

emerge excel exploit evolve

www.utRBiotech.com

Confidential – Not For Distribution

#### Mission

Through our diverse team & dedication to quality, utR Biotech is focused on pure, affordable, efficacious therapeutics.

We have the knowledge and experience to take a target from conception to licensure.

### Vision

Our vision is to be a company with a global presence that positively impacts the lives of people with chronic or lifelong illnesses, helping them to live a longer, fuller live with the ability to afford the treatments they will need while delaying, reducing, or eliminating disease complications.

We will drive research forward to marketable products with the goal of being profitable, ethical, sustainable & to contribute to science in a meaningful way.

## utR Biotech Currently Working Towards:

- A human & veterinary insulin product that is combined with a peptide showing promise to reduce, delay or eliminate a wide variety of diabetes related complications
- A refinement in how insulin is manufactured that will reduce the cost of insulin for end users by better meeting demand & significantly lowering production costs
- An insulin with a 12-to-24-month shelf life, far exceeding what is currently available
- A sublingual delivery system for insulin/peptide combination
- In 2020, we have obtained a Mitacs grant (\$90,0000, with approximately \$24,000 of personal funds) for developing a COVID-19 product and funding through Research Manitoba for a similar amount
- Applied for a \$2 million CIHR grant for our diabetic product (7 professors involved, 5 labs). Entrance past LOI For full grant application known April 1, 2021 (Up to \$4 million more from Mitacs to match, if expense profile can be justified
- Forged a partnership with a global AI firm to help develop our diabetic product

### utR Biotech Research

utR Biotech is actively seeking funding in the form of grants & investors to research a peptide that has been shown to influence a variety of systems & biological processes in the body.

The goal will be to bring this product to from development to market as a stand alone additive, licensed or as an insulin/peptide combination.

We believe, after compiling information from over 400 papers, that there is a significant opportunity to produce this peptide and include it with insulin formulations in order to reduce, eliminate or delay the onset of: retinopathy, neuropathy, circulation complications, cardiovascular disease, cancer, Alzheimer's Disease, NAFLD, nephropathy, premature aging and other Type 1 Diabetes related complications.

Funding innovation to change diabetes outcomes



### utR Biotech Readiness

- utR Biotech was founded in September 2016 & incorporated in July of 2019, trademarked in USA
- Branding, Website/Social Media live in 2019
- We have engaged MITACS for matched funding for research
- Several world class researchers/companies have signed NDA's to advance our science
- We have initial quotes for work with a large, high quality, CMO in Europe to manufacture our research, pre-clinical and clinical trial materials beyond the concept studies

Our current needs for 2022-2026 are for 30 million USD in investment for development of Pre-clinical through Phase 1 trials, pending receipt of CIHR grant in 2021



#### Our Executive Team

#### David Petch M.Sc. – CEO/CSO, Founder

Mr. Petch has over 25 years in the Biotech industry, ranging from Cell Culture, bioassay development, protein purification, product development & hyper-immune processes. His specialty in Cell Culture/fermentation processes and work identifying disruptable markets was the spark for the formation of this company. Mr. Petch has run a stock market information website & published peer reviewed papers on stock market analysis as a hobby. A total of 8 professors have been brought on board to conduct research and expertise pending funding for development of our product.

Mr. Petch serves as CEO and CSO for our company. His vision, knowledge, determination and drive bring focus and direction to our research team. David has been instrumental in compiling the science and attracting interest from top Canadian Scientists, and CMO's to utR Biotech.

#### Lyle Kirchner – VP Sales and Marketing, Founder

Mr. Kirchner is a Canadian entrepreneur who has 26 years experience in owning and running his own businesses. His company, Business Information & Development currently provides technology consulting services, website and software design, hosting & email services, & Information Technology supports to over 100 small & medium businesses in Canada. Mr. Kirchner has extensive management experience having owned and run retail stores, service companies and a communication company. He has worked for several "Top 50 Managed Canadian Companies".

