

# **Argos Therapeutics Inc**

## **COMPANY AND PIPELINE OVERVIEW REPORT**

A comprehensive coverage of the company and a summary of the drug pipeline portfolio.

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## ABOUT COMPANY AND PIPELINE OVERVIEW REPORT

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#### **GLOSSARY**

### **Number of Drugs in Active Development**

Number of drugs associated with the company or subsidiary that are currently in active development, i.e. the development status for the drug(s) is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

## **Number of Inactive Drugs**

Number of drugs associated with the company or subsidiary that are currently classified as inactive, i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

#### **Number of Patents as Owner**

Number of patents associated with the company where the company is listed as owner; i.e. the relationship type (or way the patent refers to the company) is: Patent Assignee/Owner, Patent owner (not assignee), Licensee for development and marketing, Licensee – marketing only (Distributor), Patent assignee of family member, Inferred assignee.

#### **Number of Patents as Third Party**

Number of patents associated with the company where the company is listed as third party; i.e. the relationship type (or way the patent refers to the company) is: Patent assignee (not owner), Ex-Licensee for development and marketing, Ex-Licensee marketing only (Distributor), Customer of technology, Ex-Customer of technology, Patent opponent or infringer, Affiliate organization of inventor, Owner of underlying technology.

#### Patents summary table

This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

#### **Number of Deals**

A count of deals where the company or one of its subsidiaries is the primary company.

#### **Key Indications**

Displays top ten key indications for the company and its subsidiaries based on frequency (indications occurring with high and identical frequency are always included, and this may result in more than ten Key Indications being listed). Includes both indications associated with patents where the company is patent owner and indications associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

#### **Key Target-based Actions**

Displays top ten key target-based actions for the company and its subsidiaries based on frequency (actions occurring with high and identical frequency are always included, and this may result in more than ten Key Target-based Actions being listed). Includes both target-based actions associated with patents where the company patent owner and target-based actions associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended. A target-based action is one that is associated with a target.

#### **Key Technologies**

Displays top ten key technologies for the company and its subsidiaries based on frequency (technologies occurring with high and identical frequency are always included, and this may result in more than ten Key Technologies being listed). Includes both key technologies associated with patents where the company relationship is patent owner and key technologies associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

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PLEASE NOTE: the financials section where present in the report includes: Share Information, Stock Performance chart (including the consensus recommendation), and Major Shareholders. Financial Performance presents graphical and tabular data on Worldwide Sales, Operating Income and Net Income over time, together with a Quarterly earnings update. Balance Sheet lists Assets, Liabilities and Stockholders Equity, and Forecasts includes: EPS Forecast and Other Forecasts. The data reported in all sections (except share information and major stock holders) are correct as of the publication date of the report (and not the download date). For share information and major stock holders the data is correct for the date shown with these sections



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## **Argos Therapeutics Inc**

#### **COMPANY OVERVIEW**

Company Name	Argos Therapeutics Inc
Parent Company Name	Argos Therapeutics Inc
Website	http://www.argostherapeutics.com/
Country	US
Number of Drugs in Active Development	4
Number of Inactive Drugs	5
Number of Patents as Owner	17
Number of Patents as Third Party	2
Number of Deals	16
Key Indications	Autoimmune disease, Transplant rejection, HIV infection, Inflammatory disease, Renal cell carcinoma, Systemic lupus erythematosus, Allergy, Asthma, Diabetes mellitus, Heart transplantation, Kidney transplantation, Multiple sclerosis, Myasthenia gravis, Psoriasis, Tissue
Key Target-based Actions	Interferon alpha ligand inhibitor,CD40 ligand receptor antagonist,CD80 antagonist,CD83 antagonist,CD86 antagonist,HLA class II antigen inhibitor,IL-10 antagonist,IL-12 antagonist,IL-2 receptor alpha subunit inhibitor,Proteasome inhibitor,SL cytokine ligand inhibitor
Key Technologies	Biological therapeutic, Cell therapy, Injectable formulation, Intradermal formulation, Parenteral formulation unspecified, Immunoglobulin-G, Infusion, Intravenous formulation, Monoclonal antibody humanized, Small molecule therapeutic, Subcutaneous formulation, T-lymphocyte

#### **COMPANY PROFILE**

#### **SUMMARY**

Argos Therapeutics (formerly Merix Bioscience Inc) is a venture-backed, start-up immunotherapy company dedicated to the treatment of metastatic cancers and chronic infectious diseases resistant to current therapies. In October 2004, the company changed its name from Merix Bioscience Inc to Argos Therapeutics Inc.

