



Argos Therapeutics, Inc.

Company Overview

Argos Therapeutics is developing breakthrough immunotherapies that target the unique features of a patient's disease. This new generation of personalized cancer and infectious disease therapeutics, created using the Company's "Arcelis" technology, trains the immune system to recognize and attack the disease. Argos' scientific leadership in RNA-loaded dendritic cells and advanced manufacturing processes provide a platform to tackle virtually all forms of cancers and infectious diseases.

Argos is a private biotechnology company headquartered in Research Triangle Park, NC. The Company has clinical trial programs in cancer and human immunodeficiency virus (HIV) and has an ongoing co-development and commercialization alliance with the Pharmaceutical Division of Kirin Brewery Company, Limited.

Quick Facts

DATE FORMED

Argos Therapeutics was founded in 1997.

COMPANY LOCATION

Corporate headquarters are located in Durham, North Carolina.

NUMBER OF EMPLOYEES

The company employs 75 individuals.

ARGOS THERAPEUTICS LEADERSHIP

John N. Bonfiglio, Ph.D., President, Chief Executive Officer

Timothy W. Trost, C.P.A., Vice President, Chief Financial Officer

Frederick M. Miesowicz, Ph.D., Chief Operating Officer, Vice President, Manufacturing

Lothar H. Finke, M.D., Chief Medical Officer, Vice President, Regulatory Affairs

Charles A. Nicolette, Ph.D., Chief Scientific Officer, Vice President, Research & Development

Jeffrey D. Abbey, M.B.A., J.D., Vice President, Business Development

KEY INVESTMENTS TO DATE

To date, the company has raised approximately \$50M from investors. Argos has a broad spectrum of value-added life sciences investors, including TVM Capital, Intersouth Partners, MDS Capital, Forbion Capital (formerly, ABN AMRO), Aurora Funds and GeneChem Management.

COLLABORATIONS

Argos and Kirin Brewery's Pharmaceutical Division signed a collaboration agreement in June 2004 for developing therapies using dendritic cells. The companies share worldwide research and development costs and future net profits on a 50/50 basis. Kirin is co-funding all Arcelis immunotherapies currently under development and will contribute an estimated \$35 million during the first three years of the collaboration. As part of the agreement, Kirin made a



\$5 million equity investment in Argos and has a representative on Argos' board of directors. The term of the agreement is, in essence, indefinite, and, therefore, the co-funding of research and development costs continues indefinitely.

Argos and Geron reached an agreement in March 2004 in which Argos received 5 million shares of Geron stock, valued at over \$43 million at the time of the transaction, in exchange for granting Geron co-exclusive rights to use Argos' platform technology in cancer therapeutics using defined antigens. Argos retains co-exclusive rights to use the platform technology with defined antigens and exclusive rights to use it with total tumor RNA and other uncharacterized antigens.

Argos and Novo Nordisk entered into an agreement in February 2006 under which Argos licensed to Novo Nordisk its anti-IFN-alpha antibody technology for research and development of a treatment for systemic immune disorders, including systemic lupus erythematosus (SLE). Under the terms of the agreement, Argos will receive up to \$69 million comprised of up front and milestone payments, in addition to royalties on potential future sales of products.

Argos and the NIH announced in October 2006 that Argos had been awarded a \$21 million NIH contract to further develop our Arcelis HIV immunotherapy. In addition to determining the immunogenicity of our therapy currently in the clinic, the goal of the contract is to subsequently develop then test in the clinic even more potent next generation product candidates.

TECHNOLOGY OVERVIEW

Arcelis Technology

The cornerstone of our Arcelis technology involves the coupling of particular cells from an individual patient's immune system, dendritic cells ("DCs"), with a sample of messenger RNA ("mRNA") isolated from their disease (tumor in the case of cancer, pathogen in the case of infectious disease). This patient-specific treatment approach mounts a broad and potent immune system response tailored to that patient's individual disease.

