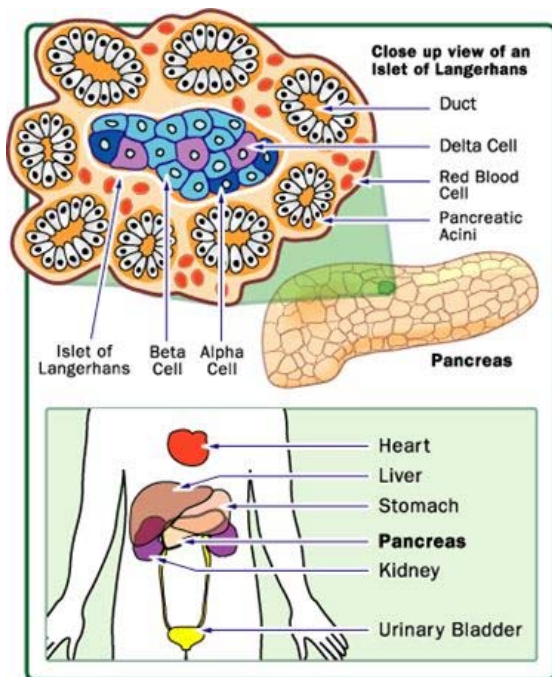


## Executive Summary

### Introduction

DiaKine Therapeutics, Inc. is a start-up biopharmaceutical company developing new, proprietary drugs that have the potential to restate the diabetes market by stopping the progression of diabetes and reversing damage already caused by the disease. Because of their unique immune modulating and anti-inflammatory properties, our therapies may potentially benefit people with type 1 and type 2 diabetes and represent a total available market opportunity of approximately \$13 B.

Our lead compound Lisofylline (LSF), works at the cellular level by protecting insulin-producing islet cells from damage and premature death caused when the body's immune system turns on itself. This autoimmune action is the cause of type 1 diabetes and Latent Autoimmune Diabetes in Adults (LADA), which combined affect approximately three million people in the U.S. Additionally, about three million people with type 2 diabetes use insulin due to diminished insulin production and an increasing resistance to insulin.



Results from pre-clinical studies show that LSF improves insulin secretion and protects islet cells from damage caused by cytokines, components in the inflammation pathway that destroy pancreatic  $\beta$ -cells. LSF, when used alone or in combination with other drugs, either stabilizes or actually reverses established type 1 diabetes in animal models; the results of this study were presented to the American Diabetes Association in June 2005.

LSF presently is administered intravenously; studies to determine the potential for subcutaneous administration are planned for the near future. Also under development are DT 22669 and DT 23552, our next generation of orally bioavailable immune modulators which have a similar spectrum of action to LSF.

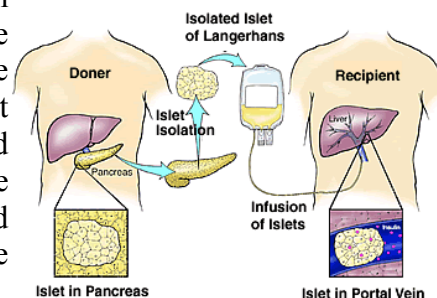
*Beta cells are found situated in the Islets of Langerhans which are contained in the pancreas. The beta cells ( $\beta$ -cells) produce insulin. Islet cells also contain other hormone producing cells. Throughout this document and within the medical literature, islet cells and beta cells are used interchangeably*

## Product Pipeline

The diabetes and related complications market opportunities for LSF and our related oral compounds are large and growing. Segments include islet cell transplant therapy, type 1 diabetes, Latent Autoimmune Diabetes in Adults (LADA), insulin-using type 2 diabetes, and diabetes-related complications such as nephropathy and retinopathy. Lead indications are:

- **As an adjunct therapy, to improve outcomes during islet cell or any other cellular transplantation engineered to reverse type 1 diabetes.**

The islet cell transplant (ICT) market represents a near to intermediate term \$20-40 MM opportunity with a \$150 MM potential upside as technology improves. Planned uses for LSF are two-fold. First, it will be used as a component in the islet cell culture media, thus improving the viability and function of islet cells during the procedure to isolate only the islets that contain insulin-producing  $\beta$ -cells from a pancreas. Second, it will be administered as a post-transplant drug therapy to keep the patient's body from destroying the new islets. If successful, islet transplantation can restore normal blood sugar without the need for insulin injections and can improve quality of life. LSF will be one of the new drugs tested in a Phase 2 clinical trial sponsored and funded by the National Institute of Diabetes and Digestive and Kidney Diseases in the second half of 2005.



