

Talecris Biotherapeutics

YOU WOULD BE EXCUSED FOR SUPPOSING THAT

Talecris Biotherapeutics, Inc., founded on April 1, 2005, is a young company. In truth, though, its roots go much deeper – both scientifically and into the North Carolina Piedmont – than might be obvious at first glance. Talecris was formed when two private investment firms provided the capital to acquire the blood-plasma business of Bayer HealthCare LLC’s Biological Products Division. Among those assets were Bayer’s state-of-the-art Clayton, NC, blood plasma-therapeutics production facility and its headquarters in Research Triangle Park (RTP).

But Talecris acquired much more than buildings, equipment, and products from Bayer. Along with those tangible assets came a 60-year history of providing life-saving products for patients with rare diseases, and a workforce with the ability and experience to build upon a legacy of innovation. In fact, the company’s name reflects just those values. A combination of top industry TALEnt, focused on the delivery of biologics for providing optimal CRITICAL care to patients, with a vISion toward pioneering product advances, TALECRIS recognizes that people are at the heart of its business.

In the two short years since its formation, the strength of those values has been exemplified by the company’s success and rapid growth. At the time of its formation, Talecris also acquired the plasma-fractionation capabilities of Precision Pharma Services, located in Melville, NY. Since then, Talecris has expanded into Canada, with offices in Ottawa and Toronto, and into Europe with regional headquarters in Frankfurt, Germany. It also acquired 58 plasma-collection centers to form the subsidiary, Talecris Plasma Resources. The Talecris workforce now exceeds 3,000. By the end of June 2006, sales exceeded \$1 billion per year. These and other major strides led *Triangle Business Journal*, PricewaterhouseCoopers, and the Council for Entrepreneurial Development to name Talecris Biotherapeutics a 2006 “Fast 50” award winner, designating Talecris as one of the 50 fastest growing privately held companies in the Raleigh-Durham-Chapel Hill “Research Triangle.”

Talecris actually has five locations in the area. Beyond the production facility and headquarters are two laboratories and a plasma-testing facility. The Triangle provides a rich source of talent and intellect,



with its three major research universities and thriving biotech-business community. Indeed, one of the company’s laboratories is housed at North Carolina State University’s Centennial Campus, and it’s no surprise to find many graduates of State’s premiere engineering school occupying key positions at Talecris.

Separation of laboratories, storage, and production is especially well suited to the nature of the plasma-therapeutics business, because it reduces the risk of contamination for these precious, life-saving materials. Although plasma is collected one unit at a time, it is processed in bulk, and just one sample contaminated with virus or bacteria could ruin an entire batch. Collection centers are FDA certified, and donors are rigorously screened for diseases. Then, before a unit is even shipped from a collection center, a sample is sent to the Raleigh Testing Lab, where it is analyzed for the presence of HIV, hepatitis C and B, and other viral contaminants. Talecris’s Raleigh Testing Lab processes more than 10,000 samples per day, and it is the only plasma-fractionation facility to perform in-house testing of these viruses using FDA-licensed protocols.

Once a sample has passed testing, the unit from which it originated is shipped from the collection center ▶



Above: Talecris’ primary manufacturing facility is located in Clayton, NC. Below: A Talecris scientist monitors critical solution conditions during an optimization experiment in the development laboratory.



Above: A Talecris scientist works in the TSE (Transmissible Spongiform Encephalopathies) suite at their R&D facility in Research Triangle Park. Below: Talecris Packaging staff perform 100% inspection of product.

to a storage facility, where it is once again cross checked with the tested sample. After a minimum of 60 days storage, it is trucked to the Clayton facility for fractionation, a process by which water, which makes up about 92% of plasma, is removed, and the components that can be turned into therapeutic biologics are separated.

The Clayton plant is divided into two zones that are environmentally isolated to prevent early-stage materials from coming into contact with more purified product. These zones have completely separate space-conditioning systems, and movement of employees and materials between the zones is strictly limited. In Zone 1, the plasma undergoes fractionation and initial viral inactivation. In Zone 2, the product undergoes further viral inactivation, purification, and separation. From there, various proteins go to different production buildings – also divided into zones – where further viral inactivation and purification eventually lead to sterile filling and packaging.

