

FORM 7

MONTHLY PROGRESS REPORT

Name of Listed Issuer: **XORTX Therapeutics Inc.** (“XORTX” or “the Issuer”).

Trading Symbol: **XRX**

Number of Outstanding Listed Securities: **62,919,691** (as at December 31, 2019)

Date: **January 8, 2020**

Report on Business:

1. Provide a general overview and discussion of the development of the Issuer’s business and operations over the previous month. Where the Issuer was inactive disclose this fact.

The Issuer is a research and development company focused on developing small molecules to treat progressive kidney disease. XORTX Therapeutics Inc currently has one late stage drug development program XRx-008 for autosomal dominant polycystic kidney disease (ADPKD) that is advanced and a second program under a co-development agreement with Teijin Pharma Ltd to develop TMX-049 in type 2 diabetic nephropathy (T2DN)– this program is at a phase 2b stage. XORTX has developed and submitted a PCT patent application for a proprietary reformulation of Oxypurinol (“XRx-008”), a xanthine oxidase inhibitor (“XOI”).

The primary development program for the Issuer’s XRx-008 – a proprietary reformulation of Oxypurinol. Oxypurinol is a xanthine oxidase inhibitor that is well characterized as safe and effective in man. Although never approved for clinical use, this class of therapeutics has been previously reviewed by the FDA and has a well-known clinical safety and effectiveness profile for use in the treatment of gout, although published evidence suggests a much broader use of this therapy should be developed. XORTX anticipates advancing development of XRx-008 into a phase 3 registration trial to demonstrate the efficacy and safety of Oxypurinol in individuals with ADPKD. ADPKD is an orphan disease indication and XORTX believes its XRx-008 formulation, if approved, will be a first in class treatment for this progressive kidney disease.

XORTX is focused on developing XRx-221 (TMX-049), a xanthine oxidoreductase inhibitor under a co-development deal which would be developed for the treatment of individuals with T2DN. The Issuer believes T2DN represents a large and underserved market opportunity for this class of therapies.

XORTX intends to grow its business by completing a pivotal phase 3 trial in ADPKD and a phase 2 clinical trial in T2DN with a plan to out-license these to commercial partners worldwide. In addition, XORTX plans to grow by expanding its knowledge and technical expertise into new programs to treat orphan progressive kidney disease, fatty liver disease, and health issues related to diabetes.

XORTX's overall strategic goal, subject to sufficient funding being available, is to have two late stage phase clinical trials underway in early 2020, advancing two proprietary products into scientifically rigorous phase 3 and phase 2 clinical testing.

- 2. Provide a general overview and discussion of the activities of management.**

In December 2019, XORTX continued to advance its ADPKD program to clinical trial and to obtain 'orphan designation' for this program. The Company also continued advancing its access to an XOI inhibitor for the treatment of T2DN (see announcement of March 11, 2019) with Japan's Teijin Pharma Limited ("Teijin").

With regard to the Company's ADPKD program, and subsequent to the Company's US Food and Drug Administration ("FDA") submission and meeting in September 2018, XORTX's clinical development plan has been reviewed and accelerated. In its review, the FDA confirmed that XORTX's proposed chemical, manufacturing and formulation was confirmed with no material changes, further after characterizing the bioavailability of XRx-008 in non-clinical animal species and man a single, pivotal phase 3 clinical trial which would be eligible for special protocol assessment (SPA), and thereafter consideration for marketing approval. XORTX has defined four clear steps to develop XRx-008 for ADPKD through marketing approval of XRx-008: (i) manufacture GMP drug product in advance of clinical study; (ii) complete the IND filing and characterize the bioavailability and pharmacokinetics of XRx-008 in humans; (iii) complete the ODD process for this program; and, (iv) complete a pivotal phase 3 clinical trial. This accelerated clinical development plan will substantially decrease the time and cost to bring this important therapy to patients with PKD. XORTX will seek a special protocol assessment (SPA) for its combined phase 3 study which if granted, will provide for XORTX and the FDA to co-negotiate the design of a clinical trial that will support an efficacy claim for marketing approval. Further, a response from the FDA regarding XORTX's ODD application submitted in September has clarified the additional information needed to obtain ODD status for the use of XRx-008 as a treatment for ADPKD. XORTX is continuing to advance pre-clinical trial activities and progressing of the additional information requested by the FDA to obtain ODD status for XRx-008.

With regard to Company access to an XO inhibitor for the treatment of T2DN, XORTX's LOI with Teijin provides a near term focus for the promising TMX-049 molecule to test the safety and effectiveness of TMX-049 in a Phase 2b Study in patients with progressing kidney disease due to T2DN.

On September 19, 2019, the Company announced the results of the TMX-049DN-201 U.S. Phase 2 clinical trial in individuals with T2DN indicating that the study achieved the primary endpoint for the efficacy of the study and that TMX-049 was well tolerated. The study was entitled – “A Randomized, Placebo-Controlled, Double-Blind, Multicenter, Phase 2 Study to Assess Safety, Tolerability, and Renal Effects of TMX-049 in Subjects with Type 2 Diabetes and Albuminuria”. The study was designed to test whether the inhibition of XO using TMX-049 over a 12 week treatment period, would decrease uric acid levels, and would provide a safe and effective therapeutic approach to decreasing albuminuria. Highlights of the results of this study showed that in patients with T2DN:

1. TMX-049 could be safely administered to individuals with T2DN in the tested dose range and was well tolerated;
2. Oral daily doses of TMX-049 could substantially and significantly decrease serum uric acid (SUA).
3. Oral daily doses of TMX-049 decrease Urinary Albumin (UA) proteinuria to a substantial and statistically significant degree.