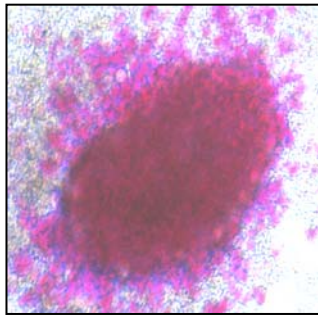
*LSF has the potential to double the size of the islet transplant market and improve outcomes.*

- **Reversing or arresting the progression of diabetes in type 1, LADA and insulin-using type 2 patients.**

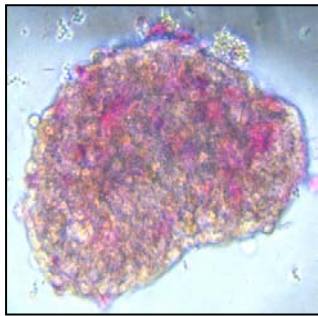
Patients with type 1 diabetes treated with LSF, or our oral drugs with a similar spectrum of action to LSF, may be protected from further disease progression. By protecting the insulin producing  $\beta$ -cells, these patients may also be protected from the complications of diabetes. A planned indication for LSF is to halt the progression of type 1 or actually reverse the disease. Similar studies are planned with LADA patients our next generation of oral drugs.

New information suggests that, in addition to insulin resistance, type 2 diabetes is associated with progressive loss of the insulin producing  $\beta$ -cells. Therefore, use of our oral immune modulators with anti-inflammatory actions could prove therapeutic by preventing loss of the  $\beta$ -cells and improving glucose control.

Clinical studies in insulin-using type 2 adults with diabetes are planned using our next generation of oral drugs.



*Islet cell in cytokine solution being destroyed*



*Islet cell in cytokine solution protected by DiaKine drug*

The type 1 market represents a nominal \$1 B sales opportunity assuming 150,000 patients at \$6,000 per year are treated on an on going basis. At the same average selling price, (ASP) a projected 25% LADA utilization rate for an oral drug with a similar spectrum of action to LSF represents approximately a \$3 B U.S. market. A utilization rate of 10% of all insulin-using type 2 patients represents a sales potential of approximately \$2 B at the same ASP.

LSF for injection has completed Phase 1 clinical studies; two lead candidate compounds that have demonstrated oral bioavailability in primates are in preclinical development. One of these, DT 22669, has also demonstrated pre-clinical efficacy in protecting human  $\beta$ -cells from cytokine damage and in reducing the development of type 1 diabetes in a mouse model.

- **Diabetes complications**

The Company has identified two complications of diabetes that are targets for development with our next generation of oral drug: diabetic nephropathy and diabetic retinopathy.

Diabetic nephropathy, or kidney disease, is one of the most frequent complications of diabetes. Up to 21% of all patients with diabetes have nephropathy. Nephropathy often ends in kidney failure or end-stage renal disease (ESRD). Approximately 43% of new cases of ESRD are a result of diabetes progression. Although certain high blood pressure medications have been found to be helpful in slowing the progression of kidney disease in diabetics, there is currently no cure.

Diabetic retinopathy leads to proliferation of blood vessels in the retina of the eye and is another frequent complication of diabetes. It represents the major cause of blindness in adults. Nearly all type 1 diabetics who have the disease for 20 years will have evidence of diabetic retinopathy. As many as 21% of people with type 2 diabetes present with retinopathy at initial diagnosis and most eventually develop some degree of retinopathy. It is estimated that between 12,000 to 24,000 people lose their sight in the United States each year due to diabetes, making it the leading cause of new cases of blindness in adults. There is no drug treatment or cure for diabetic retinopathy.

Two lead candidate compounds (DT 22669 and DT 23552) have demonstrated oral bioavailability and are currently in pre-clinical development to target prevention and treatment of diabetic nephropathy and diabetic retinopathy.

These two complications combined cost the US Healthcare system \$48.9B in 2002. This represents an average healthcare cost of \$3.7K and \$5.5K per patient each year for retinopathy and nephropathy, respectively.

