Boom and Bust in Biotechnology

Southern Biotech, a Tampa company that went public last August, is in financial and legal trouble; a shakeout in the biotechnology industry may be hastened

Employees of Southern Biotech got the bad news without much warning on 30 April. Instead of receiving paychecks for the month they had just worked, they were given a memo informing them that the Tampa-based company had run out of cash and could not meet its payroll. In less than a year, Southern Biotech has thus slipped from being potentially one of the largest contenders in the race to commercialize biotechnology, to the brink of bankruptcy. It is being sued by several creditors and former employees, it is in trouble with the IRS, several of its directors have resigned, and it is facing a mountain of bills with scant prospects of generating enough income to pay them off.

If Southern Biotech's financial ills prove to be terminal—which seems likely—the company's demise could signal the start of a long-expected shakeout in the fledgling biotechnology industry. Several other companies which, like Southern Biotech, have raised capital in the past few years on the basis of little more than grand promises, are facing cash-flow problems and finding investors much less willing to open up their checkbooks. Southern Biotech's troubles have some unique features, however. As one disgruntled, unpaid employee put it, "it is the worst possible case imaginable" of the financial problems afflicting the new industry.

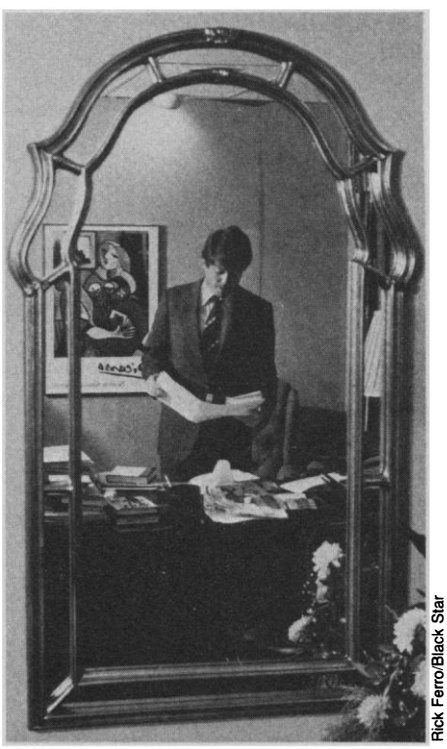
A year ago, everything looked rosy for the young company. It had just started producing leukocyte (or alpha) interferon from white blood cells and its directors were predicting that the product would be a big money-spinner. William Stewart, a respected interferon specialist at the Sloan-Kettering Institute for Cancer Research, had agreed to join the company as research director. Shearson Loeb Rhoades (now Shearson American Express), one of Wall Street's best known underwriters, had agreed to take the company public with a stock offering of some $25 million. A team of young scientists was being recruited. And prospective investors were told about a broad array of technologies that the company hoped to develop.

Southern Biotech's fortunes soured very quickly, however. Its troubles began last summer when the stock market became increasingly skeptical of the promises touted by biotechnology companies, and Southern Biotech's stock offering raised far less cash than originally anticipated. This setback was compounded by a series of disastrous policy decisions, a large financial transaction, personnel problems, and regulatory tangles. The company was virtually out of cash and desperately looking for new investors by the end of last year; almost none of its principal product, interferon, has been sold; and its new research facilities have never been in full operation.

This is an ironic predicament for a company which, in the words of one of its stock sale advisers, "was out to take the whole thing . . . every conceivable aspect of biotechnology." The strategy, common to many biotechnology companies, he said, was "a program of getting as much visibility as possible." It is important to recall the "gold-rush attitude" that prevailed: "You've got to grow as fast as you can to get market share. . . . You go out and gain a position in the market first, and then the position pays for the cost of gaining it." In short, tout the stocks first, and later worry about producing something. But this time the gold-rush strategy did not work.

The following account of the company's troubles is based on numerous interviews with current and former employees and associates of Southern Biotech, most of whom asked to remain anonymous; documents on file at the Securities and Exchange Commission (SEC); and court records. The company's president and most other senior executives declined to answer repeated telephone calls and requests for interviews.

Southern Biotech's origins stem from a company launched in 1977 by John M. Kilgore, then a 28-year-old family physician living near Tampa, Florida. Kilgore and some business associates established a company that collected blood from prisoners and sold the plasma to a pharmaceutical company. The business was relatively lucrative from the start, and by 1981 was reporting revenues of more than $1 million a year. Collection facilities were established in two Florida prisons, and inmates were paid $5 per unit for their blood. In 1979, the company was reorganized as Southern Medical and Pharmaceutical Corporation and the chief officers and stockholders were Kilgore, E. C. Watkins, Jr., a lawyer and former school friend of Kilgore's, and Dick A. Greco, Jr., former mayor of Tampa and then chairman of the board of the Metropolitan Bank and Trust Co. of Tampa.



