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Cancer Economics

Biotherapeutics Restructures, Oldham Forced Out, West Is CEO

Robert Oldham's plan to provide state of the art research treatment to cancer patients who could afford to pay for it has failed.

After going through nearly all of the $40 million in capital raised through a public offering, the company failed to come up with another placement, has gone through restructuring and a name change.

In the aftermath of the collapse of the old Biotherapeutics:

▸The new company, called Response Technology Inc., is preparing to open a number of outpatient cancer centers along with IV pharmacies and blood banks.

▸Oldham, who has been forced out of the business, now faces the task of raising $5 million over the next three years to finance the operation of Biological Therapy Institute, a nonprofit institute that used to be supported by Biotherapeutics.

▸Following a disagreement related to the cessation of funds from Biotherapeutics, Oldham has resigned from chairmanship of the National Biotherapy Study Group.

RTI's new CEO, William West, said the company is in the middle of negotiating a private placement of capital that would enable it to start a number of cancer centers.

"We are attempting to define a unique concept of pharmacy and blood bank extension that would be extension of local oncologists' outpatient capability," West said to **Cancer Economics.**

The centers would facilitate administration of higher doses of chemotherapy and reduction of hospital stays.

In addition to the center in operation in Memphis, in the next two months the company plans to open centers in Tampa and Hollywood, FL.

West said the new company will not provide experimental treatment to patients who are able to pay for it. Instead, it will concentrate on reimbursed treatment precertified through third party payers.

More information on the company's plans will be available in the next few months, after the place-

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Biogen Reports First Profitable Year, Agrees On Licensing With Genentech

Biogen Inc. (NASDAQ: BGEN) has reported the first profitable year since its founding in 1978.

For the year ended Dec. 31, 1989, the company reported net income of $3.2 million on the revenues of $40.9 million.

In the previous year the company lost $1.2 million on the revenues of $30.2 million.

"A significant increase in ongoing royalties from Schering-Plough's alpha interferon and expansion of our hepatitis-B licensing program," said Jim Vincent, the company chairman and chief executive officer.

In addition, Vincent said, "Biogen's gamma interferon development program achieved major milestones in 1989 as the product was launched in West Germany and received marketing approval in Japan."

A recent public offering of the company's convertible exchangeable preferred stock raised $69 million, the company said.

"The result is that we begin this decade with over $110 million in cash, no debt, rapidly rising revenues from our product line, and an expanding research pipeline," Vincent said.

In a related development, Biogen and Genentech have entered into a crosslicensing agreement for human recombinant gamma interferon in the U.S.

Under the agreement, each company will be able to sell its gamma interferon product for specific therapeutic and diagnostic applications.

At the same time, Biogen granted Genentech a nonexclusive worldwide license for process patents relating to the secretion of proteins.

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Biotherapy Study Group Reorganized As Nonprofit Research Group

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ment of capital is finalized, but, West said, the new company plans to maintain a lower profile than the old Biotherapeutics.

The National Biotherapy Study Group, founded by Oldham and supported by Biotherapeutics, has reorganized as an independent not for profit research group and replaced Oldham as chairman with Robert Dillman.

The study group's problems came to a head when Biotherapeutics ran out of money and, for all practical purposes, went out of business.

Biotherapeutics, whose stock had reached a high of $30 at one time had dipped to less than $1, was controversial from the start: Oldham had started it as a for profit firm which provided cutting edge research treatment to cancer patients who could pay for it--the cost sometimes reaching $35,000 or more.

Convinced That Patients Could Benefit

Selling experimental research, with the intent of profiting from it, was more than many traditional medicine people, academics, NCI, and others, could stomach.

But Oldham convinced many others that not only was it ethical and practical, but it was the only way many patients could benefit from participation in clinical trials, and that his program could be at the forefront of clinical research into biological forms of cancer treatment.

He also convinced Wall Street, which enthusiastically embraced his concept and generated millions for the Franklin, TN, company.

It wasn't enough; when Oldham was forced to surrender control of the company, and later to see it go out of business, he said the big problem was that the concept could have succeeded if he could have raised more money.

RTI inherited the obligation to support NBSG, but that support will end in June.

Oldham retained the Biological Therapy Institute, which was also supported by Biotherapeutics.

