IN THE CIRCUIT COURT OF THE 11TH JUDICIAL CIRCUIT, IN AND FOR MIAMI-DADE COUNTY, FLORIDA

CASE NO.

ZEO SCIENTIFIX, INC., a Nevada corporation, f/k/a Organicell Regenerative Medicine, Inc.,

Plaintiff,

v.

ASSUREIMMUNE, LLC, a Florida limited liability company, a/k/a ASSURE IMMUNE L.L.C., AISHA KHAN, an individual, and XIUMIN XU, an individual,

Defendants.

#### **COMPLAINT**

Plaintiff, ZEO ScientifiX, Inc., f/k/a Organicell Regenerative Medicine, Inc. ("Organicell" or "ZEO"), sues Defendants, AssureImmune, LLC, a/k/a Assure Immune L.L.C. ("Assure"), Aisha Khan ("Khan"), and Xiumin Xu ("Xu"), and alleges:

#### **NATURE OF THE ACTION**

1. This case arises from the egregious misconduct and contractual breaches of Assure, a company that designs FDA clinical trial studies, including consulting services in connection with the submission of Institutional Review Board ("IRB") and Investigational New Drug ("IND") applications, and the negligence of Assure's two consultants, Khan and Xu, who acted incompetently, consistently delivering misguided advice and failing to grasp the true nature of the work they performed for Organicell. 2. The actions of Assure, Khan and Xu caused substantial financial harm to Organicell, n/k/a ZEO ScientifiX, Inc., a publicly traded, clinical-stage biopharmaceutical company focused on the development of innovative biological regenerative therapeutics.

3. Assure agreed to provide consulting services and "expertise" to "assist Organicell in maximizing the efficacy of its mission", acknowledgment that Organicell "is relying on the expertise, experience, advice and direction of Assure associated with critical functional executive level roles of [Organicell] as it relates to the oversight and management of [Organicell's] regulatory, research and development and laboratory operations, consistent with [Organicell's] corporate mission and strategies and subject to the resource limitations of [Organicell]".

4. Organicell paid Assure compensation exceeding \$1 million in consulting fees and approximately 70 million shares of Organicell common stock were paid by Organicell to Khan and Xu.

5. Assure, Khan and Xu, however, failed to honor their contractual and common law obligations to Organicell. For example, Assure, Khan and Xu selected and designed studies for Organicell that were unnecessary, excessive, wasteful and costly, causing Organicell to enter into substantial contractual financial obligations and a resulting squandering of Organicell's funds. Some of those studies were designed to produce unnecessary efficacy data of limited practical value. Most studies involved were never completed. In addition, Assure engaged in activities that interfered with its contractual commitment to fully engage available time outside of its principals' full-time work with The University of Miami Miller School of Medicine ("UOM"), and, upon information and belief, directly competed with the requirement to use all their available time outside of UOM towards the activities of Organicell and directly competed with the activities of Organicell, contrary to the agreement. Moreover, to date, Assure has failed to deliver all

proprietary and confidential materials in Assure's possession to Organicell relating to Organicell's business as specifically required by the agreement.

#### JURISDICTION, PARTIES, VENUE, AND CONDITIONS PRECEDENT MET

This is an action for damages in which the amount in controversy exceeds
\$50,000.00, exclusive of interest, attorney's fees and costs.

7. Plaintiff, ZEO, is a Nevada corporation, with its principal place of business in Broward County, Florida. ZEO was formerly known as Organicell.

8. Defendant, Assure, is a Florida limited liability company, with its principal place of business in Palm Beach County, Florida. Assure became a wholly owned subsidiary of AX Biotech, LLC in September of 2015. AX Biotech is owned by Khan and Xu.

9. Defendant, Khan, is an individual over the age of eighteen, and upon information and belief, resides in Broward County, Florida. Khan is the Executive Director, Laboratory Operations of UOM.

10. Defendant, Xu, is an individual over the age of eighteen, and upon information and belief, resides in Miami-Dade County, Florida. Xu is the Director, Laboratory Services of UOM.