Rick Ferro/Black Star

John M. Kilgore

Founder and president of Southern Biotech

Early in 1980, Kilgore was looking around for new ventures for the company. At that time, venture capital was pouring into biotechnology companies, and interferon was being widely touted as an antiviral agent that might have an important role in cancer therapy. Since some types of interferon can be produced from white blood cells, which the company was already collecting, Southern Medical and Pharmaceutical seemed

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ideally placed to set up an interferon production facility and cash in on the biotechnology boom.

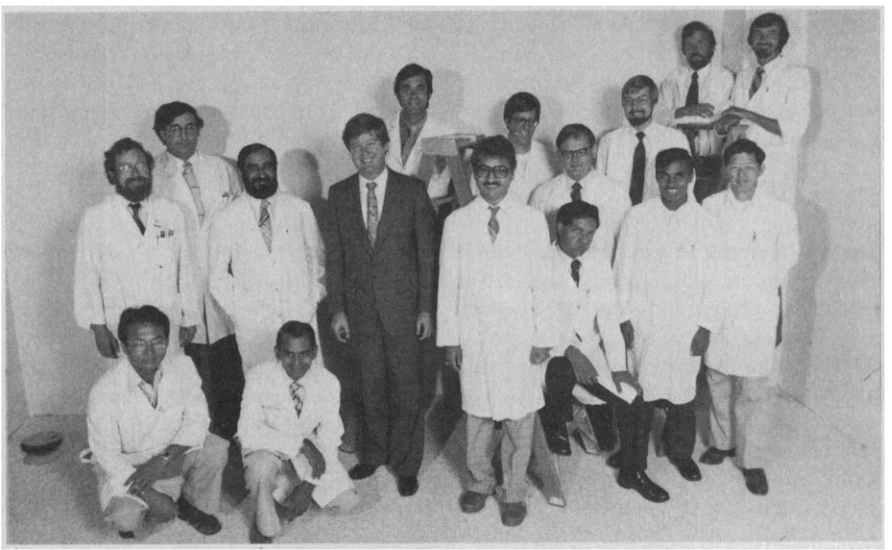
In the early summer of 1980, Kilgore and Watkins went to the Sloan-Kettering Institute to seek the advice of William Stewart, a leading authority on the production and properties of interferon. Stewart says he told them it would take at least $1.5 million to set up a good production facility. The money was evidently easy to raise, for in July, Key Energy Enterprises, a Tampa holding company whose chief business involves selling gasoline to retailers, put up $1.67 million. A joint venture, initially to produce alpha interferon and later to manufacture beta and gamma interferons (see box on p. 1078), was established by the two companies. Key Energy contributed a further $590,000 to the venture in 1981.

Soon after that deal was struck, it became evident that Wall Street was dazzled by the promise of biotechnology. Genentech, a San Francisco–based biotechnology company, offered some stock for public sale and saw the value of its shares soar from $35 to $89 within minutes of opening. Kilgore and his associates began to explore the possibility of taking Southern Medical and Pharmaceutical public.

Stewart was hired as a part-time consultant in October 1980, and plans were hatched for a major expansion of the company's research and development activities. With a steady income from its plasma collection business, prospects of substantial future revenues from sale of interferons, and a research capability that might produce new products further down the road, Southern Medical and Pharmaceutical looked like it would be a hot item on Wall Street. The prospect was sufficiently enticing for Shearson Loeb Rhoades to agree to underwrite public sale of the company's stock and for Stewart to decide to leave the Sloan-Kettering Institute to join the company full time as its vice president for research.

Stewart's international scientific reputation and Shearson's high standing in the financial community gave the company considerable visibility and credibility. In particular, their association with the company made it easier to attract many bright young scientists to work for a totally unproven enterprise.

Shearson laid down two conditions for its participation. First, the underwriters insisted that Greco be removed from the board of directors. The Metropolitan Bank, whose board he chaired, was then under investigation by federal examiners for millions of dollars worth of questionable loans. It has since gone bankrupt in perhaps the biggest financial scandal in Tampa's history. Second, Shearson required Southern Medical and Pharmaceutical to purchase Key Energy Enterprises' share of the joint interferon venture as soon as the public offering was completed. Key Energy has also fallen into a parlous financial state and it was involved in several business ventures with the Metropolitan Bank. According to one U.S. law enforcement official in Tampa, the bank, Key Energy, and Greco are among those now under investigation by the FBI, the Justice Department's Organized Crime Strike Force, and a local grand jury. The official added that Southern Biotech is also being looked into by the FBI.



