL CONFERENCE TO FEATURE BIOTECHNOLOGY INDUSTRY ISSUE PANELS AND LEADING RESEARCH SCIENTISTS

Over 150 Vendors to Participate in Trade Exposition

The MBC Annual Conference, to be held April 28 and 29 at the World Trade Center in Boston, will feature leading biotechnology business and research leaders as well as a trade exposition of biotechnology and related products. The MBC has expanded its traditional annual meeting format to a two-day conference that includes the MBC annual meeting and biotechnology business seminars on April 28, a science symposium and MBC committee meetings on April 29, and a trade exposition taking place both days.

Dr. Edward Scolnick, President of Merck, Sharpe & Dohme Research Laboratories, will give the luncheon keynote address on "Molecular Approaches to Drug Design" at the science symposium on Thursday, April 29. Dr. Scolnick has worldwide responsibility for Merck's research and development programs in human and animal health and agriculture. Featured panels of the science symposium include: "Biotechnology and Structure-Based Drug Discovery," moderated by Vicki Sato, Ph.D., Vice President of Research, Vertex Pharmaceuticals, and Robert Kamen, Ph.D., President, BASF Bioresearch; and "Nucleic Acid-Based Therapy," moderated by Alison Taunton-Rigby, Ph.D., Senior Vice President, Biotherapeutics, Genzyme Corp.

The first day of the Annual Conference, Wednesday, April 28, will incorporate the MBC's traditional annual meeting sessions, including a morning plenary session open to MBC members only. The plenary session will feature the

Continued on page 2

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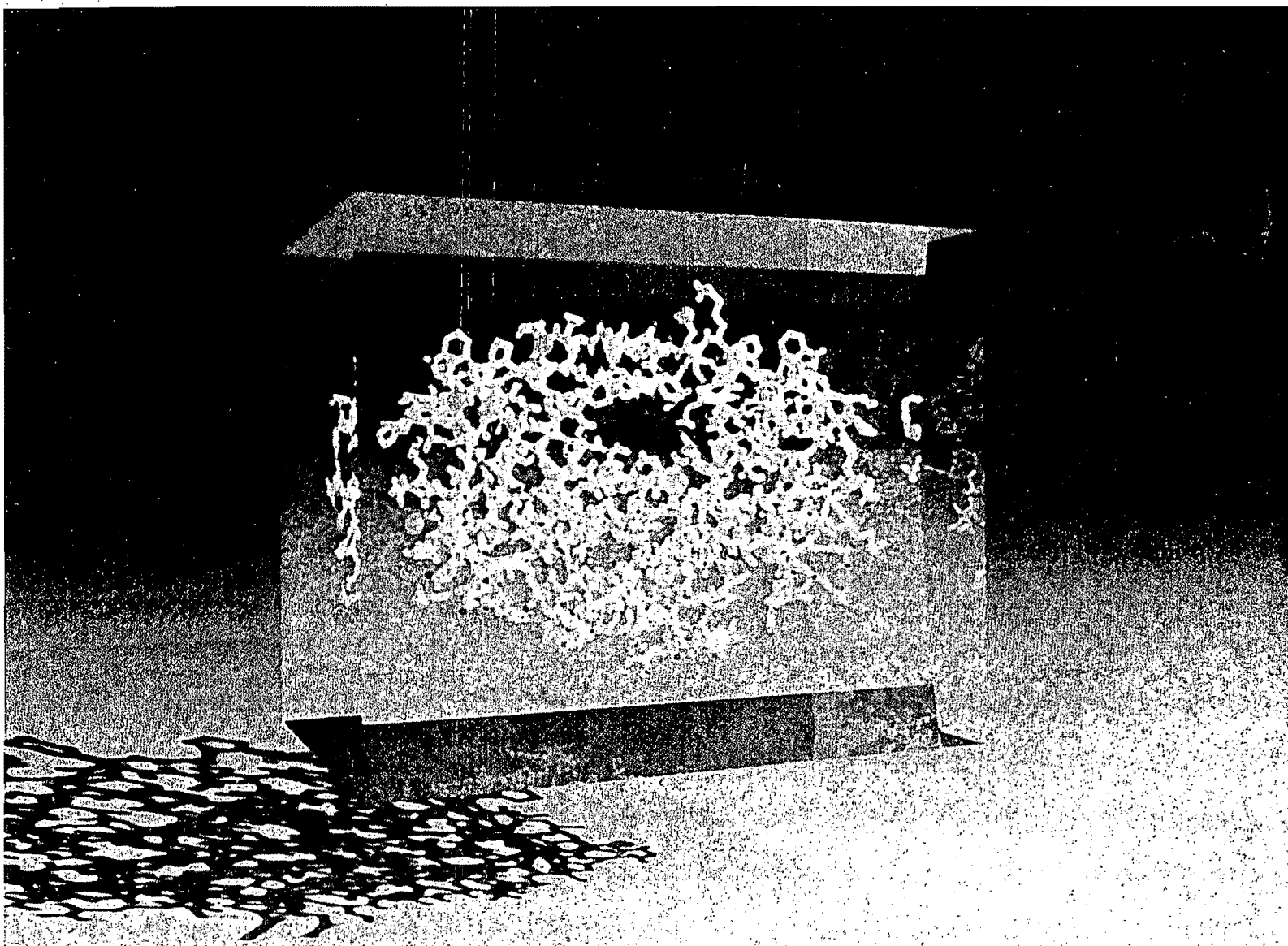

MBC 1993 ANNUAL CONFERENCE

APRIL 28 AND 29

ANNUAL MEETING **COMMITTEE MEETINGS**

SCIENCE SYMPOSIUM **TRADE EXPOSITION**

WORLD TRADE CENTER BOSTON, MASSACHUSETTS

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OVERVIEW

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MEMBER COMPANY PROFILES

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