## **COMPANY LOCATION**

In October 2014, the company planned to develop a nearly 100,000 sq.foot state-of-the-art biomanufacturing facility in the Research Triangle Park area in Durham, NC. In October 2014, the company held a groundbreaking ceremony at the site.

In October 2001, Merix established a wholly owned subsidiary, Merix Germany GmbH, in Erlangen, Germany, to conduct dendritic cell research focusing on Merix's RNA platform. This subsidiary was renamed Argos Therapeutics GmbH, when the parent company changed its name in October 2004.

#### LICENSING AGREEMENTS

Argos Therapeutics and Therakos, a subsidiary of Johnson & Johnson, have entered an agreement to research and develop regulatory T cell technology-based treatments. The technology was previously developed by Argos.

In April 2006, Argos licensed exclusive rights to use the soluble protein, CD83, for autoimmune disorders and transplant rejection, from Beckman Coulter. Beckman Coulter licensed rights to the protein from the Dana-Farber Cancer Institute, and retained rights to diagnostic use of CD83.

In June 2004, Merix and Kirin Brewery Co Ltd signed an agreement for the development of therapies using dendritic cells, initially for the treatment of cancer and HIV. The companies would jointly conduct research and development and share profits worldwide. Merix would commercialize in the US and Canada and Kirin in Asia. Opportunities in Europe and the rest of the world were to be decided jointly. Kirin made an equity investment in Merix and appointed a member to Merix's board. Each company was to contribute \$45-65 million during the first three years of the collaboration.



In March 2004, Geron Corp and Merix entered into second agreement, in which Geron acquired exclusive rights to use Merix's platform technology in therapeutic cancer vaccines using telomerase as an antigen. Geron and Merix also gained coexclusive rights to use the Merix technology in cancer vaccines using antigens other than telomerase, while Merix retained exclusive rights to use it with total tumor RNA and other uncharacterized antigens. The companies also agreed to a cross licensing arrangement with respect to a new technology in the same field. Geron issued 5 million shares of its common stock to Merix in connection with the deal. The companies entered the first agreement in August 2000, to assess the clinical and commercial potential of hTERT RNA as an antigen for cancer immunotherapy using Merix's delivery system. Geron provided expertise and proprietary rights in the field of telomerase. Under the terms of the collaboration, Geron would sponsor preclinical studies at Duke University to confirm the safety and efficacy of hTERT RNA-modified dendritic cells to mediate immune responses against tumors. Studies would be performed in parallel with Merix. Geron and Merix would jointly determine the clinical development plan for the combined technology platform.

#### **EARLY R&D**

In June 2009, the company reported results from studies investigating the progression of HIV infection. The HIV viral protein R (Vpr) was believed to be required for the establishment of HIV infection. Some known C terminal VPr mutations did not reduce the block of IL-12 production by the virus, but an amino acid substitution, R90K, completely reversed this suppression.

In October 2008, data were published showing that the company's RNA-electroporated dendritic cells generated high-avidity cytotoxic T cells in vitro. Later that month, further results published showed that the company's dentritic cells could improve dendritic cells-based immunotherapy.

#### **IP NEWS**

In November 2001, the USPTO issued Merix a core patent, which had previously been licensed on an exclusive worldwide basis from Duke University, and which provides the company with substantially more options for treating cancer and infectious diseases. Using defined RNA antigens Merix could target certain cancers and infectious diseases, such as hepatitis C, with autologous dendritic cell vaccines.

#### **R&D GRANTS**

In October 2006, the NIH awarded Argos Therapeutics a 5-year, \$21 million contract to develop novel HIV immunotherapy candidates. The goal of the contract was to determine the immunogenicity of Argos' HIV immunotherapy candidate and then develop more potent next-generation product candidates. Optimized therapies would then be tested in a multicenter, randomized, placebo-controlled clinical trial. Argos teamed up with several leading institutions which would participate in the development program. The award would cover all of the costs associated with the development of the next-generation HIV immunotherapies, plus portions of costs related to Argos' existing HIV candidate development. Argos would retain commercial rights to any candidates that were developed.

