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Rebiotix Highlights 2017 Achievements and 2018 Objectives

A transformational 2017 paves the way to clinical and R&D milestones in 2018

- Presented positive data for RBX2660 in Phase 2 open-label study – third study in successful Phase 2 program
- Initiated Phase 3 clinical trial of RBX2660, Rebiotix’s lead microbiome drug candidate for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection
- Presented [research at major medical conferences](#) highlighting efficacy data from key changes to the human microbiome profiles of patients who received RBX2660
- Expanded Phase 1 investigator sponsored clinical trial of RBX7455, Rebiotix’s non-frozen, oral capsule formulation for prevention of *C. diff* infection

ROSEVILLE, MN – January 09, 2018 – [Rebiotix Inc.](#), a clinical-stage microbiome company focused on harnessing the power of the human microbiome to treat debilitating diseases, provided a review of its 2017 key business achievements and clinical activities as the company anticipates multiple milestones during 2018 involving its industry-leading [Microbiota Restoration Therapy™ \(MRT™\) drug platform](#).

[Lee Jones, president and CEO of Rebiotix](#), stated, “2017 was truly a transformational year for Rebiotix as we achieved multiple clinical and corporate milestones. We believe these achievements demonstrate the significant potential of our MRT drug platform and solidify our position as the most clinically successful microbiome company. Our clinical and scientific accomplishments have set the bar and will continue to shape research to come in microbiome drug development.”

During 2017, Rebiotix advanced its [lead microbiome drug product, RBX2660](#), into a Phase 3 randomized double-blind placebo controlled [clinical trial](#) for the prevention of recurrent *C. diff* infection. This followed a positive Phase 2 program involving three separate studies of RBX2660 where treatment demonstrated efficacy and concurrent microbiome analysis showed a significant change in patient’s microbiomes after treatment with RBX2660. Also featured in 2017 was [research presented at major medical conferences, including ID Week™ and ACG2017](#), which highlighted efficacy data from key



changes to the human microbiome profiles of patients who received RBX2660. The work in our Phase 2 program culminated in successful End-of-Phase 2 clinical and CMC meetings with FDA, paving the way for initiation of our Phase 3 study in Q3 of 2017.

During 2017, Rebiotix also made important and significant progress with [RBX7455, its non-frozen, lyophilized oral capsule formulation](#). In late November, the Company reported the investigator-sponsored Phase 1 study of RBX7455 was expanded to two additional cohorts, which included reduced dosing regimens after the successful completion of the initial two study arms. Rebiotix also completed its pre-IND meeting for RBX7455 with the FDA paving the way for a 2018 IND filing and Phase 2 study launch.

“We believe RBX7455 is a ground-breaking product in that its non-frozen oral capsule design enables patients to administer RBX7455 at home as they would a typical oral capsule medication. We are the first company we are aware of to design, develop and clinically study a broad consortium microbiota capsule with these characteristics,” stated Jones.

In addition to its progress in the clinic, Rebiotix reported several corporate and business achievements during 2017. Rebiotix added leadership positions including the appointments of Chief Business Officer, Chief Scientific Officer and Head of Regulatory Affairs. Furthermore, strong gains were made in expansion of Rebiotix’s intellectual property estate with the issuance of five new US patents and nine patents outside of the US.”

Jones concluded, “We expect 2018 to build on the momentum from 2017 with key milestones expected during the year, including presenting efficacy and safety data from the Phase 1 trial of RBX7455, the start of our Phase 2 trial of RBX7455, and completion of enrollment for the Phase 3 clinical trial of RBX2660.”

About *Clostridium difficile* Infection

[Clostridium difficile \(C. diff\) infection](#) is a serious and potentially fatal gastrointestinal disease, characterized by severe diarrhea, fever, and loss of appetite. It is a leading healthcare-associated infection (HAI), and in the U.S. alone, there are about 500,000 people infected and over 29,000 deaths annually from the disease. Currently, 20-30% of patients with *C. diff* go on to experience more than one episode of the disease, which is known as recurrent *C. diff* infection. Recurrent *C. diff* infection is especially challenging to treat as, to date, there are no approved microbial-based drugs to treat patients with two or more recurrences.

About Rebiotix Inc.



Rebiotix Inc. is a late-stage clinical microbiome company focused on harnessing the power of the human microbiome to revolutionize the treatment of debilitating diseases. Rebiotix possesses a deep and diverse clinical pipeline, with its lead drug candidate, RBX2660, in Phase 3 clinical development for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection. RBX2660 has been granted [Fast Track status](#), Orphan Drug and [Breakthrough Therapy designation from the FDA](#) for its potential to prevent recurrent *C. diff* infection. Rebiotix's clinical pipeline also features RBX7455, a lyophilized non-frozen, oral capsule formulation, which is currently the subject of an [investigator-sponsored Phase 1 trial for the prevention of recurrent *C. diff* infection](#). In addition, Rebiotix is targeting several other disease states with drug products built on its pioneering Microbiota Restoration Therapy™ (MRT™) drug platform. MRT drug platform is a standardized, stabilized drug technology that is designed to rehabilitate the human microbiome by delivering a broad consortium of live microbes into a patient's intestinal tract via a ready-to-use and easy-to-administer format. For more information on Rebiotix and its pipeline of human microbiome-directed therapies, visit www.rebiotix.com.