The two precursor components are DCs (obtained from a blood sample via a "leukapheresis" procedure) and a disease sample (from surgery/biopsy or also taken from a patient's blood). Importantly, relative to the disease sample, only a minute specimen is required and from that, several years of therapy can be manufactured from one production run. After harvesting, both components are sent by overnight courier to our facility. We believe this aspect of the process (i.e., using day-old cells) both validates a commercializable business model (centralized manufacturing) and also provides a critical barrier to entry for a similar approach.

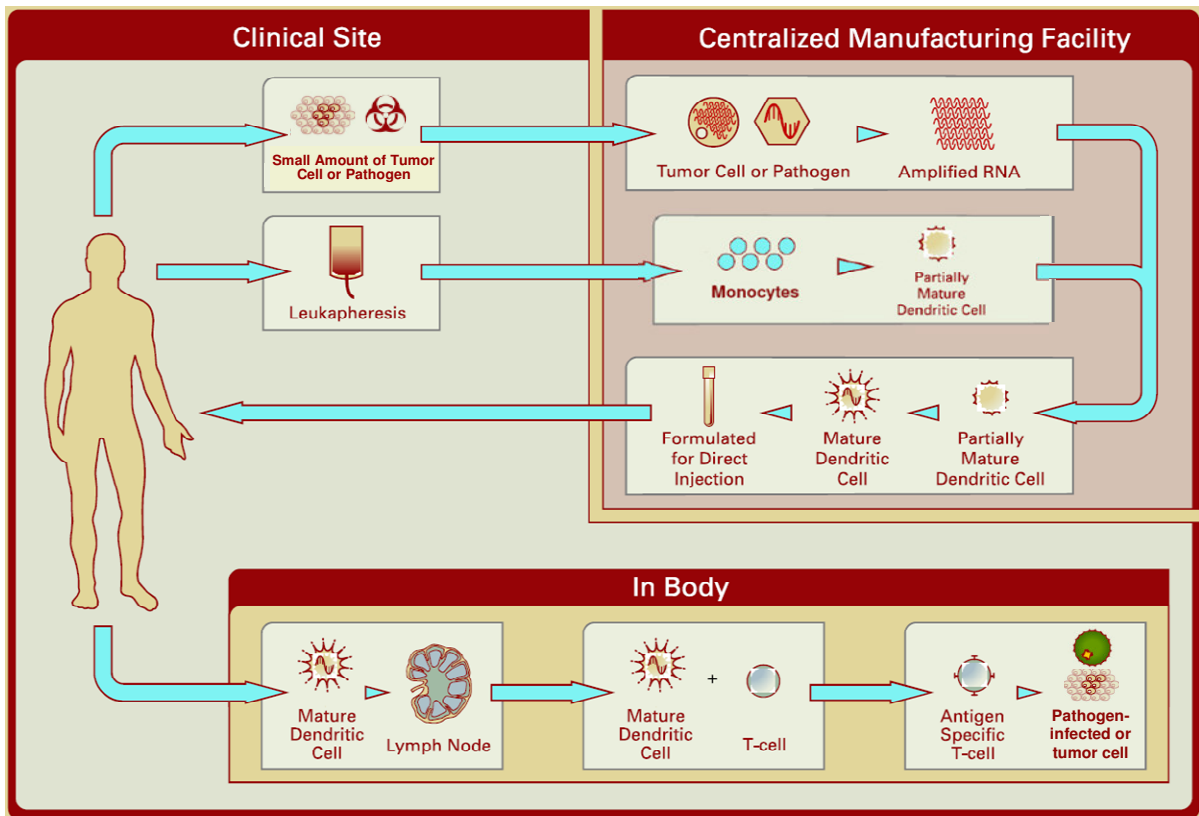
At Argos, mRNA from the patient's disease is extracted and amplified. In parallel, monocytes from the patient's blood are isolated and then cultured to a state of partial maturation, at which point the amplified mRNA is transfected into the cells by a process known as electroporation. These mRNA-loaded DCs are then formulated into a series of individual doses, which are shipped overnight on a just-in-time basis back to the clinical site, where the doses are thawed then administered.