BTI was a nonprofit medical research institute which conducted clinical trials for various biopharmaceutical companies. BTI and its affiliated hospital, Williamson Medical Center, are major participants in NBSG, contributing more than 30 percent of the patients enrolled in its protocols.

With the support from Biotherapeutics gone, Oldham was faced with the prospect of raising funds to support BTI. He has undertaken the task of raising $5 million over three years, concentrating on industry and "high level individuals," he said in an interview.

Oldham had hoped that NBSG, which he felt was a "jewel" surviving from the fall of his enterprise, could play a role in his fund raising efforts.

The majority of NBSG participants felt otherwise. When they refused to go along with his plans, he resigned as chairman, although remaining on the executive committee and an active member of the group. Dillman was elected as the new chairman.

Dillman, medical director of the Hoag Memorial Hospital Cancer Center in Newport Beach, CA, had been one of the principals in Biotherapeutics' operations.

He had joined the organization when he was in La Jolla, and then when he moved to Hoag, he established a laboratory which contributed to Biotherapeutics' ability to produce individualized biotherapy for cancer patients.

With the demise of Biotherapeutics and its concept for providing individualized biotherapy, the labs have been closed, or severely cut back.

NBSG protocols were not affected so much by the changes; by nature of a multi-institution collaborative clinical research effort, they had to be standardized. Dillman said these efforts will be continued, at 26 institutions around the country and in Hong Kong.

Protocols include IL-2, interferons, hematopoietic growth factors, intensive therapy with autologous stem cell support, vaccines, and monoclonal antibodies. Patient accrual was 363 in 1989.

The group's central office will remain in Franklin, and Rosalie Avent will continue as executive coordinator.

Oldham will continue as director of BTI, which he said will continue clinical research programs on the testing of new forms of biotherapy; education

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Editor: **Paul B. Goldberg**
Associate Editors:
Jerry D. Boyd, Kirsten B. Goldberg

Editorial/Subscriptions Office
PO Box 15189, Washington, DC 20003
Tel: (202) 543-7665 Fax: (202) 543-6879

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programs for physicians, nurses, and data managers in biotherapy cancer research and treatment; patient advocacy, in which programs will focus on developing methods of bring the patient and the family directly into the center of the cancer research and treatment process; and communications.

BTI is the majority owner of Pulse Publications, which publishes "COPE," a magazine for physicians and other cancer research and treatment professionals; and "COPING," a magazine for patients, families, and others interested in cancer research and treatment.

Biogen, Genentech, In Crosslicensing For Gamma Interferon, Trials Begun

(Continued from page 1)

Genentech has filed for FDA approval for its gamma interferon, trade name actimmune, for the treatment of patients with granulomatous disease, a rare, inherited disorder characterized by an impaired immune system.

Genentech is also conducting phase 3 trials to evaluate the agent's usefulness in treating in patients who have endured severe trauma and as adjunct therapy in the treatment of malignant melanoma and small cell lung cancer.

Biogen has conducted clinical trials in the U.S. with its gamma interferon, trade name immuneron, for treatment of rheumatoid arthritis and venereal warts.

Trials Of ImmunoGen Product, Anti-B4 Blocked Ricin, Show 50% Response

ImmunoGen Inc. of Cambridge, MA (NASDAQ: IMGN), announced that phase 1/2 clinical trials of the company's first product, anti-B4 blocked ricin, have yielded a preliminary response rate of 50 percent in relapsed lymphoma patients.

The company has completed one phase 1/2 trial, initiated three more trials and has received FDA approval for a fifth phase 1/2 clinical trial. All of the trials involve the use of highly specific monoclonal antibodies to deliver the extremely toxic, blocked ricin to tumor cells of non-Hodgkin's lymphoma, acute lymphoblastic leukemia and chronic lymphocytic leukemia.

The phase 1/2 trial recently completed at Dana-Farber Cancer Institute evaluated safety and preliminary efficacy of the product. The drug was delivered by constant infusion of the drug, and resulted in a preliminary response rate of 50 percent with little or no side effects. Trials have also begun at Children's Hospital of Boston for the treatment of pediatric ALL.

Phase 1/2 clinical trials using ImmunoGen's second product, Anti-My9 blocked ricin for the treatment of acute myelogenous leukemia and chronic myelocytic leukemia are being conducted at Dana-Farber.