Mr. Kirchner serves as the wheels to our organization, providing a "Swiss Army Knife" set of skills to utR. His business experiences help shape the business side of our company including day to day management, HR, finance, sales and marketing.







After reviewing data compiled from over 200 peer reviewed papers, utR Biotech has expressions of interest to participate in concept studies from the following well respected researchers:

### Our Research Team

#### Dr. Vernon Dolinski

Dr. Dolinski's research is focused on the mechanisms that predispose youth for th development of obesity, diabetes & related cardiovascular disorders. He is an Associate Professor at the Department of Pharmacology & Therapeutics within the Children's Hospital Research Institute of Manitoba.

With utR Biotech, Dr. Dolinski will be performing cardiovascular disease studies in mice to determine if the novel peptide reduces, minimizes or delays disease onset.



Dr. Sabine Kuss is an Assistant Professor at the University Of Manitoba, Faculty of Science, Department of Chemistry. Her research focuses on electrochemistry & its application to biological systems in the fields of endocrinological diseases, antibiotic drug resistance in pathogens, mitochondrial dysfunctions and cancer development.

With utR Biotech, Dr. Kuss will be looking at the interactions between the novel peptide and it's putative receptor, which may help to elucidate the novel protein signalsome.

#### **Dr. Shao Ling Zhang**

Dr. Shao Ling Zhang is a full professor at the Department of Medicine at the University of Montreal. Her research focuses on impairment of renal function and development leading to renal dysfunction and CVD.

With utR Biotech, Dr. Zhang will be performing renal function studies to determine if the novel peptide reduces, minimizes or delays disease onset.







After reviewing data compiled from over 400 peer reviewed papers, utR Biotech has expressions of interest to participate in concept studies from the following well respected researchers:

## Our Research Team

#### **Dr. Benedict Albensi**

Dr. Albensi sits as the current Manitoba Dementia Research Chair. His research is centered around the biological basis of memory, impairment & target mechanisms for treatment to reverse or repair a variety of conditions such as Alzheimer's disease, stroke, head trauma. He is a Professor - Department of Pharmacology & Therapeutics, University of Manitoba & Principal Investigator and Everett Endowment Fund Chair - Division of Neurodegenerative Disorders, St. Boniface Hospital Research Centre.



With utR Biotech, Dr. Albensi will be conducting a study in mice to examine the behavioral deficits & look to minimize, prevent, or delay the response for onset of Alzheimer's Disease with a novel protein supplemented group. Pathological analysis will also be performed.

#### **Dr. Donald Miller**

Dr. Miller's research is themed around Neuropharmacology, blood brain barrier function, & drug delivery with a focus on understanding the cellular mechanisms involved & changes in function with neurological conditions such as MS, neuro-AIDS, stroke, brain tumors & brain trauma as the BBB becomes compromised. Dr. Miller is a Professor - Department of Pharmacology & Therapeutics, Kleysen Institute for Advanced Medicine, University of Manitoba.



With utR Biotech, Dr. Miller will be conducting epithelial studies to examine upregulation & downregulation of some 20,000 genes using microarray analysis on primary diabetic cell lines relative to the control. The data will be analyzed to aid in mapping out the novel protein signalsome forming the backbone of IP around our product.

#### Dr. Suresh Mishra

Dr. Mishra's research is centered around PTMs & their regulation of protein functions with specific study in pathways to type 2 diabetes, insulin resistance and mitochondrial dysfunction, changes in protein function and protein-protein interactions. Dr. Mishra patented mouse models for studying diabetes with cancer and diabetes with NAFL. Dr. Mishra is an Associate Professor, Department of Internal Medicine, University of Manitoba.



With utR Biotech, Dr. Mishra will be working with utR Biotech to study our protein in diabetic/cancer mice and diabetic/NAFLD mice and look to minimize, prevent, or delay the response for onset of cancer and liver disease with a novel protein supplemented group.