Southern Biotech in happier times

Kilgore (center) with his scientific team; 6 months later, the cash ran out

Kilgore and company agreed to both of Shearson's conditions. Shearson began the formal process of taking the company public by filing a registration document in May with the SEC, setting out the company's record and its future plans. The document envisaged a public offering of 1.25 million shares at $20 apiece, for a total of $25 million. With this capital, the company would hire about 35 Ph.D. scientists, build a new research facility, expand its interferon production plant, and develop an array of new technologies, the document said.

It is a telling reflection of the financial interest in biotechnology stocks at the time that a respected Wall Street investment firm could seriously propose raising $25 million for a company that had barely begun to produce, let alone sell, interferon; that had hired almost no research scientists; and that had established no track record at all in the other areas that were expected ultimately to be its chief lines of business. Potential shareholders were in effect being asked to put their money into little more than a grand promise.

On the strength of the expectation of a large cash influx, Southern Medical and Pharmaceutical began recruiting research staff last spring. Most of the scientists who agreed to talk with *Science* say they were attracted to the company by Stewart's involvement with the enterprise and by the prospect of being able to work for a well-capitalized company at its outset. Stewart, who at the time was still officially on Sloan-Kettering's payroll, Kilgore, and Watkins went on a tour of some 14 cities to interest potential investors in the company. (Stewart's heavy involvement with the company eventually led to an acrimonious break with the Sloan-Kettering Institute; he was dismissed on 30 June, although he had intended to resign on 1 August.) By the end of the summer, the company had some 20 scientists under contract.

While the company was taking shape, however, Wall Street was starting to take a more skeptical attitude toward the new glamour stocks. Several biotechnology companies that had hoped to emulate Genentech's performance saw their shares meet with only lukewarm interest when they went public. Shearson, taking note of the shifting financial winds, decided that its earlier expectations were overblown. The registration statement was therefore amended to offer only 550,000 shares for public sale at $10 apiece—a capitalization of only $5.55 million instead of the $25 million originally envisaged.

The company prospectus, issued in August shortly before the public offering

took place, lays out plans that were almost as ambitious as those in the earlier registration document, however. Southern Medical and Pharmaceutical was still planning to hire 30 Ph.D. scientists, move into research involving gene splicing, hybridomas, and peptide synthesis, and expand its production of interferons by conventional methods. "The Company plans to investigate the application of recombinant DNA and other advanced technologies to various areas, including agriculture, chemicals, and energy," proclaimed the prospectus.

The prospectus contains substantial qualifications that warned prospective investors that the company is a high-risk venture and that nothing was assured. It also leaves the impression, however, that there was a good prospect of healthy income from sales of interferon. The prospectus details plans to expand the capacity for producing interferons by conventional methods to a level that, if fully utilized, would turn out about $13 million worth of product a year. Some $400,000 worth of alpha interferon had already been shipped, the prospectus states, and the company had contracts to supply substantial quantities of beta and gamma interferons to Italian and Japanese companies and to the M. D. Anderson Hospital in Texas. These sales have, however, not materialized. In any case, the public offering, which took place in August, sold out, and Southern Medical and Pharmaceutical realized about $4.8 million after fees and expenses were deducted, according to financial reports on file at the SEC. Kilgore, who owns 2.136 million shares, became a multimillionaire—at least on paper.

While the gloss was going off biotechnology stocks in late summer last year, the relationship between Kilgore and Stewart was becoming strained. According to Stewart, part of the problem revolved around how much money would be available from the stock offering to establish the research facilities. The prospectus stated that "The Company plans to utilize approximately $1,825,000 of the proceeds of this offering to provide

Gambling on Interferon

The interferon boom erupted 4 years ago when the American Cancer Society (ACS) announced at a press conference in New York that it was making available $2 million to buy interferon for use in clinical trials with cancer patients. At that time, one of the major barriers to research was the sheer scarcity of interferon. Extracting it from human blood was costly and time-consuming. There was only one major supplier: the inventor of the extraction technique, Kari Cantell of Finland. A single course of therapy using his interferon cost around $15,000.

With the advent of gene splicing, in which segments of human DNA are inserted into *Escherichia coli* bacteria and made to produce interferon, the price has dropped by a factor of 10 to 100, according to a pioneer user of the substance, Thomas Merigan of Stanford. At the same time, the purity of injectable solutions has increased from around 1 to 99 percent.