ImmunoGen reported second quarter revenues of $222,803, mainly from interest income derived from the company's recently completed initial public offering.

Revenue was below the $352,438 realized during the same period of 1988, $300,000 of which was attributable to a milestone payment by E. Merck. The net loss of $2 million for the second quarter was above the $872,442 recorded during the same period of 1988.

The expenses and loss were "in line with our expectations," said Mitchel Sayare, the company's president and CEO. "Among other things, they reflect the costs of five ongoing clinical trials on our first two products and the increased staffing required of our GMP-qualified manufacturing facility."

Companies

Repligen Posts Profit For Quarter; Oncor Raises $1.5 Million

Repligen Corp. of Cambridge, MA (NASDAQ: RGEN), announced a profit of $128,000 for the company's third quarter ended Dec. 31, compared to a loss for the same period last year of $857,000. For the nine months ended Dec. 31, the company reported a loss of $915,598, compared to a loss of $2.6 million last year. The company also completed a $9 million private financing in the United Kingdom to boost cash reserves for the quarter to $26 million.

Revenues for the quarter increased 80 percent to $4 million from $2.2 million last year. The increase was due primarily to a payment from Merck & Co., Repligen's collaborator in developing an AIDS vaccine.

A Repligen study published recently in "Science" appears to demonstrate the ability of platelet factor 4 to block the inappropriate formation of new blood vessels that occur in Kaposi's sarcoma, malignant tumors, diabetic retinopathy, and other diseases. The company produces a modified form of PF4 that it calls Endostatin B.

Oncor Inc. of Gaithersburg, MD, raised $1.5 million in capital in the fourth quarter of 1989, the company announced. The first stage, received in October, consisted of private placement of 510,000 Oncor common stock shares, and the second stage, in

December, of private placement of 700,000 Oncor common shares and $300,000 of debt convertible into 300,000 common shares.

The additional funding will help the company move toward posting an eventual profit, company officials said.

The company has obtained FDA approval for the B-T Gene Rearrangement Test and expects to begin shipping the product this quarter. The test is to help diagnose leukemia and lymphoma.

Roche Holding, the Swiss based parent company of **Hoffmann-La Roche** announced that it intends to purchase 60 percent of **Genentech** for $2.1 billion.

T Cell Sciences Inc. of Cambridge, MA (NASDAQ: TCEL), has received in excess of $3 million as a result of the exercise of 90 percent of the total outstanding publicly traded warrants. The funds will enable the company to expand its therapeutic product development in soluble and T cell receptor technology, company officials said. All unexercised warrants will be redeemed by the company at 10 cents per warrant.

Cetus Corp. of Emeryville, CA (NASDAQ: CTUS), posted a net loss of $15.9 million for the quarter ended Dec. 31, compared to a net loss of $11.5 million for the same quarter last year.

Total revenues increased by nearly 50 percent to $9 million for the previous year's quarter mainly due to improved contract revenues and growth in the company's generic chemotherapeutic business, the company said.

Cost and expenses increased by $6.3 million. Half the increase was due to one time costs for acquisition of the OncoScint and OncoTec product lines for marketing by EuroCetus, the company's European subsidiary, and cost associated with the October Loma Prieta earthquake.

The remainder was due primarily to investments in the sales, marketing and manufacturing as the company introduced its Proleukin interleukin-2 in four European countries.

Increased research and development revenues for the quarter were due to an agreement reached with Hoffmann-La Roche Inc. in mid-1989 to commercialize products and services based on PCR technology. Cetus has transferred four PCR-based tests to the partner's clinical laboratory and plans to transfer six more products this year. The company also recently introduced its first forensics product, the AmpliType HLA-DQ alpha kit, based on PCR technology.

Unimed Inc. of Somerville, NJ (NASDAQ: UMED), announced revenues for the fiscal year ended Sept. 30 of $4.25 million, compared with $4.28 million the previous year. Consolidated net loss for the year totaled $1.9 million, compared with a year earlier net loss of $1.4 million. Research and development expenses increased 39 percent, from $1.75 million to $2.44 million.

Pharmaceutical revenues increased 23 percent, reflecting growth in the company's Marinol (dronabinol) and Serc (betahistine) and an increase in research contract revenues. Sales of dronabinol, the antinausea drug for chemotherapy patients, were supported by aggressive promotion, the introduction of unit dose packaging and new documentation on its benefits with a combination therapy regimen, the company said.