Upon reintroduction into the subject via intradermal administration, the dendritic cells, which now are coated with disease-specific epitopes, are equipped to migrate to the lymph nodes



draining the anatomical site of the injection. Once in the lymph node, the dendritic cells come into contact with T-cells. It is through this interaction that the dendritic cells orchestrate the differentiation and expansion of antigen-specific T-cells imparting cytolytic effector function. These cytotoxic T-cells (CTL) are then able to seek out and destroy tumor or pathogen-infected cells that express the identical antigens as those by which they were educated. This mechanism of action underscores the rationale for employing the maximum number of the patient's disease-specific antigens to provide the potential to mobilize a broad-based and completely relevant immune assault on the intended target cells.

Diagram of Arcelis Technology



Key competitive advantages of our approach include the fact that the Arcelis technology includes all known and unknown antigens, which enables the broadest possible immune responses in both cancer and infectious disease. (Most existing technologies focus on one or a limited number of antigens not relevant to all patients.) In addition, since mRNA can be amplified from minute disease specimens obtained through relatively non-invasive procedures, the Arcelis technology enables treatment of earlier-stage patients. Another advantage is that this technology can be applied to diverse indications utilizing the same expertise and manufacturing techniques, allowing transitions between indications without “reinventing” the platform. Finally, Argos has developed a cost-effective, high-throughput automated production solution to reduce labor and other manufacturing costs, to increase capacity to meet the needs of future pivotal trials, and to accommodate commercial production.

Down-Regulation Technologies



In addition to our Arcelis technology, we have developed two additional technologies, which generally involve down-regulation of the immune system and which lie outside the Kirin collaboration. The first technology is the monoclonal antibody for treatment of systemic immune disorders, including systemic lupus erythematosus (SLE), that we licensed to Novo Nordisk in 2006.

The second technology is the recombinant protein, CD83, which has been shown to be an effective immunosuppressant and, therefore, has applicability to transplantation rejection and autoimmune diseases. Through outside collaborators, encouraging murine data has been generated relative to multiple sclerosis, skin and heart transplantation, and autoimmune diabetes. Strikingly, CD83 distinguishes itself from other immunosuppressants in that it does not appear to require chronic administration and does not leave the patient globally immunosuppressed. This observation provides a significant competitive advantage over all other immunosuppressive agents whether FDA approved or in development.

CLINICAL PIPELINE

Metastatic Renal Cell Carcinoma (RCC)

Our initial RCC trial completed enrollment in April 2005. Results of the trial, which had 15 evaluable patients, were presented at Kidney Cancer Association and AACR/NCI/EORTC meetings in the fourth quarter of 2005. The trial generated encouraging data in a subset of patients having progressive disease prior to first dose. Patients who had disease progression during the pre-treatment phase experienced a substantial decrease in disease progression upon treatment with the Arcelis therapy, indicating that the administration of the therapy had a measurable effect on the rate of tumor growth. In addition to this positive progression data, overall survival of approximately 25 months compares favorably to approved therapies, as does the side effect profile of our Arcelis therapy.

In May 2006, we began treating patients in a Phase 2 RCC trial using a significantly more potent formulation of our Arcelis technology developed from the data we observed in our initial RCC trial.

Chronic Lymphocytic Leukemia (CLL)

CLL, like other hematologic indications, is appealing to Argos because of (1) easy access to malignant cells and (2) the ability to monitor tumor burden via routine blood counts on virtually a real-time basis. Applying the same optimized Arcelis technology used in the current RCC trial, we are currently enrolling and treating patients in a Phase 1/2 trial in CLL at McMaster University in Hamilton, Ontario, Canada.

Human Immunodeficiency Virus (HIV)

Although current therapies (primarily highly active antiretroviral therapy) constitute a \$5 billion market, they have a number of limitations and challenges and often ultimately fail due to viral mutation and resistance. Our Arcelis HIV immunotherapy addresses a number of these issues by mobilizing a broad-based and completely relevant immune assault on the patient's own virus. Additionally, like CLL, HIV is an attractive disease target as it too provides the ability to obtain access to efficacy markers like viral counts via routine blood draws. We are currently enrolling and treating patients in a Phase 1 HIV trial at McGill University in Montreal, Quebec.