## Intellectual Property

DiaKine holds an exclusive, world-wide license to develop and market products based on the discoveries associated with Lisofylline and the next generation of orally bioavailable immune modulators with a similar spectrum of action for the treatment of both type 1 and type 2 diabetes and related complications. The company holds more than 50 patents and patent applications for LSF and related compounds with patents issued or pending in all major jurisdictions.

As part of the license agreement with Cell Therapeutics, Inc., (CTI) DiaKine has acquired the Investigational New Drug Application (IND) for LSF as well the use of the manufacturing information, pre-clinical, and Phase 1 data for use in the Phase 2 human clinical islet transplant trial and additional trials. The ownership of the technology (*i.e.* drug development and safety data) **represents a four year savings in time and development costs.**

The licensed intellectual property also includes an extensive library of structurally related immune modulators with anti-inflammatory activity for use in other indications such as LADA, insulin using type 2 diabetics, and diabetic complications. Over 2,000 chemical variants of the LSF structure in several families have been synthesized. Composition of matter and use patents have been issued and 260 compounds to date have been tested in anti-inflammatory screening assays. Thirty-seven compounds with potency equal to or greater than LSF were discovered and seven compounds have shown greater stability in human liver microsomes (used to predict the metabolism of a drug) when compared to LSF. Two of our lead oral compounds were further analyzed for toxicity using a pharma screen and for pharmacokinetics in primates. Both demonstrated oral bioavailability (BID) and no significant toxicity in the pharma screen (Non-GLP). Thus, these two compounds are lead candidates for further development in indications of interest to the Company.

*DT 22669 and DT 23552 are oral drugs we are developing to address type 2 diabetes and eye and kidney diabetes-related complications.*

Although many of its patents and patent applications enjoy broad scope and applicability, the following represents an exemplary (but not necessarily a conclusive or definitive) itemization for the clinical indications and market(s) sought by DiaKine with their respective patent term expectancy.

Indication	Patent Term Expectancy
Islet cell related therapeutics	Through 2020
Autoimmune diabetes	Through 2015
Type 1	2019
Type 2	2020

The patent claims for these patents include both claims for compositions, as well as claims for methods of use for various therapeutic indications with terms through as late as 2020. New and additional filings may extend the scope and terms of these indications as a result of DiaKine’s continuing research and development efforts.

### Strategy

DiaKine’s strategy is to leverage its experience in the pathogenesis of diabetes and related complications to advance development of Lisofylline and its next generation of orally bioavailable immune modulators with a similar spectrum of action to LSF. Our focus is to develop drugs that protect and enhance the body’s insulin producing capabilities and reduce or prevent diabetes-related complications for both the type 1 and larger type 2 markets.

In support of its strategy, the Company plans to:

- Deepen its position as a preeminent diabetes company by leveraging and extending its expertise; and
- Partner with pharmaceutical and biotechnology companies, foundations, academic institutions and government organizations to accelerate product development, as well as defray costs in the form of non-dilutive financing.

*DiaKine therapy for improving islet cell transplant outcomes is scheduled to begin a National Institutes of Health-sponsored Phase 2 clinical trial later this year.*

### Clinical Status

DiaKine is poised much like a development stage company because it is entering a Phase 2 clinical trial in islet cell transplantation for type 1 diabetic patients with its lead compound, LSF.

Concurrently, the company is focusing its Phase 1 development activities on arresting type 1 diabetes with LSF; LADA patients may also benefit from treatment with LSF, however, an oral drug may prove to be a more appropriate therapy. Preclinical activities are focused in the therapeutic areas of both LADA and insulin-using type 2 diabetes, specifically, the restoration of islet cell insulin production with the use of orally bioavailable immune modulators.

Product	Use	Launch			
LSF cell culture media	Pretreatment of islets	2007			
Drug products	Indication	Preclinical	Phase 1	Phase 2	Phase 3
LSF, IV	Adjunct therapy to improve outcomes in beta cell replacement therapy or any cellular therapy engineered to reverse of diabetes				
LSF, SC	Reverse or halt progression of type 1 diabetes				
DK11558/DK12441	Treatment of insulin requiring type 2 diabetes				
DK1558/DK12441	Treatment/prevention of LADA				
DK11558	Treatment/prevention of diabetic nephropathy				
DT 23552	Treatment/prevention of diabetic retinopathy				

## Competition

Every company that is marketing and/or developing products to treat diabetes and associated complications is effectively a competitor to DiaKine Therapeutics. These include multi-national pharmaceutical firms (e.g. Eli Lilly, Pfizer, Novo Nordisk, and Novartis) as well as smaller and mid-size biopharmaceutical companies. DiaKine competes on the basis of its scientific approach to treatment options, the proprietary nature of its products and the level of resident expertise associated with the Company.