After reviewing data compiled from over 400 peer reviewed papers, utR Biotech has expressions of interest to participate in concept studies from the following well respected researchers:

### Our Research Team

#### Dr. Yagna Jarajapu

Dr. Yagna Jarajapu is an Associate Professor in the School of Pharmacy at the University of North Dakota. One of his main research interests involves targeting Angiotensin Converting Enzyme-2 (ACE2)/Angiotensin-(1-7) System in Bone Marrow-Derived Cells for Vascular Repair in Diabetes.

With utR Biotech, Dr. Jarajapu will be involved using his expertise with the Renin-Angiotensin system to help fill in gaps for the data with other labs that can be used to provide a more solid base for obtaining patents



## Current State of Insulin Therapeutics

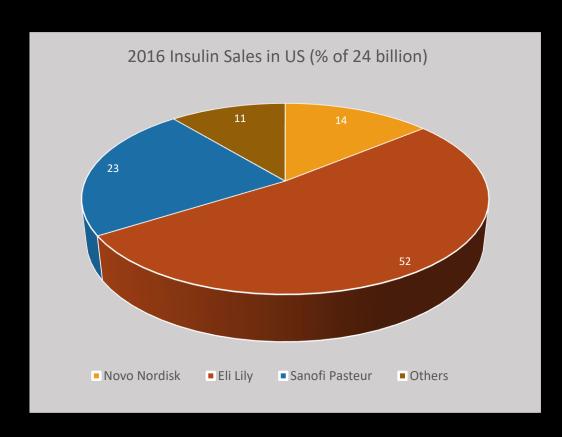
- Global market for insulin is dominated by Novo Nordisk, Eli Lily and Sanofi Pasteur
  - \$24 billion in the US alone (2016)
  - Expected to increase to \$48 billion by 2025 based on the current rate of increase of diabetes
- Current formulations have a shelf life of 3 months at 2-8°C
- Manufactured using old technologies with low product yields – drives the cost up for the end user
- Estimates are that there will be an ongoing shortage of insulin supply for the next decade
- Patients are "stretching" their medications in order to afford them, putting their health at increased risk
- Over 1.4 trillion USD/year currently spent on treating the associated symptoms and diseases of T1D and T2D globally (over 3 trillion when considering other secondary diseases

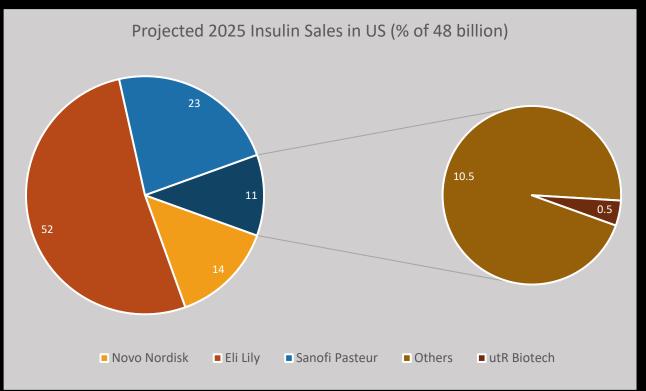
All commercial insulin products are insulin/insulin NPH or analogues and exclude a critical protein absent in non-diabetic persons

Current insulin formulations do not prevent the typical symptoms of peripheral neuropathy, retinopathy, CVD, NAFLD, and reduced microvasculation experienced by a large majority of Type I diabetes patients

ACCISS has suggested governments produce native insulin, not analogues, to target lower-middle income patients. We plan on following their guidelines, alongside a lyophilized formula and inclusion of a special protein to minimize/mitigate or delay onset of secondary diabetic diseases