These dramatic achievements have been a cause of distress as well as joy in the interferon business. Companies unable to keep up with the frenetic pace of innovation are having trouble.

Interferon, a protein molecule, was recognized in 1957 as a substance that helps the body's natural defenses attack tumors and viruses. Interest in it revived in the late 1960's after Cantell found a way to extract it from human blood. A few experimenters reported good results using this extract in treating cancer. Researchers also hoped to combat viral diseases such as herpes, hepatitis, and perhaps even the common flu with interferon. But antiviral testing has been carried out on a smaller scale than the cancer trials.

Jordan Gutterman of the University of Texas' M. D. Anderson Hospital asked the ACS in 1978 to buy the new Cantell interferon for his cancer patients. The ACS agreed and recruited several other clinics, including Merigan's, to carry out the first major trials. This triggered an explosion of media coverage, with *Time* magazine, for example, suggesting in a flashy cover story that interferon might be a cure for cancer. Speculation like this generated more than media hype: many investors and researchers leaped into the interferon gamble.

When the importance of interferon was first understood, little was known about its origin or about the mechanism by which it works. Although much remains obscure today, more is known about the sources and types of interferon found in the human body.

There are essentially three types: alpha, beta, and gamma (or immune) interferon. Alpha is produced by white blood cells (leukocytes) in a defensive reflex when they are exposed to a virus. Researchers have identified at least a dozen different genetic variations of alpha, all of which are found in the "soup" of natural interferon in the body. The beta type is produced by the cells of the connective tissues (fibroblasts) in response to a virus. It is more difficult to grow and purify than alpha, and it comes in two genetic varieties. Gamma is produced when cells of the lymph system (T cells) are exposed to virus antibodies. Only one variety of gamma has been found.

The Cantell process, the only one avaliable until recently, and the one used by Southern Biotech, produced alpha interferon exclusively. In addition to being low in purity, Cantell's extract contained all 12 genetic varieties, making it impossible for researchers to determine just which one was producing the effects.

The gene splicers have changed all this. By programming bacteria to make the precise genetic type of interferon desired, they have been able to get large quantities of nearly 100 percent pure alpha, beta, and—last October—gamma interferon. There is a slight difference between a bacterial and a natural interferon, in that the former lacks the carbohydrate fraction found in the latter. However, research completed this year at the National Cancer Institute shows that the gene-spliced alphas have essentially the same effects and potency as the natural alphas. (The bacterial versions used in these trials were produced by the first American biotechnology company, Genentech, in partnership with its large co-venturer, Hoffmann–La Roche Inc.)

Merigan, Gutterman, and Robert Oldham, coordinator of federally sponsored trials at the National Cancer Insti-

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working capital for its research and development program." Kilgore wanted to set aside only $500,000 of this amount to build and equip labs in office space the company was leasing; this was about half the sum originally planned, Stewart claims. After repeated tangles over the budget, Stewart says, "a very hostile situation between the scientific team and the management team developed." Other scientists in the company say that it soon became clear that tensions between Stewart and Kilgore had become intolerable and that Kilgore was effectively freezing Stewart out of decisions on research matters. In September, just one month after the company went public, Stewart was abruptly fired by Kilgore. (Stewart has since brought suit against Kilgore and some other directors for breach of contract over sale of some stock he owns in the company.) Thus, the man who was largely responsible for attracting other scientists to the company was gone even before the research facilities were completed. Kilgore, a physician with no apparent research experience, made himself director of research.

Construction of the labs was completed in early November, and most of the equipment arrived by early January. But the labs have never been fully operational, according to several sources. For one thing, there was not enough money for some key pieces of equipment, such as laminar-flow hoods, and there were shortages of common items such as pipettes. The peptide synthesis group, for example, was forced to try to operate without an amino acid analyzer. And for another thing, a freeze was placed on ordering reagents and other essential supplies in January, when the labs were finally in a position to start some work.

The company was thus clearly experiencing cash-flow problems less than 4 months after it raised more than $4 million from its stock offering. And this was in spite of the fact that the prospectus had stated that "The Company does not anticipate requiring additional external financing . . . for approximately 12 months." Many bills, in fact, have not

tute, say that the basic work with Cantell material is now complete. The research that began with the ACS press conference in 1978 has now shown that Cantell's soup had a noticeable effect on tumors in some patients with advanced cancer. Because the same effect has been obtained with gene-spliced interferon, there is little interest in using Cantell's extract any longer.

