BY KIM RIBBINK

Regal Legal

Years of experience representing the life-sciences industry during his career as a lawyer have given ***DAVID KING*** a wealth of insight and a fresh perspective on the biotechnology industry. Today, he draws on that expertise and his ever-growing enthusiasm for biotech to lead a young company, BioRexis, and a dedicated team.

From biotech's early days in the mid-1980s, David R. King has played a central role in the industry, gaining a deep appreciation for science, the broad range of phases of business development, and what it takes to succeed.

As one of the most highly respected lawyers for life-sciences ventures, Mr. King has a vast portfolio of biotech companies that he has represented. He has worked with venture capital firms to raise funds for nascent biotech companies and garner new rounds of financing for up-and-coming companies.

Mr. King explains that as a lawyer this experience has given him insights into many different areas of a company's development.

"I have been able to view the entire business continuum starting from how a company germinates from an idea to how it gets off the ground, obtains capital, goes public, and grows to become successful, and at times become acquired," he says.

This knowledge has helped him grow with the companies, learn the concerns of each of the parties, and develop techniques to bring disparate parties together.

"I developed a reputation for being able to get things done — not because I jumped up and down, screamed, or threatened, but because I was creative, intelligent, and tried to bridge the gap between the parties during a transaction, acting as a positive force in getting the deal done," Mr. King says.

Today, that extensive experience is paying dividends for Mr. King as founder and CEO of the young biopharmaceutical company BioRexis Pharmaceutical Corp.

BioRexis was formed to develop and produce novel biopharmaceuticals with superior pharmacology using efficient manufacturing systems. The company uses its fusion technology platform to enhance the half-life, efficacy, and safety of therapeutic proteins and peptides. The company's proprietary approach to protein engineering uses a natural variant of the human plasma protein transferrin as a carrier protein and as a scaffold for the effective presentation of proteins and peptides. The same patented technology also is used to create Trans-bodies, which can replace conventional monoclonal antibodies (MAbs). Both are produced in cost-effective and efficient yeast expression systems. (For more information, see box on page 58.)

Mr. King has taken BioRexis, which commenced operations in July 2002, through the start-up stages of raising capital and team building to the point where the company is preparing to enter the clinic with its lead product.

A Self Starter

Without the family resources to pay for the entire cost of his education, Mr. King had to hold several jobs and borrow money to put himself through college. He graduated in three years from the University of Pennsylvania with a degree is sociology and then, aided by a scholarship, went on to Harvard Law School. Having to work around the clock was an experience that shaped the person, lawyer, and ultimately biotech CEO he has become, as did his undergraduate degree.

"I used to kid around that sociology was a wasted degree, but I realize it wasn't, and it really did help me understand a lot about people, how diseases affect society, and how people react to illness," he says. "A background in sociology has been extremely valuable."

The law is something Mr. King more or less fell into. Having planned to combine a law degree with a Ph.D. in sociology, he quickly

Trial, Without Error

DAVID KING — RESUME

JULY 2002 — PRESENT. CEO and Cofounder, BioRexis Pharmaceutical Corp., King of Prussia, Pa.

JANUARY 2001 — OCTOBER 2001. President, Delsys Pharmaceutical Corp., Princeton, N.J. Managed the sale of Delsys to Elan Corp.

JULY 2000 — SEPTEMBER 2000. CEO, Principia Pharmaceutical Corp., Norristown, Pa. Successfully negotiated the sale of Principia to Human Genome Sciences Inc.

SEPTEMBER 1974 — JULY 2000. Morgan, Lewis & Bockius LLP, Philadelphia. Became a partner in October 1981. Created and led the venture capital and emerging business practice; focused on representing life-sciences companies, venture capital firms, and underwriters of life-sciences companies; actively involved in managing the firm.

BOARD MEMBERSHIPS

2003 — PRESENT. Trustee, Ursinus College, Collegeville, Pa.

2001 — PRESENT. Board member, Innovation Philadelphia, Philadelphia

2001 — 2003. Director, Morphotek Inc., Exton, Pa.

2000 — 2003. Director, 3-Dimensional Pharmaceuticals Inc., Yardley, Pa.

1999 — 2001. Director, Cephalon Inc., West Chester, Pa.

1997 — PRESENT. Board member, Pennsylvania Biotechnology Association, Malvern, Pa. Served for three years as cochair of the association's annual symposium.

EDUCATION

1974. J.D., Harvard Law School, Cambridge, Mass.

1971. Sociology Degree, University of Pennsylvania, Philadelphia

found himself enamored with the study of law. In addition to 26 years in a large Philadelphia law firm, an experience he treasures, his law degree gave him the foundation to run his own company.

"The law degree also has been extraordinarily invaluable in terms of my skills as a businessman and as a CEO in particular," he says.