The company filed registration documents for the product in the U.K. and Australia, and formed a collaboration with Dott. Formenti, SPA, an Italian pharmaceutical company. A marketing application is pending in Canada.

The Israel Ministry of Health last month concluded that marinol is "approvable" for marketing in Israel. Final registration and introduction in that country is expected to occur later this year, following resolution of labeling, scheduling and distribution requirements, the company said. The product will be marketed in Israel by ABIC Ltd. Pharmaceutical and Chemical Industries.

Medisperse, the company's joint venture with Sterilization Technical Services Inc., continues to collaborate with NCI and with pharmaceutical firms on cancer compounds.

Schering-Plough Corp. of Madison, NJ, said fourth quarter net income increased 20 percent to $111.1 million, compared to $92.9 million in the prior year. Net income for the year rose 21 percent to $471.3 million, compared to $389.8 million in 1988.

U.S. pharmaceutical sales rose by 18 percent. Leading the way were some anticancer products, including Eulexin, approved in January 1989 for prostate cancer therapy, and Intron A, the company's alpha-2 interferon.

The company last month filed a product license application with the FDA for granulocyte macrophage colony stimulating factor based on studies in cancer and AIDS patients. The compound is being developed jointly by Schering-Plough and Sandoz Pharmaceutical Corp. The company said this was the first application filed for GM-CSF. The application requests FDA approval for use of GM-CSF in the treatment of patients with low white blood cell counts.

Medicorp Inc. of Montreal has sublicensed HemaCare Corp. of Sherman Oaks, CA, to commercialize passive hyperimmune therapy for AIDS on an exclusive basis in California. PHT was

developed by Abraham Karpas, assistant director of research at Univ. of Cambridge, who recently received a U.S. patent for the invention.

PHT involves taking the blood of HIV positive, asymptomatic individuals whose plasma contains an high concentration of HIV-neutralizing antibodies, purifying it against viruses and bacteria, and infusing it into AIDS patients whose immune systems have been destroyed by HIV. No adverse side effect has been found with PHT in initial studies at St. Stephen's Hospital in London, Medicorp said.

HemaCare is expected to initiate clinical trials of PHT under a California Investigational New Drug Application.

Salick Health Care Inc. of Beverly Hills, CA (NASDAQ: SHCI), reported net revenues for the first quarter ended Nov. 30 of $16.4 million, compared to $11 million for the same quarter of the prior year. Income for the quarter was $1 million, compared to the same amount last year.

During the quarter, the company completed its interim cancer center at Temple Univ., and began providing radiation therapy at the Desert Hospital Cancer Center in Palm Springs, CA. The company expects to begin providing medical oncology services at Desert Hospital this spring.

Roberts Pharmaceutical Corp. of Eatontown, NJ, announced an initial public offering of 2 million shares of common stock at $6 a share. The stock will trade over the counter and has been included on NASDAQ under the symbol RPCX. The stock will also trade on the Boston Stock Exchange under the symbol RPC.

Patents

Cetus Corp. Issued Eight Patents For IL-2, TNF, Taq DNA, Others

Cetus Corp. of Emeryville, CA (NASDAQ: CTUS), has been issued seven U.S. patents relating to several of the company's products, including interleukin-2, tumor necrosis factor, certain immunotoxins and processes for producing and using them.

In addition, the company has received an eighth patent for a purified thermostable enzyme, Thermus aquaticus (Taq) DNA polymerase.

The issuance of the total of eight patents brings to 122 the number of issued U.S. patents held by the company.

Patent 4,889,818 covers purified thermostable Thermus aquaticus DNA polymerase either isolated from Thermus aquaticus or derived from a genetically engineered organism containing a gene that codes for the production of the enzyme. The Taq polymerase is widely used in the company's GeneAmp PCR technology.

It has enhanced the utility of PCR and helped speed its application to a wide range of research and commercial tasks. This is the fourth U.S. patent issued to Cetus that protects aspects of the company's PCR and related enzyme technology. The company has an additional 40 PCR related applications pending in the U.S.

The Cetus scientists listed as inventors for the purified Taq DNA polymerase patent are David Gelfand and Susanne Stoffel.