What are the business prospects of a company like Southern Biotech whose only product, perhaps its only asset, is Cantell interferon? They cannot be bright, unless the interferon can be unloaded on a specialized market outside the mainstream of research.

In the United States, it is not legal to charge patients for any interferon shipped across state lines because the Food and Drug Administration (FDA) considers it an unproven, experimental biologic. The only legitimate sales are between laboratories, with the clinical researcher usually spending grant money to buy the interferon and giving it free of charge to patients. Southern Biotech, to its detriment, has not been able to persuade the FDA that its alpha interferon is fit for human use—even on an experimental basis—in U.S. cancer clinics. Thus, Southern Biotech appears to have sought other markets.

According to the FDA, the government of Jamaica last year requested a formal exemption to allow Southern Biotech to bypass the FDA's approval process for exports of drugs and biologics. The FDA has the request under review and has asked for more supporting data. It has not granted permission.

Southern Biotech opened offices on the Grand Cayman Island and formed a partnership with a company in Jamaica in order to sell interferon on the international market. Neither Southern Biotech nor its Jamaican partner, Federated Pharmaceuticals, would respond to questions about a report that interferon has been shipped from Florida to Jamaica without FDA approval.

However, Southern Biotech's attorney, Marc Bozeman of Bozeman and Geller of Los Angeles, did say that he thought shipments of this sort would be legal, contrary to what the FDA asserts. In his view, a company could escape FDA jurisdiction simply by labeling its interferon an "unprocessed biological product." He said he considered this a defensible policy in spite of the fact that the FDA requires a license to export human blood cells.

According to *Genetic Engineering News*, there are about 30 interferon companies in the United States. Nearly all are aiming to produce a variety of interferons, both by natural and synthetic means. Southern Biotech mentioned in its prospectus last August that it intended to produce all three types of interferon. The company noted that it had already "contracted to supply a major United States cancer research center" with about $500,000 worth of gamma interferon beginning in September 1981, a month after the stock sale. This agreement was made with Gutterman's clinic at the M. D. Anderson Hospital.

However, in September the company fired its chief scientist, William Stewart, and failed to get its gamma production line going. Gutterman says the agreement had been "based on Dr. Stewart's past reputation as a scientist." When Stewart left, "the contract was simply terminated." Gutterman's clinic, which began the first FDA-approved trial of gamma interferon on 9 February, found a new supplier: Meloy Laboratories of Springfield, Virginia, a co-venturer with a much larger company, Revlon Industries.

The pattern of the small, specialized laboratory combining with the large marketer may now be firmly established in the genetic engineering business. This kind of partnership may become more important as the interest in gene splicing grows. Companies with large financial resources will be better able to keep up with the pace of innovation and the demands of this volatile market. Although researchers like Gutterman and Merigan say that much work with natural interferons remains to be done, it is clear that the important competition in the future will be over the gene-splicing methods of production.

At the annual meeting of the American Society of Clinical Oncology in St. Louis in April, the National Cancer Institute released a list of current interferon trials. The only ones using natural substances employ the relatively untested beta and gamma types. Advanced tests (phase II trials) using alpha interferon will rely on the products of gene splicing.

As the trials progress, the FDA will require that the interferons meet higher standards of purity. This will favor manufacturers who have mastered the techniques of gene splicing. So will the growing competition to cut costs.

—ELIOT MARSHALL

been paid since November. According to complaints filed in April in the thirteenth circuit court in Hillsborough County, Florida, Curtin Matheson Scientific, Inc., is suing the company to recover some $177,000 in unpaid bills for laboratory supplies and equipment ordered last November, and Ruder Finn and Rotman, which handled public relations for the company, is seeking payment of $127,000 in outstanding bills for a period that also began in November. In addition, Beckman Instruments, Inc., which provided more than $300,000 worth of equipment to the company under a lease-purchase arrangement has also not been paid.

How did the company run out of cash so quickly? Kilgore and the company's financial director, John Lilly, declined to discuss the matter with *Science*. One reason, however, concerns the arrangement, mentioned in the prospectus, to buy up Key Energy Enterprises' share of the joint interferon venture. Soon after the stock offering, Key Energy was paid $2 million in cash, plus a promissory note for $897,990, which is due on 25 August 1982, and 440,000 shares of the company's stock. That deal drained away almost half the company's capital.

Another problem arose because anticipated sales of interferon have not materialized. Although the company was churning out substantial quantities of alpha interferon until the end of last year, it did not gain approval from the Food and Drug Administration (FDA) to ship the material for clinical trials. According to a financial report filed with the SEC, the company had about $2.3 million worth of clinical grade alpha interferon on its hands at the end of the year. (The estimate was based on then-current market prices.) With the recent advent of highly pure interferon produced by genetically engineered bacteria, there may no longer be much of a market for the company's product (see box on p. 1078).

