

## Report to Investors

20.7.08

**The largest clinical trial ever conducted by an Israeli medical instrumentation company**

### **Exalenz received FDA approval to begin Pivotal Phase III trials for diagnosing severity of liver diseases**

**The Company will begin trials in 412 patients in the 12 largest hepatic centers in the US and in Hadassah Hospital in Israel**

**Jerusalem, Israel, July 20, 2008** – Exalenz Bioscience (TASE – "EXEN") (formerly BreathID), which develops and sells systems for the diagnosis and management of liver and gastrointestinal health today announced that it had received FDA approval to begin Pivotal trials for approval of the BreathID instrument and the specialized material, methacetin, for the purpose of diagnosing liver damage. In August, the Company will begin the trial in 412 patients, in 12 of the largest hepatic centers in the U.S. and in Hadassah Hospital in Israel. The trial is expected to be completed at the end of the first quarter of 2009.

Testing of liver function and the ability to monitor chronic liver patients is the primary hepatic application of the BreathID system. The Company estimates that after the product's penetration, the size of the potential market for such tests will be hundreds of millions of dollars annually.

**According to Dr. Uri Geiger, Chief Executive Officer of Exalenz**, "we are pleased with receipt of FDA approval to immediately begin the Pivotal Phase III trial – the most significant milestone since the Company's offering. This approval constitutes a final and decisive step for the use of BreathID to diagnose the severity of damage to the liver and its functioning, and represents a significant step toward penetrating the American market. The FDA essentially approved the concept behind the Company's test, the specialized material and the manner in which it is produced, and the design of the trial. The Company must now repeat controlled blind testing of results it already achieved in the past outside the U.S., for a similar sample of patients. I am proud to be part of a team that is commencing the largest trial ever conducted by an Israeli medical instrumentation company, and in the world's leading centers, in Harvard, New York, Cleveland and others. We assess that already in 2009, we will be able to begin sales in the hepatic sector, which will join the recently-reported sales in the H. Pylori sector".

As a reminder, the Company announced one month ago that based on official information in the United States, there was significant growth in the market at which the Company is directed, and according to which the size of the market for the Company's additional product for diagnosis of the H. Pylori bacteria is estimated at 6 million tests annually, compared with the 1 million tests reported in the Company's prospectus. Exalenz is expected to launch the application for testing for the H. Pylori bacteria using the Company's BreathID system in May 2009, and it already has FDA approval for the product and insurance coverage from most of the insurance companies in the U.S.

Additionally, the Company announced two weeks ago that it has completed the development of a specialized material for diagnosing NASH disease, toward Phase II trials in the U.S. that will begin in the summer, following completion of preliminary trials in approximately one hundred patients. The Company has received a one million dollar grant from the BIRD Foundation, for a joint project with

Pfizer, to develop tools for diagnosing and monitoring NASH disease, which afflicts eight million Americans. The Company assesses that the NASH market constitutes sales potential of hundreds of millions of dollars.

**About Exalenz**

Exalenz specializes in hepatic and gastrointestinal health. The Company develops and sells the revolutionary BreathID instrument for diagnosing and monitoring hepatic and gastrointestinal diseases. The systems developed by the Company are presently sold in Europe and Asia, and are undergoing the regulatory approval process in the United States. The Company is currently conducting approximately ten clinical trials in hundreds of patients in 14 centers internationally, in applications for liver and gastrointestinal disorders, some jointly with pharmaceutical companies.

**For additional information:**

Iris Lubitz [iris@gk-biz.com](mailto:iris@gk-biz.com)

972-54-4569120

**Respectfully,**

**Exalenz Bioscience Ltd.**