XORTX THERAPEUTICS INC.

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Developing Treatments for Progressive Kidney Disease - Diabetic Nephropathy and Polycystic Kidney Disease

XORTX is a therapeutics company with a fast track strategy for licensing and market approval targeting lucrative orphan diseases such as - Autosomal Dominant Polycystic Kidney Disease (ADPKD) and Diabetic Nephropathy (DN).

Our Technology: Includes a lead drug candidate that is repositioned / reformulated drug - Oxypurinol, new molecular entities and other new generation drugs focused on treatment of Progressive Kidney Disease (PKD). XORTX's lead programs focus on developing treatments to slow or stop PKD in patients with PKD and DN. Notably, there are currently no drugs yet approved for this purpose despite promising phase II clinical trial pilot results.

XORTX's strategy is to develop Oxypurinol for orphan kidney diseases, a group of diseases where no drugs are currently approved to treat PKD. Though never approved for marketing, Oxypurinol is well characterized as safe, well tolerated and highly effective for managing uric acid levels in several previous phase II clinical trials. For the ADPKD market, XORTX expects licensable phase II results within two years, and currently has several specialty pharmas that have expressed interest in post phase II licensing of this program. Strong barriers to entry in the ADPKD field, include composition of matter and use of patents and applications and an additional seven years marketing exclusivity granted by the FDA upon orphan drug marketing approval.

PKD Foundation recognition of XORTX as a leader and collaboration with XORTX for the development of treatments for PKD.

The Market: In the United States, Europe and Japan, PKD is considered an orphan disease with approximately 120,000 patients. DN occurs in both type I and type II diabetes contributing approximately 200,000 and 9,000,000 patients, respectively. Taken together DN and PKD cause nearly 50% of all PKD, leading to end stage renal failure and dialysis.

Value Proposition and Competitive Advantage: XORTX's strategy is to develop and license the first treatment for ADPKD using an Oxypurinol formulation (XRx-008) that improves bioavailability and builds upon strong existing clinical trial success record of this molecule. This program is an attractive, lucrative acquisition target as orphan drug marketing approval results in a seven year market exclusivity in the US, and 10 years in Europe combined with strong pricing, tax credits and margin protection.

Total and Target Market Opportunity for Uric Acid Related Disease:

Type of Incidence – North America (Past 5 Years)	Individuals Affected	% of US Population	US Market ($USD)
Hyperuricemia	76 Million	22%	500 M
Diabetic Nephropathy – Type I [2]	0.1 Million	0.03%	2 B
Diabetic nephropathy – Type II [3]	10 Million	3%	6 B
Diabetes	86 Million	34%	55 B
ADPKD [1]	~120,000	0.004%	2 B
IgA nephropathy	3000-6000	Rare	2 B
[1,2,3] **Early target markets for XORTX**	**Total Market opportunity:** **Target Market opportunity:**		**$258 B** **$10 B**

- Developing safer therapies to treat rare and major diseases caused by improper uric acid metabolism
- XORTX technology is fundamentally an agent to manage purine metabolism, and can be used to treat a variety of chronic kidney diseases
- XORTX technology treats rare diseases such as ADPKD and Type 1 DN and large market Type 2 DN
- Patent portfolio - University of Florida, Washington and XORTX
- PKD Foundation recognition and collaboration for the development of treatments that will redefine how physicians treat ADPKD
- ~ $10 M previous funding used to define causative role of SUA in kidney disease and progression
- Orphan disease focus provides a fast track through FDA, seven years exclusivity in US and 10 years in Europe combined with lucrative product pricing, resulting in a strong financial model.
- Current Specialty Pharma interest in licensing ADPKD program
- **Funding**
  - ~$10M Research: pre-company formation
  - $3.7 M equity investment to date
- **Shares Outstanding**
  - Current - 62.9 million
  - FD – 69.3 million