# Market Opportunities (US)





0.5% of Global Market Share of "Others" = 525 Million In Sales

## Specialties of utR Biotech

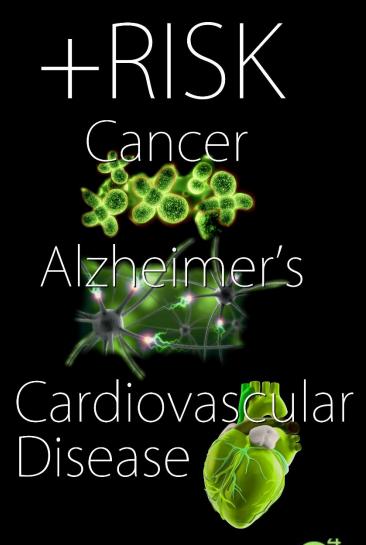
- Concept studies & research
- Pre-clinical study design (Toxicology & pK)
- Process development, purification & optimization of recombinant and native proteins
- Development and optimization of cell cultures (ie. Yeast, CHO, E. coli)
- Scale-up and tech transfer
- Analytical development
- Process qualification & validation
- Formulation development & stability
- Project Management of Biopharmaceuticals



## Problems In Diabetic Treatments

- Global Insulin shortage for type 1 and 2 diabetes
- For T1D, insulin solves the problem of helping glucose transport, yet the following symptoms still persist:
  - Lack of microcirculation leading to neuropathies
  - Patients are reducing insulin intake to manage costs
  - Increased frequency for developing CVD, NAFLD, AD, cancer, neuropathies, nephropathy (and other kidney-related issues), retinopathy
  - Treating complications costs hundreds of billions of dollars

There is currently no product on the market to address diabetes complications or rising insulin cost, only "manage" the disease



## Technology & Product

- Cheaper insulin due to the use of a high output expression system (12 to 20 g/L)
- Addition of a novel protein to minimize/mitigate or delay the onset of usual side effects associated with T1D (AD, cancer, CVD, neuropathies (and other kidney-related problems), NASH and NAFLD, lack of microcirculation)
- Lyophilized formula with a 24-month shelf life compared to 3 months currently, which in turn will help reduce pharmacy dispensing fees
- Novel enzyme digestion scheme to minimize purification costs, lower end product costs



#### Proposed Additive Product Functions for Diabetic Product:

Function In Vivo*	Negative Effects based on Absence In Vivo
Maintains nerve function and prevents neuropathy	Peripheral neuropathy, pain, inflammation, amputation
Preserves and improves residual B-cell function	Reduced immune function
Maintains intracellular signalling	Fatigue, sickness
Positive influence on endothelial nitric oxide synthase (eNOS) which prevents microvascular complications	Reduced blood flow, tissue death, potential links to CVD, AD, Cancer, Liver Disease
Promotes transcription of genes encoding RNA	Reduced cellular functions, reduced QOL
Reduces inflammation	Joint pain, fatigue, reduced QOL
Improves blood flow into tissues (skeletal muscle)	Chest pain, breathing issues, pain, inflammation
Protects against apoptosis of renal cells	Reduced kidney function, decreased urinary health, pain, discomfort

<sup>\*</sup> More functions to be experimentally confirmed



### Future State with utR Biotech

- Decreased manufacturing costs (~30-70%) with newly developed cell culture system using *Pichia* yeast genetically modified with MeOH genes replaced with Glc genes (One of the largest CMO's in the world).
  - Our CMO has validated an expression system for this cell line to reduce the overall culture time and boost expression levels
  - Product extra-cellularly making the purification process less laborious
  - Live cell-based enzyme cocktail for post-translational modification of product to reduce costs
- Inclusion of special protein
- Lyophilized formulation to extend shelf life and decrease dispensing fees passed on to the end user (cost reduction)
  - The drug substance will include 3 forms of insulin and novel protein combinations giving the end user flexibility in choosing the formulation best suited for their needs.
  - Subcutaneous and sublingual (partnership opportunity) administrations
- Target markets are for veterinary use (utRinsulin A) and US low-middle income human patient use (utRinsulin H). Former to generate revenue to lower future dilution
- Further development of COVID-19 project based upon results

## utR Development Path

Investment Concept

Patents –
Peptide treatment to
minimize/mitigate or
delay Type 1
complications &
secondary diseases
(Expect 6 to 8 patents)

Studies

(2022-2024)

CMO
Development
Work for
product &
enzyme cocktail
(2023-2025)