The Company also competes with other pharmaceutical and biopharmaceutical firms developing immune modulating compounds. These include a variety of biopharmaceutical firms marketing and developing biological compounds having effective immune modulating characteristics. A number of multi-national pharmaceutical firms are marketing or developing synthetically derived compounds as immunosuppressive agents.

*As part of the license agreement, DiaKine acquired the IND from Cell Therapeutics, Inc. This data package represents a four year savings in time and development costs for DiaKine.*

While these firms may be current competitors, some of these firms will also be candidates for corporate collaborations in the development of certain products that in combination may produce an enhanced therapeutic outcome and partners in the sales and marketing of the DiaKine's product candidates.

## **Operating Plan**

DiaKine currently operates with resources from the Founders, Note Participants, and government grants. The Company intends to build its operations incrementally as scientific and business milestones are achieved. Plans are in place to develop a near term (islet media) sales revenue stream which will further assist in product validation. The end game is to become a product development firm addressing the diabetes market initially and perhaps additional diseases where immune-modulation may be therapeutic in the future. DiaKine expects to collaborate with corporate partners on the initial product pipeline as clinical milestones are achieved and would expect to continue with that model in future programs. The longer-term view may permit the Company to market certain products to specified markets directly.

The Company has clinical data and product manufacturing protocols acceptable to FDA, and is thus prepared for the Phase 2 human clinical trial with its lead compound, LSF. These data will be applied to its first indication as an immune modulating treatment for islet cell transplant recipients. The data will also be available for use with additional studies for other indications using the same compound

The Company has already received financial and technical support from the National Institute of Diabetes & Digestive & Kidney Diseases/National Institutes of Health (NIDDK/NIH); it is estimated this support is valued at approximately \$250,000. Two requests submitted in 2004 to the T1D RAID program were accepted into the program. From the first request, NIDDK/NIH will produce LSF clinical trial supplies for an upcoming clinical trial that seeks to determine if LSF is effective as adjunct therapy in islet cell transplant recipients. In the second request, a new cell culture media will be developed with LSF to improve the yields and function of transplanted islet cells. It is expected that more support will be forthcoming with positive clinical results.

The immediate milestones for the Company involve securing the financial resources to complete the Regulatory requirements for a full Phase 2 clinical trial on the first product and to develop the corporate infrastructure to support the operations of the Company both on the R&D level and business development side. The completion of Phase 2

studies will facilitate the development of corporate partnerships to develop and market product as well as to secure resources to address new product opportunities.

Over the next eighteen to twenty-four months, DiaKine will focus on several key tasks, including:

- Secure the financial resources to support its corporate development and operating plan;
- Develop LSF as culture media product for use in the preparation of islet cells for transplant;
- Produce clinical trial supplies with existing batches of LSF active ingredient;
- Conduct dose ranging studies in appropriate patient populations;
- Develop LSF as a product to treat patients undergoing islet cell transplantation;
- Bring forward a lead oral immune modulator with novel anti-inflammatory actions for chronic indications to protect the insulin producing  $\beta$ -cells and halt diabetes complications; and
- Establish an operating team to execute scientific, regulatory and business objectives.

Corporate collaborations are anticipated as a means of advancing the science as well as the products to the marketplace. In addition to some of the obvious corporate partners in the diabetes market (Eli Lilly, Pfizer, Bristol Myers Squibb, Novo Nordisk, and Novartis among others), there are a series of other companies that may provide nearer term collaborative opportunities of benefit to both partners. One near term revenue opportunity is to supply LSF media for the world wide islet transplant market.

## **Management and Directors**

The Company is supported by an experienced team with demonstrated success in their respective fields. They are supported by a recognized group of research and development experts.