Patent 4,894,227 claims compositions of interleukin-2 and immunotoxins which augment anti-tumor activity when used for prophylactic or therapeutic treatment of ovarian, breast and certain other cancers. Paul Stevens, Lou Houston, Kirston Koths, Brian Issell and Robert Zimmerman were listed as inventors on the patent.

Patent 4,894,225 covers combination therapy using immunotoxins with tumor necrosis factor administered simultaneously or in tandem. The patent describes the synergistic antitumor effect obtainable through combination use and discloses methods and protocols of administration. Zimmerman was the inventor.

Patent 4,894,226 covers solubilization of proteins for pharmaceutical compositions using polyproline conjugation. Inventors Lois Aldwin and Danute Nitecki covalently joined a biologically active protein to polyproline using a flexible spacer arm and dissolved it in an aqueous carrier medium in the absence of a solubilizing agent.

Patent 4,894,330 protects improved methods for purifying recombinant interferon beta utilizing reverse phase high performance liquid chromatography and also claims the resulting product. Susan Hershenson and Ze'ev Shaked were responsible for this invention.

Patent 4,894,334 covers a method for improving the yield of heterologous proteins produced by recombinant bacteria, such as the genetically engineered ricin A toxin protein used in the company's immunotoxin products.

The method, invented by Arie Ben-Bassat, Glenn Dorin and Keith Bauer, involves supplementing the nutrient medium in which the bacteria are grown with an ethanol and/or an amino acid mixture during the last phase of cultivation. In addition, a method for improving yields of such proteins under the control of the PL promoter is described.

Patent 4,894,439 covers the selective separation of recombinantly produced proteins using microporous PTFE (teflon) membranes to create highly purified

biologically active products. Inventors were Dorin, Wolf Hanisch, James Thomson, Leo Lin and Sidney Wolfe.

Patent 4,894,441 claims various immunotoxin conjugates invented by Lawrence Greenfield, Donald Kaplan and Danute Nitecki. It describes the linking of antibodies to peptide toxin/spacer composites prepared by recombinant techniques using a novel class of polypeptides.

Products

Market For New Therapeutics To Reach $1.4 Billion, Report Says

The market for superoxide dismutase and compounds known as lazaroids will reach $1.4 billion within a decade, according to a report by the **Technology Management Group.** This new class of therapeutics will be used primarily to prevent reperfusion damage which occurs when blood flow is cut off to an organ and then resumes.

Oxygen radical scavengers are now in clinical trials for at least 23 conditions, including cancer of the colon, skin and lung. Markets for these products are expected to grow from about $2 billion worldwide in 1989 to over $4.5 billion within 10 years, the report said. Oxygen radical scavengers include vitamin A derivatives, beta carotene, vitamin C and vitamin E.

At least 75 companies and 380 other organizations worldwide are involved in the research, development or production of oxygen radical scavengers.

The report is available from the company for $1,987. Contact Technology Management Group, 25 Science Park, New Haven, CT 06511, phone 203/786-5445.

Sales of work stations for molecular modeling in pharmaceutical companies are expected to grow from $93 million in 1989 to $770 million in 1993, according to another report by Technology Management Group.

Altogether, the worldwide market for pharmaceutical molecular modeling software is expected to increase from $129 million in 1989 to $1.7 billion in 1993, the report said.

The report on pharmaceutical markets is available from the company, 25 Science Park, Mew Haven, CT 06511. 203/786-5445. The price is $2,500.

Bioproducts for Science has introduced a rat monoclonal antibody to the mouse F4/80 antigen. The antigen is a maturation marker for macrophages in bone marrow culture.

Mouse mononuclear phagocytes possess a 160Kd plasma membrane component that is recognized by this new monoclonal antibody and making the antibody suitable for identification of mouse macrophages by immunocytochemical methods.

It can also be used for differentiation, physiology and heterogeneity studies of mouse macrophages.

For more information contact the company, P.O. Box 29176, Indianapolis, IN 46229. 317/894-7536.

Oncor Inc. has introduced the first commercially available molecular biology based test system for in situ characterization of human chromosomes. The new system, which couples DNA probe technology to classical cytogenetics, reduces test time to hours, as opposed to weeks with traditional methods, the company said.

One of the main features of the system is its ability to characterize chromosomes in cells that are not dividing, the company said.