Patent –
Development of
cell system to
digest pro-insulin

Winnipeg Office (Established 2019)

Preclinical (2024)

Patent –
Lyophilisation &
resuspension
with two
different pH
systems

Patent –
Development of
sublingual insulin
delivery

Go public option (IPO or SPAC)

Clinical Trial Phase 1 (2024)

Series B Clinical Trial
Phase 2
(2026)

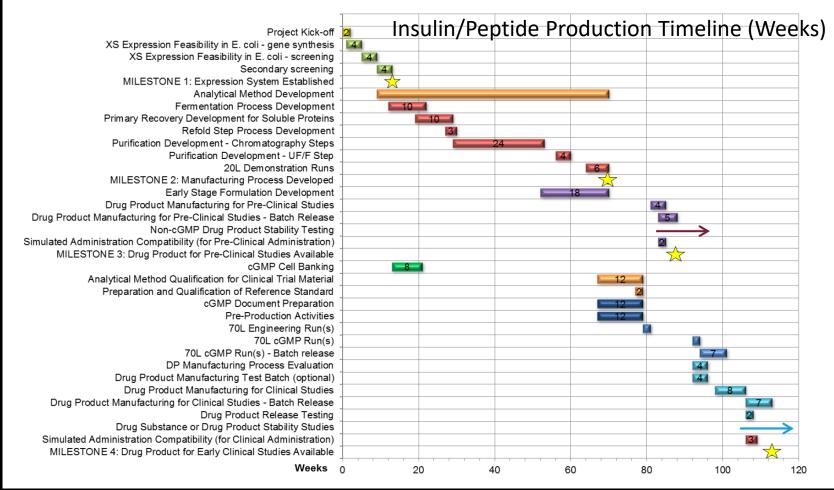
Veterinary Target

**Animal Safety** 

(2025)

## Development Path of Product (Post Concept Studies)

Concept study
research on our
peptide is expected to
start in 2022 and
complete within 24 to
36 months months of
initial funding.



# **Employment for Staffing Office**

Position	2023	2024	2025	2026	2027	2028
CEO/CSO	X	X	X	X	Χ	Χ
VP R&D	X	X	X	X	Χ	Χ
VP Sales/Marketing	X	X	X	X	X	X
CFO	*	X	X	X	Χ	Χ
Regulatory	-	X	X	2X	2X	2X
Biostatistician	X	X	X	X	Χ	Χ
QA Associates	-	X	X	2X	2X	2X
Legal Associate	*	X	X	X	Χ	X
Scientists	5X*	5X*	5X*	3X	3X	3X
Clinical Associates	-	2X	2X	2X	2X	2X
Totals	9	15	15	15	15	15





\*Externally contracted

## Financial Investment

	2021-2023	2024	2025	2026	2027	2028
Preclinical Research & Patents – Peptides (24 Months)	6*	-	-	-	-	-
Process Development/Preclinical Supply	-	3.2	5.9	-	-	-
Process Development for Enzyme Cocktail	-	3.0				
Preclinical	-	-	0.32	2.4	-	-
TAS for Vet Market	-	-	-	0.6	-	-
Clinical Supply (Phase 1,2)	-	-	-	0.8	-	-
Clinical Studies (Phase 1,2)	-	-	-	-	4.0	4.0
Salaries	-	1.75	1.75	2.5	2.5	2.5
Legal	-	0.25	0.25	2.0	0.25	0.25
Travel/Training	-	0.2	0.2	0.2	0.2	0.2
Other (Lease, IT, lab setup/supply)	-	1.2	1.2	1.2	1.2	1.2
Totals (millions \$USD)	6*	9.60	9.62	9.70	8.15	8.15

\*Possibility of matched MITACS matched grants

## utR Biotech, Moving Science Forward

Thank you for considering utR Biotech. Many aspects of market analysis, white paper of comparators of failed products and why they failed discussed in business plan as per below.

For more information, a copy of our 132 page business plan with financials (over 350 references to date), or to learn more about our company, please contact us at:

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