**KEITH D. IGNOTZ, PRESIDENT AND CHIEF EXECUTIVE OFFICER AND DIRECTOR**

Keith Ignotz is a senior corporate executive with over 25 years of experience in the global healthcare market and 14 of those in diabetes. He joined DiaKine from SpectRx, Inc., a diabetes management company which he co-founded in 1993 and took public in 1997. Previously, he was President of Humphrey Instruments SmithKline Beckman (Japan), President of Humphrey Instruments (Germany), and Senior Vice

President of Allergan Humphrey. He has a B.A. from San Jose State University and an M.B.A. from Pepperdine University. Mr. Ignatz is on the Board of Directors for Paradigm Medical Industries, a publicly traded company and AerovectRx, a privately held corporation and is a trustee of the Pennsylvania College of Optometry and Audiology.

**JERRY L. NADLER, M.D., CHAIRMAN OF THE BOARD, FOUNDER, AND CHIEF SCIENTIFIC OFFICER**

Jerry L. Nadler, MD is Chief of Endocrinology and Metabolism at the University of Virginia and Director of the Diabetes and Hormone Center of Excellence. Dr. Nadler is recognized as a noted expert in the pathogenesis of diabetes and related complications. He has been conducting basic science and pre-clinical research on Lisofylline and oral immune modulators for the past six years under grants funded by sources including the Juvenile Diabetes Research Foundation. Dr. Nadler has been invited to sit on major advisory groups of the National Institutes of Health and the Juvenile Diabetes Research Foundation. Dr. Nadler received his M.D. degree from the University of Miami and additional specialized training at the University of Southern California. He was the Director of Diabetes and Endocrinology at the City of Hope National Medical Center prior to coming to the University of Virginia.

**MARY ANN LATONA NADLER, FOUNDER, VICE PRESIDENT OF REGULATORY AFFAIRS, AND DIRECTOR**

Mary Ann Nadler has over 20 years of pharmaceutical and medical industry experience, primarily in the area of Regulatory Affairs. She was Director of Regulatory and Governmental Affairs for Adenosine Therapeutics. She was employed by NeXstar Pharmaceuticals as a Regulatory Affairs Project Manager and by International Medication Systems, Ltd. as Assistant Director/Clinical Programs Manager. Ms Nadler has successfully managed preparation and submission of INDs, NDAs, IDEs, PMAs and 510ks. Additionally, she has SBIR and STTR grant preparation and management experience with \$3.2 MM awarded under her direction. Ms. Nadler holds a Bachelor of Science degree in Microbiology and is a member of the Regulatory Affairs Professional Society and the Drug Information Association.

**JAMES B. FARINHOLT, JR., FOUNDER AND DIRECTOR**

Mr. Farinholt has had an extensive career in the private and public sectors of finance and investment. He is a founder of Tall Oaks Capital, LP, a seed and early stage investment fund for life science, information technology and healthcare related companies. Mr. Farinholt has thirty

*Our oral compounds, DT 22669 and DT 23552, target diabetes eye and kidney complications, which cost the U.S. healthcare system \$2 billion annually.*

years of experience in investment banking for small and medium-sized businesses as an executive officer at The Chase Bank in New York, in addition to Wheat First Union and Galleher & Company in Richmond, Virginia. Mr. Farinholt's public directorships are: PharmaNetics, Inc. (NASDAQ: PHAR); and Owens & Minor, Inc. (NYSE: OMI). He holds a B.S. degree from Hampden-Sydney College.

**JACK W. SINGER, M.D., DIRECTOR**

Dr. Singer is a founder and Director of Cell Therapeutics, Inc. (CTI). He was appointed Chief Medical Officer in January 2004 and thereby became responsible for CTI's clinical medical strategy. Prior to joining CTI, Dr. Singer was Professor of Medicine at the University of Washington and full member of the Fred Hutchinson Cancer Research Center. Between 1975 and 1992, he was Chief of Medical Oncology at the VA Medical Center in Seattle. Dr. Singer has served as an advisor to the NIH and is a consultant to pharmaceutical industry.

## **Financing**

The Company is seeking a high, single digit Series A financing. The first phase of this financing, currently underway, is a Convertible Promissory Note Round of up to \$1.5 MM. This will bridge the Company to the close of the Series A Financing, expected by second half of 2005.

Proceeds from the Convertible Note and the Series A Financing will be used to support operations to obtain additional Phase 2 Clinical Trial data for use in one indication associated with type 1 diabetes and to develop additional applications and indications in diabetes for LSF and select next generation orally available immune modulators.