As for the contracts to supply beta and gamma interferon that were touted in the prospectus, the company has encountered a series of technical problems resulting in contamination which have prevented any substantial quantities from being produced.

Faced with difficulties in disposing of its interferon in the United States, the company last December entered into an agreement with Federated Pharmaceuticals Co., Ltd., of Jamaica to sell alpha interferon in Jamaica and abroad. The company also set up a subsidiary, Southern Biotech Caribbean, Ltd., with banking facilities in Grand Cayman Island, to manage the Jamaica operation. Cayman banks are not subject to U.S. regulation.

The company's mounting financial problems were not reflected in its public relations, however. In contrast to the partially equipped labs, the executive suites were lavishly appointed. Company personnel traveled first class and stayed in expensive hotel suites. Company cars, including a Jaguar and a Cadillac, were used by top executives. The company hired a prestigious New York public relations firm, Ruder Finn and Rotman, to handle publicity. In October, it took out a corporate advertisement in *The Wall Street Journal* claiming that "we are bringing our own products, such as native interferons to market and developing new products with major corporations through joint ventures and corporate partnership agreements." The company gained some additional prestige and respectability in September when Father Richard McCormick, a prominent Jesuit scholar at Georgetown University and authority on bioethics, was appointed to the board. And in October, the company changed its name to Southern Biotech, Inc. In a statement put out at the time, Kilgore said, "our present and prospective activities in areas such as chemical, agricultural, and energy product development, in addition to our current status of pharmaceutical products, prompted the name change."

This carefully nurtured public image was designed to attract potential investors. Soon after the company went public, Kilgore told the scientists that they should try to come up with proposals that might bring in some capital, through joint ventures, and he brought a stream of businessmen through the company. As one company scientist noted "at least Kilgore should be given credit for hus-

Shaky Firms Make Poor Sponsors

Like most other small biotechnology companies, Southern Biotech moved quickly to establish links with a nearby research university. In September last year, the company agreed to provide grants worth a total of $63,600 to the University of South Florida at Tampa to support research and doctoral and postdoctoral fellowships. On the strength of that agreement, the university brought over a specialist on interferon from China, Zhang Jian-Lin, on a 1-year research appointment. But Southern Biotech has failed to make scheduled payments and the university has had to scramble for money to keep the projects and fellowship support going.

According to Riley Macon, dean of sponsored research at the university, Southern Biotech agreed to provide $30,000 for pre- and postdoctoral fellowships, and $33,600 to support research to characterize interferon and study its mechanism of action. The first of four scheduled quarterly payments of the grants was made last October, but no further payments have been made.

Zhang, a researcher at the Wuhan Institute of Virology in Wuhan, China, arrived in Tampa in early February to begin work in the Department of Microbiology under the direction of Herman Friedman, the department chairman. He was to be supported by the Southern Biotech research grant. Four graduate students and one postdoc were receiving support from the fellowship grant, according to Friedman.

Friedman says he has never been informed by the company that the grants would not be paid, and it was not until the university business office told him in March that a payment was long overdue that he realized there was a problem. He says Southern Biotech's president, John Kilgore, has not returned telephone calls to discuss the matter.

Alternative support for Zhang and others working on projects that were supposed to have been sponsored by Southern Biotech has been found, says Friedman, but the affair has made him wary of future links with small companies. "In the future," he says, "we will not even consider initiating any work unless we have full payment in advance."

Southern Biotech has received some favorable publicity from its brief link with the university. In March, with considerable chutzpah, it arranged for Zhang to meet a local reporter and describe his work under Southern Biotech's generous sponsorship. That prompted a flattering write-up in *Tampa Bay Business*, describing Zhang's research and Southern Biotech's broad research agenda.—COLIN NORMAN

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tling. If he raised $10 for every investor he brought through, we might still be in business." Another scientist who left the company before the boom fell, said, however, that Kilgore "was never concerned with science, only with the question of what would be good for the stock market."

By the end of the year, when the cash flow problems were starting to get severe, the search for external financing became desperate. Kilgore began to pin his hopes on negotiations with Monsanto for a deal that might have resulted in a cash injection of about $3 million from the chemical company. Monsanto has developed a new process for fractionating plasma, and it was apparently interested in access to a secure plasma supply. Southern Biotech's plasma collection business looked attractive, and the two companies went through a long series of talks about a joint venture involving the establishment of a new facility in Tampa. After five drafts of an agreement had been produced, Monsanto in mid-March abruptly broke off negotiations. Neither side is willing to discuss the reason for the breakdown. Although talks were still under way with the Scottish Development Board and with Prutech, the venture capital arm of the British Prudential Assurance Co., for some international deals, the company's prospects began to look bleak indeed.

