



Wave 80 Biosciences

Contact: Richard Goozh

Location: San Francisco, CA

Email: richard.goozh@wave80.com

Tel: 415.707.1281

Website: www.wave80.com



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Profile

Industry Sector: Molecular diagnostics

Company Overview: Wave 80 Biosciences develops next-generation molecular diagnostics consumables and instruments for high-unmet-need human health conditions including hepatitis C, hepatitis B and HIV. Distinguished by walk-away automation, fast turnaround times, compact form factors, near-zero routine maintenance, and a one patient-one test usage model, Wave 80's pipeline products address unmet needs of diverse patient populations worldwide with gold-standard performance and a superior value proposition.

Target Market(s): Wave 80's target markets include increasingly affluent patient populations in rapidly developing economies, such as China and India, with healthcare systems favoring molecular diagnostics testing systems and one patient-one test usage models over conventional batch-format systems. The global patient population for one of Wave 80's lead disease targets, hepatitis C, is estimated at 170 million, with some 45 million in China. Wave 80's HIV molecular diagnostic will be distributed to developing nations, benefitting from \$9M USD non-dilutive grant funding for development and testing.

Key Value Drivers

Technology*: Wave 80's EOSCAPE™ product line feature a self-enclosed, disposable cartridge technology with proprietary IP in three key areas—on-cartridge sample processing, assay chemistry, and highly sensitive detection—supporting gross margins over 50% in most markets. The portable EOSCAPE™ system analyzers (handheld or benchtop for parallel processing) will be sold at cost or through reagent-rental agreements to establish a large installed base for cartridge sales.

Competitive Advantage: EOSCAPE™ systems feature a “one patient-one test” usage model which makes these systems practical for use in clinics with patient throughputs as low as a few hundred patients per week. Smaller clinics without sufficient throughput to support batch-format testing currently outsource molecular diagnostic testing, foregoing the revenue and profit brought in by these high-clinical-value tests.

Plan & Strategy: Series-A financing in 2010 will fund milestones to 1) establish an operating presence in China for clinical trials support and eventual manufacturing, distribution, and marketing; 2) file patent applications and in-license key third-party intellectual property; and 3) complete regulatory approval with the U.S. FDA, the Chinese SFDA, and other high-priority ex-US regulatory agencies.

Management

Leadership:

Daniel Laser, CEO & President; founder; Stanford Ph.D.; Prev: Iolon, BP Amoco

Richard Goozh, SVP Finance & Strategy; MBA, Kellogg; Prev: CE Unterberg
Towbin, Cooper Industries, Timet

Laura Mazzola, VP Global Health Products; Stanford Ph.D.; Prev: Affymetrix,
Affymax, Symyx, Excellin Life Sciences (founder and CEO)

Andrew Arsham, Sr. Dir. Applied Cell Physiology; Univ. of Chicago Ph.D.

Key Advisors:

Wayne C. Koff, Ph.D.

SVP Research & Development
International AIDS Vaccine Initiative (IAVI)

Patrick Yang, Ph.D.

EVP Technical Operations
Roche/Genentech USA
Hoffmann-La Roche Ltd

James Laser

Former VP of Vaccine Operations
Merck & Co., Inc.

William Perry, Ph.D.

Former U.S. Secretary of Defense

Product Pipeline

Wave 80's products leverage the same core technologies for cartridge/assay performance and separately for instrument/analyzer design. Development of core technologies and products are funded by multiple grants and contracts with the U.S. National Institutes of Health totaling over \$8.9M (fully committed) between 2010 and 2014, specifically directed to develop an HIV “global health” product for HIV. The EOSCAPE™ HIV product will be sold into global health markets beginning in 2011, using existing distribution networks of PEPFAR, the Clinton Foundation and the CDC clinical laboratory network.

The EOSCAPE™ HCV product is being developed for hepatitis C testing in China. A high-margin commercial EOSCAPE HCV product is scheduled to enter beta testing in Chinese clinics in 2012. Assays for a variety of other human health conditions are in development for the EOSCAPE platform.

Wave 80 revenue will be driven primarily by sales of consumables for the EOSCAPE™ platform in China. Company revenue is projected to grow to more than \$130 million by 2014 and more than \$250 million by 2015, with gross margins over 50% in most markets and 17% operating income.