#### **FINANCIAL**

In October 2014, the company would receive approximately \$9.5 million as incentives and logistical, planning support from the State of North Carolina, Durham County, the City of Durham, and the North Carolina Biotechnology Center.

In September 2014, the company entered into a venture loan to raise \$25 million in two tranches of \$12.5 million each that bears a interest at a floating coupon rate of one-month LIBOR plus 8.75%.

In March 2014, the company was added to the Russell 2000 and Russell 3000 indices.

In February 2014, the company planned to issue 5,625,000 shares priced at \$8 per share through an IPO. Underwriters would be granted 30-day option to purchase 843,750 additional shares. At that time, Argos shares were traded under the ticker symbol 'ARGS' on the NASDAQ Global Market. Later that month, Forbion Capital Partners reported that the IPO had closed.

In August 2013, the company raised \$42.5 million in a series E financing. At that time, Pharmstandard International SA, a subsidiary of Pharmstandard OJSC had purchased 9,214,233 preferred shares and 1,417,571 warrants for US \$12 million, in a total consideration of US \$30 million in the series E financing round. At that time, the company planned for three tranches including the conditional last tranche of US \$6 million, following phase III positive data in AGS-003. In November 2013, the company increased the size of the series E financing of \$17.5 million for a total consideration of \$60 million.

In April 2012, the company raised \$25 million in a series D financing.

In July 2011, the company filed a registration statement with the SEC for an IPO of shares.

In April 2008, Argos raised \$35.2 million from series C financing. In November 2008, the company raised \$35.2 million from the second tranche of series C financing round.



In April 2007, Argos raised \$5 million in a 3-year debt financing.

In September 2001, Merix completed a \$39.5 million round of private financing. This second included previous and new domestic and international institutions. The funds would be used to advance clinical trials of a cancer vaccine and to expand the Merix platform for immunostimulation.

## **SUBSIDIARY COMPANIES**

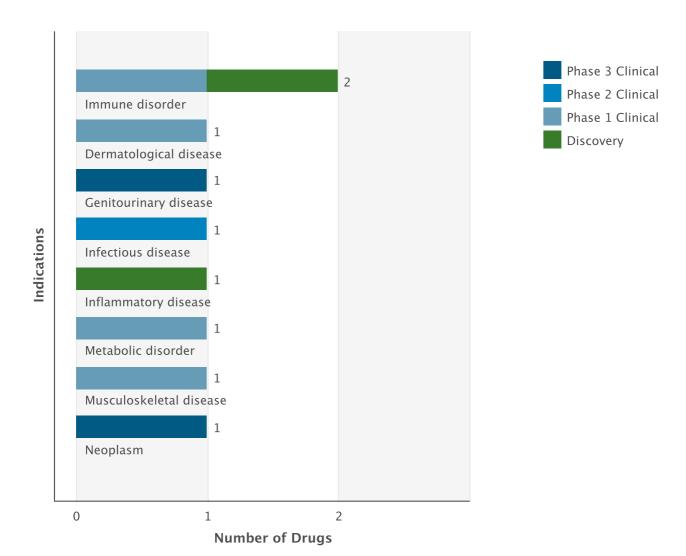


#### PRODUCT PORTFOLIO SUMMARY

#### **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart



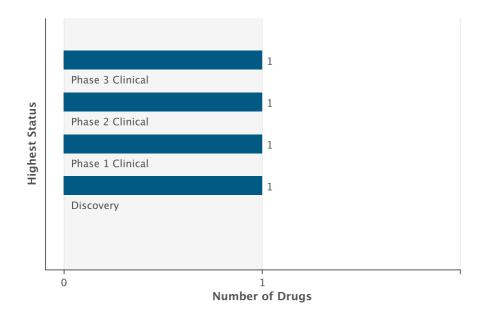


## Drugs by Indication Table

Indication	Active	Inactive	Total
Neoplasm	1	3	4
Immune disorder	2	1	3
Metabolic disorder	1	1	2
Gastrointestinal disease	0	2	2
Dermatological disease	1	1	2
Genitourinary disease	1	1	2
Infectious disease	1	0	1
Endocrine disease	0	1	1
Hematological disease	0	1	1
Andrology	0	1	1
Inflammatory disease	1	0	1
Musculoskeletal disease	1	0	1

