RapiDx

THE FIRST FULLY INTEGRATED DEVICE FOR RAPID BLOOD-BASED DIAGNOSTIC SELF-TESTS

COMPANY OVERVIEW

RapiDx develops unique and innovative solutions for blood-based rapid diagnostic tests (RDT) based on its proprietary technology. RapiDx will offer a menu of rapid blood diagnostic self and single-use tests for an array of health conditions enabling a discreet home use. Having identified one of the main obstacles associated with performing rapid blood tests as the deterring and painful lancing process and the potential risk of contamination from exposed blood, RapiDx has integrated the lancet, blood collection and RDT into one completely disposable device and at an affordable price. RapiDx is planning to launch a series of rapid blood self-tests to be used by the growing Point-Of-Care (POC) and homecare markets.

THE MARKET

The last two decades have seen a significant market trend in extending medical testing from hospitals, laboratories and POC into patients' homes (e.g. pregnancy tests and blood glucose tests). Global market for Rapid Medical Diagnostic Kits, estimated at US$19.4 billion in 2014, forecast at US$20.4 billion in 2015 and further expected to maintain a CAGR of 5.7% between 2014 and 2020 to reach a projected US$27 billion by 2020[11]. This market has a great growth potential, fueled by the strong tendency of patients and healthcare consumers to take charge and manage their own health.

THE UNMET NEED

Public awareness of the importance of early detection of disease symptoms drove the rapid diagnostic market to its current growth pattern; nevertheless, even the most advanced rapid blood tests and kits remain deterring for merely self-use. The vast majority of rapid blood tests still remain within the domain of main labs, mainly due to compliance issues associated with extracting a few blood drops from the fingertip. Such cumbersome extraction involves uncomfortable and deterring finger squeezing and lancet piercing pain, exposure to contamination, and uncontrollable extraction of the blood volume required for test adequate performance. These drawbacks have limited the penetration of rapid blood tests kits into the POC and home-care markets. An easy and simple rapid blood test device, uniquely designed to overcome the above challenges and to be used without any intervention or assistance from medical personnel, is perfectly positioned to capture the vast and growing self-diagnostic market as pregnancy and glucose tests currently do.

RAPIDX'S INNOVATION

RapiDx's unique solutions incorporate the following novel characteristics:

- Fully disposable, affordable and simple-to-use device integrating a safety lancet, blood extraction and collection mechanism, as well as lateral flow test.
- Significantly reduces the perceived pain associated with finger [piercing] lancing.
- Minimizes exposure to blood borne contamination.
- Replaces the painful squeezing protocol currently used for fingertip blood extraction by a proprietary FDA cleared elastic ring that concentrates blood at the fingertip.
- High confidence-of-use, especially for unskilled users.

IP STATUS

Two patent families are in the process of examination and approval:

1. "Integrated blood sampling and testing device and method of use thereof"; National Phase, pending in the USA, Europe and other countries, Granted in Israel, Priority date: July 6, 2006; Published: Dec 11, 2008.
2. "Device and system for blood sampling"; National Phase, Granted in Europe, pending in the USA and other countries, Priority date: Dec 25, 2007; Published: July 2, 2009.

COMPANY STATUS

- Successfully completed a clinical trial at Sourasky Medical Center, demonstrating the concept of 'passive blood extraction' and pain reduction using RapiDx solution as compared with the current method of finger squeezing.
- The Rapid Ring has been FDA cleared for marketing.
- Proof of concept was successfully achieved with Alpha Prototype, allowing user-independent blood extraction and testing.

USE OF PROCEEDS AND COMPANY ROADMAP

- Finalize product development.
- Start production phase.
- CE mark and FDA 510k submissions for an integrated device.
- Initiate marketing and sales efforts preferably together with a strategic partner.

SENIOR MANAGEMENT

Liron Hadar, Ph.D., CEO - Liron has an extensive R&D and engineering experience with multidisciplinary technical knowhow in global project management and system development. She is experienced in development and transfer to production of medical devices from their initiation, through feasibility, conceptual and detailed design.

MEDICAL-ADVISORS

Dr. Aharon Lubetzky - Has extensive clinical experience in Hematology. Dr. Lubetzky is a senior member of the Institute of Thrombosis & Homeostasis, Shiba Medical Center.

Dr. Boris Tartekovsky Ph.D. - Is a recognized expert and consultant to Orgenic, Inverness Medical, Teva and other reputable multinational biotech companies. Dr. Tartekovsky's Research site is located at Sourasky Medical Center.

Dr. Ronen Brenner - is an active advisor in evaluating project candidates by providing the clinical perspective of the technologies/devices interface between doctors and patients. An internal medicine specialist and an oncology expert specializing in oncology and radiation therapy.

[1] "Global Rapid Medical Diagnostic Kits Market - Applications and Technologies", Research and Markets, 2015.

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