Mr. King joined Morgan, Lewis & Bockius LLP, a prominent Philadelphia law firm with a large office in New York.

The years in law were good to Mr. King, affording him a multitude of opportunities to work with diverse companies both old and new — from a 175-year-old steel mill and the historic Philadelphia National Bank to up-and-coming biotech companies such as Cephalon, now a vanguard of the biotech industry.

While the law never ceased to excite Mr. King, after so many years with Morgan Lewis, he began to look for new opportunities.

"I loved the practice of law, and I wasn't burned out; but I woke up one day and something happened to me: I turned 50," he says. "After all that hard work I had a degree of success and financial comfort, which allowed me to consider what I wanted to do next. I made a couple of calls, I had a couple of offers, and I quickly made the decision to join Chris Prior at Principia Pharmaceutical Corp."

High Achiever

No matter the firm, title, or industry, Mr. King has enjoyed a string of successes.

He brought modernization to Morgan Lewis, a law firm founded in 1873. He brought buyers and sellers, venture capitalists, and underwriters to his clients. And at each of the life-sciences companies he has headed since leaving Morgan Lewis — Principia Pharmaceutical, Delsys Pharmaceutical Corp., and now BioRexis — he has brought opportunities that best suited each organization.

At Morgan Lewis, Mr. King helped lead the firm into the technology arena. Working with what is now known as the Snider Entrepreneurial Center of the Wharton School of the University of Pennsylvania, he supported the emerging technology community in the greater Philadelphia area and built Morgan Lewis' practice in that area.

Mr. King explains that it made sense for a Philadelphia law firm to be heavily involved in the life sciences, since the mid-Atlantic region is really the heart of the pharmaceutical industry in the United States. Furthermore, the region has some of the most well-respected research institutions in the world, including the University of Pennsylvania and Johns Hopkins.

"If you're going to be in the technology sphere in the Philadelphia area as a lawyer, it's natural to gravitate into the life sciences," he says.

Mr. King's tenure as CEO of Principia was relatively brief, but hugely influential. Early on, Principia had been in licensing negotiations with Human Genome Sciences Inc. (HGS). Those negotiations quickly progressed to an offer by HGS to buy Principia. Recognizing that such a deal was in the young company's best interests, Mr. King once again drew upon his vast experience in deal making and was able to secure a very favorable agreement — a sale of the company to HGS for $135 million.

"I managed many acquisitions over the years as a lawyer, and I always reminded my clients that the acquisition's success was not dependent upon how I wrote the acquisition agreement, but how management dealt with the company it was acquiring, both during the process and thereafter," he says.

Though undoubtedly Mr. King's skills played no small part in securing a smooth transition, he applauds HGS for its role in the deal and for the thoughtfulness of HGS' executives when it came to Principia's staff.

"The HGS people were fabulous, and they

A Different Type of Trial

IN AN EXCLUSIVE INTERVIEW WITH PHARMAVOICE, DAVID R. KING, A FOUNDER AND CEO OF BIOREXIS PHARMACEUTICAL CORP., TALKS ABOUT HIS INFLUENCES AND HIS HOPES AND FEARS FOR THE LIFE-SCIENCES INDUSTRY.

AS A CEO OF A SMALL BIOTECH COMPANY, WHY DO YOU BELIEVE IT IS IMPORTANT TO BE PART OF ORGANIZATIONS SUCH AS THE PENNSYLVANIA BIOTECHNOLOGY ASSOCIATION?

I've been associated with the Pennsylvania Biotechnology Association for many years. Innovation Philadelphia is another important public/private partnership in this region that I'm very active with. This region has been good to me personally, good to BioRexis, good to Principia, good to my legal practice. I feel an important personal obligation to give back to the region, and the Pennsylvania Biotechnology Association is one way I can do that.

ARE THERE PEOPLE WHO HAVE BEEN AN IMPORTANT INFLUENCE ON YOUR LIFE AND WORK AND HELPED LEAD YOU TO WHERE YOU ARE TODAY?

There have been many wonderful influences in my life. But I would say that there are two people in particular to whom I owe so much for the extraordinary learning opportunities they have given me: Frank Baldino and Jim Cavanaugh. I was honored to work with Cephalon for a number of years, and Frank, who is the company's founder and CEO, is a rare individual. He is my hero, mentor, and a man I dearly admire and love. I don't think there's been anyone I've learned more from than Frank. I really view the opportunity to have grown with Cephalon and with Frank as one of the greatest experiences I've ever had in my life. Jim was a senior partner at Healthcare Ventures. Both of these men over the years have been gracious and wonderful to me. They took me under their wings, so to speak. They really took care of me and educated me in such a wonderful way. I can't conceive of anyone ever having a greater

treated everyone with respect," he says. "When HGS made the decision reluctantly to shut down the office in the Philadelphia area, I can't tell you how well the management treated everyone. They will always have my admiration and appreciation."