## **Drugs by Highest Status**

Active Drugs by Highest Status Chart





## Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
Phase 2 Clinical	1
Phase 1 Clinical	1
Discovery	1
Discontinued	2
No Development Reported	3

## **DEALS**

Deal Type	Prin	cipal	Pai	tner	Total
	Active	Inactive	Active	Inactive	
Technology - Other Proprietary	0	0	0	0	1
Patent - Exclusive Rights	0	0	1	0	1
Patent - Non-Exclusive Rights	0	0	1	0	1
Drug - Funding	2	0	0	0	2
Drug - Early Research/Development	3	0	0	0	3
Drug - Development/Commercialization License	5	0	1	0	6
Drug - Manufacturing/Supply	1	0	0	0	1
Drug - Development Services	0	0	1	0	1

## **CLINICAL TRIALS**

## Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	1	7
Genitourinary disease	1	5
Infectious disease	1	4
Metabolic disorder	0	1
Immune disorder	0	1
Dermatological disease	0	1



Gastrointestinal disease	0	1
Hematological disease	0	1
Musculoskeletal disease	0	1

## Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	0	4
Phase 1	1	6
Phase not specified	0	1

#### **Phase Definitions**

## Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

#### **PATENTS** \*

Indication	As Owner	As Third Party	Total
Cardiovascular disease	2	0	2
Endocrine disease	5	1	6
Gastrointestinal disease	9	1	10
Immune disorder	10	1	11
Musculoskeletal disease	4	0	4
Neoplasm	11	1	12
Metabolic disorder	5	1	6
Neurological disease	5	1	6
Prophylaxis	2	0	2
Respiratory disease	2	1	3
Infectious disease	10	0	10
Inflammatory disease	8	1	9



Dermatological disease	3	1	4
Surgical procedure	0	1	1

<sup>\*</sup> This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.



## **PRODUCT PORTFOLIO DRUGS**

PLEASE NOTE: Highest status refers to highest development of that drug for one of the active companies

## **AGS-003**

Drug Name	AGS-003
Key Synonyms	
Originator Company	Argos Therapeutics Inc
Active Companies	Medinet Co Ltd, Argos Therapeutics Inc
Inactive Companies	Kirin Pharma Co Ltd, Kyowa Hakko Kirin Co Ltd, Kirin Brewery Co Ltd
Highest Status	Phase 3 Clinical
Active Indications	Renal cell carcinoma
Target-based Actions	
Other Actions	Therapeutic vaccine, Anticancer, Genetically engineered autologous cell vaccine
Technologies	Cell therapy, Biological therapeutic, Intradermal formulation
Last Change Date	14-Nov-2014

## **AGS-004**

Drug Name	AGS-004
Key Synonyms	
Originator Company	Argos Therapeutics Inc
Active Companies	Argos Therapeutics Inc
Inactive Companies	Kyowa Hakko Kirin Co Ltd
Highest Status	Phase 2 Clinical
Active Indications	HIV infection
Target-based Actions	
Other Actions	Genetically engineered autologous cell vaccine, Therapeutic vaccine, Antiviral
Technologies	Cell therapy, Biological therapeutic, Intradermal formulation
Last Change Date	14-Nov-2014

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## **AGS-009**

Drug Name	AGS-009
Key Synonyms	
Originator Company	Argos Therapeutics Inc
Active Companies	Argos Therapeutics Inc
Inactive Companies	Novo Nordisk A/S
Highest Status	Phase 1 Clinical
Active Indications	Systemic lupus erythematosus
Target-based Actions	Interferon alpha ligand inhibitor
Other Actions	Immunosuppressant
Technologies	Monoclonal antibody humanized, Immunoglobulin-G, Subcutaneous formulation, Intravenous formulation, Infusion, Biological therapeutic
Last Change Date	09-Apr-2014

#### **AGS-010**

Drug Name	AGS-010
Key Synonyms	
Originator Company	Dana-Farber Cancer Institute Inc
Active Companies	Argos Therapeutics Inc
Inactive Companies	Beckman Coulter Inc, Dana-Farber Cancer Institute Inc
Highest Status	Discovery
Active Indications	Inflammatory disease, Transplant rejection, Autoimmune disease
Target-based Actions	CD83 agonist
Other Actions	Immunosuppressant, Anti-inflammatory
Technologies	Glycoprotein, Biological therapeutic, Parenteral formulation unspecified
Last Change Date	16-Aug-2013



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