Nevertheless, on 1 April, John Lilly, the vice president for finance, sent a memo to all Southern Biotech employees saying that "The most recent cash forecast that we have put together indicates that though we will not have all the dollars we would like to have, there will

Researcher Denied Future U.S. Funds

Nearly 4 years after a tempest broke at Boston University (BU) over the falsification of data in a series of oncology experiments, Marc J. Straus, the senior researcher on the project, has been barred from receiving federal funds until 1986. It is the first time that federal "debarment" regulations have been invoked.

On 17 May, Straus signed an agreement with the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) whereby he admitted that he was responsible for work submitted to federally funded programs that contained fabricated data. The work centered on how patients responded to a complex drug regime meant to combat a virulent form of lung cancer. The debarment means that Straus, for a period of 4 years, will be unable to study investigational new drugs and will be unable to receive any form of financial assistance from the Department of Health and Human Services. The 4-year cutoff is unique to the Straus affair. Under the regulations, the period of debarment is flexible and based on "the seriousness of the offense." FDA and NIH officials, who investigated the case between June 1979 and March 1982, say they will not press criminal charges against Straus.

The controversial regulations, drafted amid an apparent rise in data falsification and misuse of federal funds, went into effect in 1980 (*Science*, 14 November 1980, p. 746).

Though now legally taking responsibility for the false data, Straus strongly maintains that he had no part in the falsifications and was victim of a conspiracy hatched in 1978 by a handful of disgruntled employees.

"I have never been party to any data frauds or manipulations," Straus said in a telephone interview, "and nothing in the settlement with the government indicates that I was such a party. I have settled with the government only after becoming convinced that this legal outcome was unavoidable since government regulations unfairly impose these penalties on a principal investigator even when he did not know of any wrongdoing. . . . I have spent four frustrating years fighting for a fair and complete peer review of my work. . . . With my limited resources, I am unable to fight an endless battle against the government."

Three years after he left BU, Straus filed in federal court in Boston a $33 million conspiracy suit against five members of his BU team, saying they had falsified data, abused patients, and conspired to blame these acts on him (*Science*, 19 June 1981, p. 1367). The court case is in pretrial discovery, and the defendants still maintain, as they have since 1978, that the bulk of the BU falsifications were ordered by Straus.

That the Straus affair ended in debarment has significance beyond the individual case. It sets a strong precedent for the liability of a senior scientist, even though he may not be aware of unethical acts performed by subordinates. In the emerging debate over the issue, Straus previously argued that a senior investigator cannot be held totally responsible. At a 1981 hearing of the President's commission for the study of ethical problems in medicine and biomedical and behavioral research, he said: "You must rely on the integrity of people who are going to fill in those multiplicity of little boxes. . . . There is a certain level of surveillance in any operation, medicine or otherwise, that requires the belief that the persons under you are acting properly."

At BU, the Straus team consisted of some 40 individuals. Their work on a drug regime, devised by Straus, allegedly led to remission in 93 percent of patients with small cell lung cancer, a disease that normally kills within 3 months of diagnosis.

A contentious issue that haunted the Straus affair was whether a senior investigator should be given federal funds in the midst of unresolved allegations of fakery. After BU forced him to resign in 1978, Straus moved to the New York Medical College in Valhalla. There in March 1980, while under investigation by the FDA and NIH, he received a $910,000 grant from the National Cancer Institute (NCI). This largess was questioned a year later at a congressional investigation by Representative Robert S. Walker (R–Penn.): "It took 10 days for Boston University to investigate Straus and demand his resignation," he said. "Yet 22 months later you are still giving him a grant." In response, NIH official William F. Raub said that the presumption of innocence meant that Straus would be funded until proven guilty.

After an NIH site visit to Valhalla that came in the wake of the congressional inquiry, however, NIH officials decided that Straus had violated some of the conditions of the award and his 3-year NCI grant was terminated in April 1982. The debarment thus merely extends the cutoff of federal funds to Straus.—WILLIAM J. BROAD

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be funds to meet our April payroll on the same basis as each of you was paid at the end of March." (Senior management had gone without pay in March and middle managers had received half pay; the rest of the employees received full pay.) But in mid-April, the company filed a report with the SEC stating that it was "unable to pay all of its suppliers and creditors on a current basis." And then on 30 April—"Black Friday," as some employees are calling it—Lilly and Kilgore informed the staff in a memo that there was not enough cash on hand to pay them. Kilgore left the building before the memo was distributed and installed a dead-bolt lock on the door to the offices.