With the sale secured and not wishing to move out of the Philadelphia region, Mr. King decided to try his hand in another area of the life sciences: drug delivery.

In 2001, he became president of Delsys, a drug-delivery company that was acquired later that year by Elan Corp.

Delsys was a difficult situation, Mr. King explains, because the technology had been in development for quite some time and the company was having problems getting the capital it needed to complete the development pathway.

Since the sale, Mr. King says financial constraints have forced Elan to trim down the Delsys operations, but as with the HGS/Principia deal, Elan treated the Delsys staff with respect and consideration.

Fresh Perspective

With the Delsys deal closed, Mr. King decided it was time to spend time away from the corporate environment. He bought a video camera and traveled around the United States conducting an oral history of his family.

"It was a fascinating personal journey," he says. "When I came back, I sat on a couple of boards and was involved with charitable and civic activities. Chris Prior reconnected with me and asked me to work with him at BioRexis. I told Chris that I really wasn't ready to go back full time; I wanted to take some time off."

Fate, it would seem, had other ideas. While in a local store one day buying onions for a dish he planned to cook that night, he was confronted by an 80-year-old woman.

"She started yelling at me, telling me I was taking all the good onions," Mr. King recalls with a smile. "So I stepped back, got on my cell phone, called my wife at work, and told her I was going back to work full time. I called Chris that evening and said let's do it."

Nearly three years later, BioRexis has a healthy chunk of cash at its disposal, is preparing to take its lead product into the clinic later this year, has a strong intellectual property portfolio, and employs a dedicated, enthusiastic staff.

Although his background is quite different from many life-sciences CEOs — he does not have experience marketing drugs nor does he have the scientific expertise that many biotech founders possess — Mr. King has a broad understanding of the life-sciences industry, how companies large and small think and tick, what drives venture capitalists, and what underwriters seek.

Mr. King says he does require his scientists to help him understand the science, and he notes that he has been in this industry long enough and gained a thorough enough understanding of the science not to be bamboozled by it.

When he was a lawyer entrusted to do an initial public offering for a biotech company, Mr. King often had to present complicated science to the SEC in plain English.

"This was one of the most challenging and exciting aspects of the job," he says. "At the same time, the explanation had to be full enough so that nothing was left out, no matter how trivial the information might be."

The same is true at BioRexis, he says, where he tries to get a full and complete understanding of the science, even if it means having to have the staff explain the technology a few times.

"It's never been an insurmountable hurdle being a CEO who's not a scientist," he says. "And, in fact, I think not being a scientist has some real benefits."

While the industry is very familiar to him, the switch to working full time in biotech did take a bit of adjusting, since small life-sciences companies are quite different from a large, multi-city law firm.

"I went from managing a law firm of more than 1,000 lawyers to managing a company of 18 people, and that was quite a culture shock," he acknowledges. "But it has been a wonderful experience."

Although he had spent 15 years or so deeply enmeshed in the biotech industry representing various companies, the view from the outside is much different from that of the internal day-to-day operations.

"As a lawyer for biotech companies, I heard about their successes and their problems, and I would visit the companies periodically," Mr. King says. "I would attend a board meeting

opportunity than I was given over the years to work with them.

THERE ARE EXTRAORDINARY EXTERNAL PRESSURES WEIGHING ON THE LIFE-SCIENCES INDUSTRY. WHAT AREAS ARE OF MOST CONCERN TO YOU?

Like many people, I worry about the public perceptions of the pharmaceutical and biotech industry, given the really unfortunate and highly publicized problems of certain drugs. I worry that the public is not seeing the big picture. There's no drug in the world that doesn't have risks; we have to weigh the risks and benefits of drugs.

I worry that the public, in a simplistic way, will demand risk-free drugs, which would be devastating for the people who have diseases that we can help. We can't help these people unless the public has a true understanding that drugs come with risks. As a lawyer — and I still consider myself to be a lawyer — it's no fun opening up the newspaper and reading the big ads that law firms are publicizing for plaintiffs.

I worry about the narrow focus on the cost of healthcare and about the lack of understanding that drugs can really improve life, save lives, and even save money. Take diabetes, for example. I don't think our drug will be inexpensive; but, on the other hand, I think the expense of not having new drugs is far greater. I fear that in today's environment people lose sight of that.

In this supercharged environment, I worry that people may be losing the big picture of the enormous value of drugs, as well as the enormous cost and difficulty of producing and developing them.

WHAT IS THE BIGGEST CHALLENGE IN DRUG DEVELOPMENT?