Oncor is marketing the system in the form of a kit, with DNA labeled probes, to clinical and basic researchers. For more information, contact the company at Box 870, Gaithersburg, MD 20884, phone 301/963-3500.

Bioproducts for Science announces the availability of two new protein G products, BioBind-G Agarose and BioBind-G ReadiPak. The products are designed to provide a simple and quick way to purify IgG antibodies from ascites fluid, hybridoma cell culture supernatant or serum containing polyclonal antibodies. For more information contact the company at 317/894-7536.

Serotec announces the introduction of a new range of oncoprotein antibodies, which are site specific probes, raised against small synthetic peptides selected from oncoprotein amino acid sequences. They can be used to recognize identical sequences in intact native proteins. For more information, contact Tim Bernard, technical manager, Serotec Ltd., 22 Bankside, Station Approach, Kidlington, Oxford OX5 1JE, phone 08675-79941, fax 08675-3899.

People

Dolores Esparza Forms Consulting Firm; New Appointments At Biogen

Dolores Esparza has formed an oncology consulting firm, **Esparza Oncology Consultants Inc.**, based in San Antonio, TX. The firm will offer support "in all phases of cancer program operations, including development of new clinical operations, strategic planning and feasibility studies for new and existing cancer programs." Esparza is the current president of the Oncology Nursing Society.

David Dennen has been appointed to the newly

created position of vice president of operations at **Biogen Inc.** He will have responsibility for manufacturing, process development and bioprocess engineering for the company. Dennen spent 35 years at **Eli Lilly & Co.**, where his most recent position was vice president of Lilly Research Laboratories.

Irving Fox has been appointed to the newly created position of vice president of medical affairs at Biogen. He will be responsible for the company's worldwide clinical development programs. He held professorships in internal medicine and biological chemistry at the Univ. of Michigan and was program director of the Clinical Research Center at the Univ. of Michigan Hospital since 1978.

Rodolfo Bryce was named senior vice president for marketing and sales of **Schering Laboratories.** He *replaces* **Charles Stroupe,** who has been appointed president of **Wesley-Jessen,** Schering-Plough's vision care business. Bryce joined Schering as finance director in 1980. **Raman Kapur** has been appointed president of Schering-Plough Animal Health, replacing Bryce. he joined the company in 1975 as a financial analyst.

Associations

IBA Draws 'Battle Lines' Over FDA Proposed User Fees

Industrial Biotechnology Association expressed concern over inclusion of the Food and Drug Administration user fees in President Bush's budget for fiscal 1991.

The budget calls for $157 million in FDA user fees, which increase new drug development costs and are particularly burdensome to small biotechnology companies, said IBA president Richard Godown.

"The battle lines over user fees are already being drawn," said Godown.

FDA is pegged to receive a $108 million budget increase over last year. However, if the user fee portion of the new budget is deducted, federal appropriations would be reduced by $49 million.

On another issue, the association applauded the budget proposal for $3.6 billion for federal biotechnology research and development, an increase of 6 percent over 1990.

"The budget denotes the kind of recognition at top federal levels we have been seeking for this industry," Godown said.

"This may be the administration's clearest endorsement to date of the anticipated contributions of biotechnology to the public health, environment and economy," he said.

Issues For The 1990s

IBA has selected several issues that it plans to work on in the 1990s. Following are some of those issues and IBA's position, as stated by Godown:

▸Animal patents: Legislation introduced in the 101st Congress, by Rep. Robert Kastenmeier (D-WI), would make it an act of patent infringement for a farmer to reproduce a patented transgenic animal through breeding, use it in the farming operation or sell its offspring. IBA believes the law "would be tantamount to no patent protection at all and would discourage investment" in agricultural advances. The association said it will work to defeat the legislation.

▸Public relations: Increasing attention to animal rights and environmental concerns continues to feed fears and misunderstanding of biotechnology, the association said. The ability of biotech companies to bring products to market is intertwined with public perceptions of the industry. IBA believes that as the public becomes more familiar with the products and benefits of biotechnology, acceptance will follow. The association will work to quell public fears with education and communication.

▸State activity: State legislation affecting biotechnology increasingly will become a factor in the industry's future. Legislation recently passed in North Carolina regulating the deliberate release of genetically engineered organisms brought this issue to the forefront. Other states have initiated legislation DNA fingerprinting, food labelling and funding for research.