Intellectual Property & Competitive Advantage: Begins with a multi-tiered patent portfolio composed of granted patents and patent applications that claim the "use of all uric acid lowering agents" for the treatment of hypertension, insulin resistance and diabetic nephropathy (DN) (granted) and similar applications for the treatment of metabolic syndrome, diabetes and fatty liver disease. Augmented by XORTX's second tier patent application, a PCT filing, that covers new formulations of xanthine oxidase inhibitor as a composition of matter and includes claims for the treatment of chronic kidney disease (CKD), cardiovascular disease, metabolic syndrome and diabetes. New chemical entity patents (granted and applications) under consideration for co-development will further extend XORTX's competitive advantage in the field of progressive kidney disease (PKD). Recent phase II pilot study successes and publications in PKD – PKD and CKD validate this this mechanism of disease pathology. These results permit XORTX to advance aggressively through phase II and pivotal clinical trials, and several lucrative licensing opportunities as a first in class therapy for the treatment of PKD and DN.

Development:

Year 1: IND Submission for ADPKD, Orphan Designation and possible grants - IND submission for DN; phase II protocol approval
Years 2 and 3 : Phase II trial initiation for ADPKD and DN
XORTX is currently fund raising to complete these steps and position both DN and ADPKD program for a licensing exit.

Milestones Achieved:

- Aggregated and composed 7 patents: 6 methods of use, 1 composition application, other composition patents under preparation.
- Advanced XORLO formulation studies to "clinical trial ready" and developed new molecule entities for diabetic nephropathy.
- Built a team of experienced drug development professionals, manufacturers, clinical trial and regulatory research organizations.
- Since incorporation, XORTX has raised $3.7 M (plus previously ~ $ 10 M spent developing the compound).

MANAGEMENT

A virtual company strategy with experienced, key leaders ready to maximize value creation.

Allen Davidoff, PhD – *Founder, Chief Executive Officer, President and Director* with 14+ years product development and clinical development experience. History of successful fundraising for several publicly traded PharmaCo.s including $3.7 M dollars at XORTX.

James Fairbairn, CA, ICD.D – Experienced public company *CFO* with extensive corporate governance and reporting experience with emerging companies.

Alan Moore, PhD – Founding Board Member and Director with 30+ years pharmaceutical and drug development experience, most with P&G. History of successful fund raising >$20 M.

Brian Mangal, MSc - *Director of Business Development* with 15 years' experience in pharma/biotechnology, including Cardiome Pharma Corp.

Board of Directors: In addition to Allen Davidoff

Bruce Cousins - Accomplished biopharma industry senior finance and operations executive with experience spanning small, early stage growth to large, international companies.

Bruce Rowlands - *Chairman* **–** Extensive experience in the biotechnology and investment banking industries.

Paul Van Damme, B. Comm., CPA, MBA – *Audit Chair* **-** Biotech industry focused experience with senior positions with a number of Canadian and US public companies.

Allan Williams - Independent businessman, brings over 30 years capital market and public company experience to the XORTX board.

OPPORTUNITY SUMMARY

Strong Management Team – History of success and experience in early drug development to market approval, tailored to developing XORLO from concept through New Drug Application (NDA). Historically, developed Oxypurinol through NDA for "allopurinol intolerant gout", an orphan indication, showing effective uric acid lowering and superior safety. Developed Vernakalant – an antiarrhythmic drug now approved and marketed in EU markets.

KOLs – Strong Scientific and Clinical Advisory board members Dr. Petter Bjornstad and Richard Johnson of the Colorado School of Medicine, Dr. Federico Maese, Texas-based Cardiologist, and Dr. Henk ter Keurs, Cardiologist, LIBIN, Cardiovascular Institute of Alberta.

Intellectual Property Portfolio – XORTX claims enable exclusive use of "all uric acid lowering agents" for treatment of Hypertension, Insulin Resistance, Metabolic Syndrome, Diabetes and Diabetic Nephropathy. XORTX has three granted patents and four applications.

Lower Development Costs and Faster Time to Market – Orphan Drug Programs (DN and ADPKD) hold potential for early lucrative approvals. Launch possible in 2021.

Four Phase II Clinical Trials Validate IP Concept –clinically meaningful and statistically significant effects on Early-Stage Hypertension & Progressive Renal Injury, ADPKD and CKD already completed, increasing probability of future success.

Recent Orphan Program Acquisitions – Demonstrable market interest and validation of the return on investment opportunity for orphan indications, with deal values ranging from $300M to $2B. Several license partners identified and waiting for phase II trial results.

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