Not only are these products extremely difficult to manufacture, they are also extremely perishable. Products must be stored, packaged, and shipped all over the globe within extremely narrow temperature ranges. Talecris has worked with various transportation and packaging companies to determine the optimal ship-

ping containers and transportation options to ensure that rigid requirements are maintained and therapeutics are safely delivered to healthcare providers and patients. To a degree not common in the rest of the pharmaceutical industry, producing therapies from plasma relies on vertical integration – the control of the entire process from acquisition of the raw material to delivery of the product.

The various proteins extracted from plasma can be used to treat a variety of diseases including immune deficiencies, genetic emphysema, and hemophilia. What these disorders often have in common is a life-long commitment to treatment on the part of the patient. Talecris products can help to eliminate symptoms but cannot, as yet, cure these diseases. For that reason, people taking these medications become very involved in their care and knowledgeable about their disorder.

Talecris personnel realize the extraordinary nature of the patients who use the therapies that this company works so hard to develop and produce. In the summer of 2006, Talecris brought in approximately 70 patients and care providers for a day of discussion and a tour of the Clayton facility. It was an exceptional experience for all involved, and both groups drew tremendous inspiration from their meeting. Talecris also reinforces its connection to its US patients by offering to ship certain therapies directly to them (with physician oversight) or to their healthcare providers via Talecris Direct. Through a toll-free number, patients can also receive assistance in coordinating nursing services for infusion and help with reimbursement and insurance. For patients in remote locations who need regular doses of medication, it can be the difference between staying and leaving home.

Managers at Talecris work tirelessly to encourage a workplace environment of innovation. Employees are encouraged to move laterally within the company to become experienced in the various phases of research, testing, development, production, and quality. Because the company is so integrated, it's vital for personnel to understand all phases of the operation. As a result, several employees have worked in at least two different departments and many have been in several. For example, crossing between R&D and production is common as a

scientist or engineer follows processes or equipment into the plant that he or she developed in the laboratory.

Talecris also spreads innovation and education into the community. The Talents Program will distribute more than \$1 million in grants during 2007 to investigators for basic science and clinical research into immune globulin intravenous therapies. In October 2006, the Immune Deficiency Foundation and nearby Duke University Medical Center collaborated to form the Duke IDF Center for Excellence for Primary Immunodeficiency Diseases. Talecris helped make this possible by providing a grant of more than \$125,000 over two years.

These are just some of the ways that Talecris Biotherapeutics invests in North Carolina and throughout the world. Every indication suggests that the investment is paying off handsomely for all concerned.

Talecris President and CEO, Alberto Martinez, MD

Dr. Martinez took the helm of Talecris Biotherapeutics in October 2005. His background and experience uniquely suit him to directing the company's growth. Educated as a physician at the University of Sao Paulo in Brazil, he followed up his pediatric residency by returning to the university to earn an MBA. Dr. Martinez began his career as a product manager at Sandoz Pharmaceutical in Brazil. During his 18 years at Sandoz, he served in Latin America, Switzerland, Spain, and the United States, where he became a citizen. Later, with Aventis Behring, he added the Middle East, Africa, Eastern Europe, and Asia to his international resume.

Immediately prior to joining Talecris, Dr. Martinez was executive vice president of worldwide commercial operations at ZLB Behring. While there, he also served as president of Aventis Bio-Services, and successfully led the acquisition and integration of Seramed. Dr. Martinez brought with him to Talecris not only a long list of accomplishments, but also a deep commitment to serving the patient community.

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Above left: Alberto Martinez, M.D., is President and CEO of Talecris Biotherapeutics.
Above right: A Talecris employee examines a valve group used for cleaning chromatography columns at the company's Clayton, NC facility.
Below: A Talecris employee takes patients a tour of their Clayton, NC manufacturing facility.