The association welcomes state initiatives serving to strengthen academic and research programs, build a strong venture capital pool and encourage interaction among researchers, manufacturers and users.

IBA opposes the concept of a patchwork of regulations which may result in product approval delays and new costs for states and industry, and ultimately the consumer.

▸Science literacy and training: A decline in science education in the U.S. threatens the quality and quantity of industrial innovation. The number of Americans with the sophisticated skills necessary to fill these positions is not keeping up with the demand for technically skilled workers. U.S. technological progress in biotechnology depends on a well trained pool of personnel.

▸Health care costs and reimbursement: The federal government and third party payers increasingly are concentrating cost containment efforts on limiting coverage and payment for drugs and medical devices. Reimbursement policies for off-label indications and

experimental drugs have been unnecessarily restrictive. The resolution of this issue will have major implications for the development of many biotechnology products, especially cancer and AIDS drugs.

▸Europe 1992: An EEC series of directives on biotechnology, which will be mandatory in 1992 for member nations, will provide the legal guidelines for the future of biotechnology activity in Europe. It remains to be seen whether disguised trade barriers may result from European integration.

▸Patent backlog: The patent process continues to be a bottleneck in the product development and marketing capabilities of biotechnology companies. The creation of the Biotechnology Institute is an important first step in improving quality and timeliness of the patent examination process. IBA is hopeful the next few years will bring improvements in both review time and quality.

▸Liability insurance: Biotechnology companies have been little affected by product liability so far. However, as biotechnology grows and more products come to market, insurance costs will mount. IBA plans to continue efforts to make product liability insurance and lower cost insurance coverage available to biotechnology companies.

▸Regulatory resources: Arbitrary regulatory delays for biotechnology products would raise to even higher levels the cost of product development. IBA plans to work with federal agencies to ensure the regulatory system proceeds with its responsibilities expeditiously and efficiently.

Meetings And Reports

U.S. Medical Technology Industry To Show Strongest Growth In 1990

U.S. medical technology industry leads the list of manufacturing industries expected to show the strongest growth in 1990; key sectors of the industry are expected to experience sales growth of up to 10 percent this year, according to a report from the U.S. Dept. of Commerce, titled "U.S. Industrial Outlook 1990."

The report forecasts a $1.9 billion trade surplus for the industry in 1990 and exports to reach $4.8 billion. The industry is estimated to reach $28 billion in shipments this year. In 1989, the industry employed 220,000. A survey by "BusinessWeek" noted that the industry spent 6 percent of sales on research and development, almost twice the rate of spending for all industries combined in 1988.

The Commerce Department report is available for $27 prepaid from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, phone 202/783-3238.

Health Industry Manufacturer's Assn. will hold its annual meeting March 11-14, at the Ritz-Carlton in Naples, FL. Topics will be EC 1992, changes in Eastern Europe, implications of an aging population, medical device legislation, FDA and product approvals. Contact HIMA at 202/452-8240.

National Research Council's Academy Industry Program is holding a symposium titled "Impact of 1992 European Market Integration of R&D Intensive Industries," March 5-6, at the National Academy of Sciences auditorium, Washington, D.C.

Main speakers will be Eric Bloch, director of the National Science Foundation, and Filippo Pandolfi, vice president of the Commission of the European Community.

For information contact Susan Turner-Lewis, public information office, 202/334-2138.

Communitech Market Intelligence of Yorktown Heights, NY, announced three conferences:

Cancer Progress V--April 23-24, St. Moritz on the Park, New York City. Topics are technologies and dynamics driving cancer product development and commercialization.

Clinical Advances in Biotechnology--May 2, Fairmont Hotel, Chicago. Topics are Clinical status and impact of major biotech drugs.

Sustainable Competitive Advantages for Pharmaceutical Companies--May 14-15, The Plaza Hotel, NY. Marketing issues, competition, strategic alliances.

For more information and for conference registration, contact the Communitech at 914/245-7764

National Assn. of Medical Equipment Suppliers will hold its 1990 spring convention May 2 in San Diego, CA in conjunction with the National Home Health Care Exposition.

The theme of the meeting is "Innovations in Management: Business Fitness in the 90s." Keynote address will be given by Uwe Reinhardt, professor of political economy and public affairs at the Woodrow Wilson School of International Relations, Princeton Univ.

For more information contact the association at 703/836-6263.