As a result, TMX-049 showed a statistically significant improvement compared to the placebo group, achieving the primary endpoint. No new concerns about the safety were observed. Details of the study design can be found at: <https://clinicaltrials.gov/ct2/show/NCT03449199?term=TMX-049&cond=type+2+diabetic+nephropathy&rank=1>

Approximately 35-40% of patients with type 1 or type 2 diabetes mellitus develop diabetic kidney disease. This is a clinical syndrome characterized in its early stages by persistent proteinuria, then followed by a relentless, decline in glomerular filtration rate (GFR). One of the first clinical signs of kidney disease is moderately increased urine albumin. If untreated, albuminuria will gradually worsen and untreated microalbuminuria will gradually worsen, reaching clinical proteinuria or severely increased albuminuria (albuminuria grade A3) over five to 15 years. Importantly, proteinuria of increasing severity is associated with a faster rate of renal decline, regardless of baseline eGFR.¹ As GFR then begins to decline and, without treatment, end-stage renal failure is likely to result in five to seven years.²

Diabetic kidney disease is a progressive chronic kidney disease that develops with diabetes and is reported to be the most common cause of dialysis. When chronic kidney disease progresses and dialysis is initiated,

not only does the patient's quality of life significantly deteriorate, but the social burden of medical care costs increases. There is a rapidly growing need for treatments that improve, slow or reverse chronic kidney disease, including diabetic kidney disease, and that suppress the introduction of dialysis.

References:

1. Turin T C, Proteinuria and Rate or change in Kidney Function, J. Am. Soc Nephrol Oct; 24(10):1661, 2013
2. Persson F., and Rossing P., Diagnosis of diabetic kidney disease: state of the art and future perspective, Kid Int Suppl v.8(1):2-7, 2018

The overall goal of the LOI recognizes the mutual interest of Teijin and XORTX to advance together to a definitive license agreement which will grant XORTX the exclusive global rights to develop TMX-049 for progressive kidney disease and the option to use this molecule for other therapeutic programs. It has been agreed that Teijin will retain the rights to the Japanese market and Teijin and XORTX will share future development costs.

In December 2019, the Company continued to advance financing activities towards closing a \$5 million non-brokered private placement to advance the XRx-008 and TMX-049 to clinical trial.

3. Describe and provide details of any new products or services developed or offered.

No new products or services developed or offered.

4. Describe and provide details of any products or services that were discontinued. For resource companies, provide details of any drilling, exploration or production programs that have been amended or abandoned.

None.

5. Describe any new business relationships entered into between the Issuer, the Issuer's affiliates or third parties including contracts to supply products or services, joint venture agreements and licensing agreements etc. State whether the relationship is with a Related Person of the Issuer and provide details of the relationship.

None.

6. Describe the expiry or termination of any contracts or agreements between the Issuer, the Issuer's affiliates or third parties or cancellation of any financing arrangements that have been previously announced.

None.

7. Describe any acquisitions by the Issuer or dispositions of the Issuer's assets that occurred during the preceding month. Provide details of the nature of the assets acquired or disposed of and provide details of the consideration paid or payable together with a schedule of payments if applicable, and of any valuation. State how the consideration was determined and whether the acquisition was from or the disposition was to a Related Person of the Issuer and provide details of the relationship.

None.

8. Describe the acquisition of new customers or loss of customers.

None.

9. Describe any new developments or effects on intangible products such as brand names, circulation lists, copyrights, franchises, licenses, patents, software, subscription lists and trade-marks.

None.

10. Report on any employee hirings, terminations or lay-offs with details of anticipated length of lay-offs.

None.

11. Report on any labour disputes and resolutions of those disputes if applicable.

Not applicable.

12. Describe and provide details of legal proceedings to which the Issuer became a party, including the name of the court or agency, the date instituted, the principal parties to the proceedings, the nature of the claim, the amount claimed, if any, if the proceedings are being contested, and the present status of the proceedings.

Not applicable.

13. Provide details of any indebtedness incurred or repaid by the Issuer together with the terms of such indebtedness.

None.

14. Provide details of any securities issued and options or warrants granted.

None.

15. Provide details of any loans to or by Related Persons.

None.

16. Provide details of any changes in directors, officers or committee members.

None.

17. Discuss any trends which are likely to impact the Issuer including trends in the Issuer's market(s) or political/regulatory trends.

There are no identified market trends that are expected to impact the Issuer. The Issuer continues to monitor research and development related to kidney diseases.

Certificate of Compliance

The undersigned hereby certifies that:

1. The undersigned is a director and/or senior officer of the Issuer and has been duly authorized by a resolution of the board of directors of the Issuer to sign this Certificate of Compliance.
2. As of the date hereof there is no material information concerning the Issuer which has not been publicly disclosed.
3. The undersigned hereby certifies to the Exchange that the Issuer is in compliance with the requirements of applicable securities legislation (as such term is defined in National Instrument 14-101) and all Exchange Requirements (as defined in CNSX Policy 1).
4. All of the information in this Form 7 Monthly Progress Report is true.

Dated: January 8, 2020.

Allen Davidoff
Name of Director or Senior
Officer

"Allen Davidoff"
Signature

Chief Executive Officer
Official Capacity

<i>Issuer Details</i> Name of Issuer XORTX Therapeutics Inc.		For Month End December 2019	Date of Report January 8, 2020
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