This business is inspiring. But let's not kid ourselves; it's also daunting. It takes huge amounts of money and time to be successful. It's daunting because the same regulatory environment that impacts a Pfizer impacts a BioRexis. There's no exclusion that says little companies don't have to comply with the same regulatory restrictions as the big companies. This is the most regulated industry in the world. What inspires me is where we can ultimately go if we're successful — and that's being able to make life better for human beings. Drug development takes an amazing amount of perseverance, patience, and dedication. Success depends on believing in what one is doing and just plugging away at the job.

every other month or quarter, and what I heard was a summary of the highs and lows."

Now, being at a company every day, hearing the ups and downs of the scientific process, especially an early-stage company, is a very different experience, Mr. King says.

"Every day has its own gigantic disaster, and every day has its own equally gigantic success," he says. "It's those ups and downs, which I now see first hand, that excite me."

To ensure there are more ups than downs, Mr. King seeks to engender an environment that encourages teamwork and input from all members of the staff.

"I truly believe that there is no limit to what the company can accomplish if we don't worry about who gets the credit for doing it," he says. "I try to inculcate this philosophy throughout the organization, and I believe this is my most important role as CEO. We have a wonderful group of people and a wonderful working environment. These people work incredibly hard and are incredibly dedicated. I think that's the magic of teamwork."

By way of example, Mr. King says recently the company was set to meet one morning with representatives from a pharmaceutical company.

"I pulled in to the parking lot around 7:00 a.m., and the lot was full already," he says. "I never told anyone or asked anyone to come in early; they just did it."✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

A Better Half-Life

BIOREXIS PHARMACEUTICAL CORP., WHICH BEGAN OPERATIONS IN JULY 2002, WAS FORMED TO DEVELOP AND PRODUCE NOVEL BIOPHARMACEUTICALS WITH SUPERIOR PHARMACOLOGY USING EFFICIENT MANUFACTURING SYSTEMS.

One problem biopharmaceuticals often struggle with is the short half-life of many drugs, which requires patients to take high and frequent doses. High dosing not only increases the risk of bad side effects but can also limit therapeutic benefit and narrow application of a product to one indication. From the perspective of the manufacturer, high dosing can drive up the cost of treatment, particularly in the case of monoclonal antibodies and other high-priced biopharmaceuticals.

The Technology

To overcome this problem, BioRexis has developed a proprietary technology platform that enables production of superior biopharmaceuticals by genetically engineering protein and peptide drugs into the scaffold of a natural variant of the human plasma protein transferrin (Tf). The peptides can be fused to either end of the Tf or inserted into the Tf sequence along one of the molecule's surface loops. The engineered fusion proteins are remarkable for significantly enhanced half lives; rather than the native peptide's half-life of minutes or hours, the fusions can last for seven days or more.

Another important part of the company's business strategy is its yeast expression system. BioRexis' fusion proteins and transbodies can be manufactured in any expression system; but as they are not glycosylated, the company can take full advantage of the economic advantages provided by yeast. BioRexis has licensed a patented, fully validated yeast expression system to develop and manufacture products for the company and its collaborators. This system has been refined over 15 years, including almost two years of development to produce multi-gram per liter yields of Tf. It is currently providing high-yield production at 8,000 liter scale and is being used to produce multi-kilogram quantities of a similarly complex protein developed by a multinational pharmaceutical company.

Products are secreted by the yeast into a simple, defined growth medium free of animal or human-derived components, making them easy to purify. Sucrose serves as the carbon source, and no methanol is needed.

According to the company, the system is significantly more efficient than conventional mammalian cell culture methods.

"A very important part of our business strategy is reducing the cost of manufacturing proteins through the use of a yeast-based process as opposed to using more expensive expression systems," says David R. King, cofounder and CEO of BioRexis. "Our yeast expression system is performing well, and we already have a cGMP facility on line producing clinical supplies."

The Lead Products

The company's lead product is the fusion protein, GLP-1 Tf, which is in preclinical trials for treating type 2 diabetes. The product comprises a fusion of Tf to a peptide (GLP-1) that improves glucose metabolism and may delay or circumvent dependence on insulin in the treatment of many cases of type 2 diabetes.

"GLP-1 itself has been studied for years because it has the promise to be an important advance in diabetic therapy," Mr. King says. "It has some unique mechanisms of action; it has been shown to increase insulin secretion and response to glucose without causing hyperglycemia and, at the same time, has a number of other corollary benefits."

Mr. King says based on the data the company has gathered, the GLP-1 compound will have a half-life of about seven days and should be very well tolerated.

"We believe that, given the extended half-life and excellent tolerability, we can really make this into a groundbreaking therapy," he says.

BioRexis has made research quantities of many fusion proteins using its proprietary technology. As a follow-on to GLP-Tf, the company is doing initial technical feasibility studies on a select group of fusions, all of which have significant proof-of-concept data from preclinical and even clinical studies and address significant market opportunities.

The company plans to choose its second development project during the second half of 2005. BioRexis also is discussing potential research collaborations with companies that have interesting peptides that would benefit from a prolonged half-life and low-cost manufacturing.