11. Venue is proper in this County because of the mandatory venue provision in the agreement at issue and this County is where the cause of action accrued.

12. All conditions precedent to filing this action, including any required notices or demands, have been performed, have occurred, or have been excused or waived.

13. Prior to filing this action, Plaintiff participated in a more than 10-hour in-person settlement meeting attended by all parties, their representatives and attorneys, and also a multi-hour mediation session conducted by an independent mediator selected by Defendants. Despite Plaintiff's lengthy, multiple, good faith efforts to resolve this dispute, the parties could not reach

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a resolution. Although the subject Consulting Agreement includes language referring to arbitration (non-binding), it remains uncertain whether non-binding arbitration is required ("If either party does not wish to abide by any decision of the arbitrator, they shall submit the dispute to litigation"), and/or whether non-binding arbitration is necessary given the pre-litigation history of this matter. Additionally, the absence of established case law in Florida renders uncertain the effect of non-binding arbitration on the tolling of statutes of limitations. Accordingly, due to the ongoing running of the statutes of limitations on Plaintiff's claims, Plaintiff files this Complaint in good faith to protect and preserve its rights and remedies. Further, because Khan and Xu are not parties to the Consulting Agreement, the dispute resolution procedure contained therein do not apply to them.

14. Plaintiff has retained the undersigned law firm as its attorneys and has agreed to pay the firm legal expenses and costs, including attorney's fees, incurred in this action.

#### COUNT I - BREACH OF CONTRACT AND THE <u>IMPLIED COVENANTS OF GOOD FAITH AND FAIR DEALING</u> (Against Assure)

15. This is an action against Assure for breach of contract and the implied covenants of good faith and fair dealing.

16. Plaintiff realleges and incorporates by reference paragraphs 1-8 and 11-14 above, as if fully set forth herein.

17. As of March 30, 2020, Organicell and Assure entered into a Consulting Agreement (the "Agreement"). The Agreement was amended in part. A true and correct copy of the Agreement and its amendments are attached as **Composite Exhibit A**.

18. Pursuant to the Agreement, Assure agreed to, *inter alia*, provide Organicell with certain consulting services and refrain from other activities. In exchange, Organicell agreed to pay Assure certain compensation.

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19. Assure materially breached the Agreement by, *inter alia*:

a. Selecting and conducting studies that were overdesigned, unnecessary and costly, which also led to scientifically unsound results.

For example, Assure designed a Phase 1/2 study for COVID LH that was budgeted to cost approximately \$1.3MM, while typical safety Phase 1 studies cost \$250k-\$300k. The cost disparity resulted from measuring over 45 additional endpoints, adopting randomized, blinded, and controlled aspects rare in early studies. These extra endpoints were uninterpretable due to the small sample size.

FDA approval was based on a maximum of 15 patients receiving the biologic (the study also called for 15 patients that were to receive placebo), a standard Phase 1 size. The biologic's risk aligned with FDA-accepted levels for Phase 1 studies. Non-safety endpoints were minimally invasive, posing negligible added risk. The FDA does not factor study cost into approval decisions, focusing only on incremental patient risk.

While a randomized, double-blind, controlled design does not increase patient risk, it significantly raises study execution costs and time to completion. Despite endpoint findings, with only 15 treated patients, the FDA still mandates a legitimate Phase 2 (with 100 or more patients). This resulted in a wasted \$700,000 for the COVID LH study, a recurring issue in study protocols designed by Assure. Assure also designed a Phase 1/2 study for COPD that was budgeted to cost approximately \$1.8MM and a Phase 1/2 study for OA that was budgeted to cost approx. \$1.3MM.

The Agreement required Assure to provide "expertise" to "assist Organicell in maximizing the efficacy of its mission," and acknowledged that Organicell "is relying on the expertise, experience, advice and direction of Assure associated with critical functional executive level roles of [Organicell] as it relates to the oversight and management of [Organicell's] regulatory, research

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