Exalenz Bioscience Receives FDA Marketing Clearance for its Laboratory System in the United States

The laboratory market is currently the largest segment in the US for breath-test diagnosis of *H. pylori* with a potential market estimated at hundreds of millions of dollars per year

Raffi Werner, Exalenz CEO: "We are delighted with the clearance, this is a significant milestone in the development of the company"

Modi'in, Israel – November 1st, 2016 – Exalenz Bioscience (TASE: EXEN), a leader in developing and marketing non-invasive medical devices for diagnosing and monitoring a range of gastrointestinal and liver diseases, today announced receiving U.S. Food and Drug Administration (FDA) marketing clearance for its BreathID® Lab System and breath-test kits, developed for *H. pylori* bacterium detection. The company is preparing to penetrate the laboratory market in the United States by engaging with national and regional laboratories, to achieve a broad and material presence in a market with a potential that is estimated at hundreds of millions of dollars in sales per year.

The BreathID® Hp Lab System aims to facilitate *H. pylor*i diagnosis, in a central location, of large numbers of breath samples that are collected and then delivered to the laboratory. At clinics and medical centers, the patient breathes into two designated collection bags and the breath samples are subsequently sent for analysis to central laboratories where the new system will be installed. The BreathID® Hp Lab System can perform sequential diagnosis in a fully automated and undisrupted process, minimizing potential human error.

This proprietary technology makes it possible to significantly increase the number of tests performed with optimal efficiency, without requiring the clinics where the samples are collected to purchase a specialized device. Until the recent marketing clearance, the company's market in the United States had been limited to a device that is designated solely for clinics, a smaller market with a limited sales potential.

"We are delighted with the clearance we have received from the FDA for the marketing of our laboratory system" said Raffi Werner, chief executive officer of Exalenz Bioscience. This is a significant milestone in the development of the company, which will allow us to achieve material penetration of the major market for *H. pylori* diagnosis in the United States. The blood tests that are currently performed for the detection of the bacterium are clinically inferior to the breath test, and we may now offer laboratories a quick and efficient testing solution with unprecedented accuracy".

According to company assessments, the laboratory market is currently the largest segment in the United States for the diagnosis of *H. pylori* in general and for *H. pylori* breath tests in particular. The number of tests performed in the United States each year is estimated at six million, which contrary to common

practice in most countries, are mostly blood tests. Since the results of blood tests are clinically inferior to those of breath tests, insurance companies and laboratories have been leading the conversion to breath tests. Consequently, the market for *H. pylor*i diagnostic breath tests is undergoing significant growth. This new FDA marketing clearance enables Exalenz to address the major segment of the market that has been previously inaccessible, and to benefit from the anticipated overall growth in *H. pylor*i breath tests in the future.

About Exalenz Bioscience:

Exalenz Bioscience develops and markets diagnostic and monitoring systems that use the breath to diagnose and help manage gastrointestinal and liver conditions. The company's flagship BreathID® Hp test detects the presence of the *H. pylori* bacterium, associated with various illnesses including peptic ulcers and gastric cancer, and is in use in over 350 US medical centers. Exalenz holds regulatory approvals in Europe, the United States, China and Israel for *H. pylori* detection and is currently in the process of obtaining approvals for additional applications. Additional information is available at www.exalenz.com.

Forward-looking Statement

This press release contains forward-looking statements with respect to plans, projections or future performance of the Company, the occurrence of which involves certain risks and uncertainties, some of which may not be under the control of Exalenz, including, but not limited to, changes in regulatory environment, Exalenz's success in penetration of the laboratory market, including engaging national and regional laboratories, sales, marketing and manufacturing plans, protection and validity of patents and other intellectual property rights, and the effect of competition.

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