The final straw occurred when the Internal Revenue Service demanded payment of $60,000 by 1 May, a claim that the memo said was an "unforeseen negative thing" that "jeopardized our cash."

The memo gave employees the option either of staying away from work in May, "in which case the company will consider your job having expired," or of reporting to work in the hopes that sufficient cash would become available to pay salaries. If not, the employees would be paid in stock, the memo said. Most of the scientists decided to take the first option and look for other jobs.

Several of the company's directors have also recently bailed out. The first to go was Marc H. Bozeman, a Los Angeles attorney and former director of compliance for the FDA's Bureau of Biologics. Bozeman, who is still handling Southern Biotech's legal matters with the FDA, resigned as director on 1 April, citing the company's inability to obtain satisfactory coverage for insuring officers and directors against liability as a reason for his departure. He was followed later in April by E. C. Watkins, one of the company's founders, and Robert Brackett, vice president for regulatory affairs, who had joined last September. McCormick was still a director in mid-May, and he told *Science* that he knew virtually nothing of the company's financial affairs.

Southern Biotech is thus faced with mounting bills, it has a promissory note to Key Energy Enterprises for nearly $1 million due in August, most of its scientific staff has left, and it still has no market for its stockpile of interferon.

Its extraordinarily swift rise and fall says a lot about the financial climate surrounding biotechnology in the past few years. Its impending collapse is likely to make the climate more hostile, however. Other companies now seeking capital will not find their task made any easier by Southern Biotech's performance. Potential investors in biotechnology should now be looking for something more than overblown promises when they decide where to put their money.

—COLIN NORMAN and ELIOT MARSHALL

Laser Wars on Capitol Hill

The House has invoked the laws of physics in a budget battle with the Senate over the best way to build space lasers

A strange and otherworldly force has intruded upon mundane politics in the nation's capital.

The laws of physics have been invoked in a battle between the House and the Senate over how the United States should build space lasers. A triumph of scientific reasoning could touch off an abrupt about-face in the U.S. laser program, which to date has consumed more than $2 billion in pursuit of long wavelength lasers that look increasingly useless. A more attractive candidate is the short wavelength laser. Alternatively, a continuation of the current program could result in the development of lasers that emphasize bravado and political muscle rather than technical excellence and the ability to slice through metal in real conflicts.

So far, the defense contractors behind the status quo seem in a position to prevail.

The House touched off the battle when it said the Administration's $156 million program in fiscal 1983 for the development of space lasers could result in a technical fiasco. From an evaluation of elemental physics, the House Armed Services Committee said the long wavelength chemical lasers currently under development by the U.S. military will be extremely difficult to convert into useful weapons and will pose hardly any threat to the Soviet military or other enemies in space. "It is the committee's judgment that emphasis is being focused on the wrong laser technology," said an April report on the Defense Authorization Act. The current effort should be scrapped, according to the committee, and in its place studies should be initiated on short wavelength lasers, which are more lethal.

On the other hand, the Senate says such a move would delay the launch of a U.S. space laser until late in the next decade. The current long-wave lasers are perfectly adequate, says the Senate, and, unless the current program moves forward vigorously, the United States will lose the race for the domination of space to the Soviets.

The war of words is currently in a deadlock. The Senate recently passed its defense authorization bill and backed the status quo. The House will not vote on its bill until sometime in mid-June. Differences in the bills will be ironed out in conference.

The Pentagon's current effort, pioneered by the Defense Advanced Research Projects Agency (DARPA), centers on chemical lasers. These produce coherent rays in the infrared portion of the electromagnetic spectrum (at about 2.7 microns). They work something like rocket engines, using hydrogen and fluorine as fuel. DARPA programs include one named Alpha, which is aimed at producing a hydrogen-fluoride laser capable of radiating 5 megawatts; Lode, which is to produce a 4-meter mirror for aiming laser beams; and a program called Talon Gold, which is to demonstrate the tracking of targets in space.

The nub of the House's argument is founded on physics. The shorter wavelength lasers it favors, operating at or near the visible part of the spectrum, could achieve the military goals of the program much more efficiently than long wavelength chemical lasers, which are fairly easy to defeat by having a target covered with special coatings or polished so it reflects much of the laser beam. The first consideration in favor of shorter wavelengths is that the optics in general are easier to make. With wavelengths 6 times shorter than the ones currently

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