

Executive Summary

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EXECUTIVE SUMMARY

THE CO-DIAGNOSTICS VALUE PROPOSITION

Co-Diagnostics' **CoDx™** portfolio of molecular diagnostics development products and tests represents a radical new advancement in the understanding of the molecular interactions of DNA,

.... using highly specialized, proprietary cooperative-theory mathematics,

.... leading to a revolutionary leap forward in the detection of infectious diseases, genetic disorders and other conditions,

.... at a fraction of the cost of other DNA-based tests,

.... designed for a new generation of affordable, mobile point-of-care diagnostic devices

... and compatible with many other devices,

*.... making state-of-the-art diagnostics available anywhere in the world,
including developing nations.*

THE COMPANY

Co-Diagnostics, Inc. ("Company,"), a Utah C corporation headquartered in Sandy, Utah, is a molecular diagnostics company that develops, manufactures and markets a new, state-of-the-art diagnostics technology. Using the power of computers to create unique mathematical models instead of relying on costly laboratory infrastructure, the Company has created a revolutionary new DNA-based testing platform, resulting in tests that are faster, much more affordable, flexible; simple to use, accurate, and adaptable to both high-volume and portable, low-cost analytical devices.

The Co-Diagnostics Difference – It's in the Math Co-Diagnostics scientists were the first to understand the complex mathematics of DNA test design, to "engineer" a DNA test and to automate algorithms on standard personal computers that rapidly screen millions of possible options to pinpoint and develop an optimally-designed test in weeks instead of months or years.

PRODUCTS – A NEW BIOENGINEERING APPROACH

The technology combines multiple software, hardware and reagent technologies into a single platform under the brand name Co-Dx™. Traditional lab-based molecular diagnostics tests require complicated procedures, including detection, sample preparation, and DNA amplification. Co-Dx™ integrates and streamlines these steps.

Current Tests - The Company has an expanding menu of tests, either ready for clinical trial or in late-stage development: tuberculosis screen, drug-resistant tuberculosis, malaria, hepatitis B and C, HIV, HPV, Zika virus, STD panel and a blood bank multiplex test. The Co-Dx™ tuberculosis test completed a 2014 internal study in India, confirming its superior sensitivity and specificity in a head-to-head comparison with both Cepheid's Xpert™ assay and an Indian PCR test, as well as its capacity to detect a wide array of TB strains. An expanded clinical trial in India is forthcoming in the first quarter of 2017.

Additional Tests - Co-Diagnostics is constantly expanding and improving its current test menu. Longer term, the Company anticipates development of tests in other categories, such as: women's health, oncology, heart disease, auto-immune disorders, additional infectious diseases, genetics and security.

Co-Dx™ Reagents & Software – Co-Dx™ offers three products for licensing to biotech companies' and CLIA labs' DNA test development – the same tools it uses to create its own test portfolio.

Rapid Probe™ - A 6th generation of PCR probes that is up to 2.5 times brighter, much faster and up to 10,000 times more specific than standard probes. **CoPrimers™** - A master mix of primers and probes that is the Company's most powerful and versatile PCR enhancement technology to date. CoPrimers™ are highly accurate and virtually eliminate the formation of primer dimers during PCR multiplexing. They were recently the subject of both a descriptive article and commentary in *The Journal of Molecular Diagnostics*, in which the technology was cited as a technical advance, providing a 2.5 million-fold improvement in the reduction of amplification errors. **Co-Dx™ Design Software** – Design and analytical software that facilitates rapid and accurate DNA test design by taking the guesswork out of development, significantly reducing development time and the possibility of human error.

INTELLECTUAL PROPERTY

The Company's technologies are now protected by several granted or pending US patents, as well as by certain trade secrets. The platform also bypasses existing third-party patent royalties required by other test systems, making Co-Diagnostics the low-cost leader in molecular diagnostics.

THE MARKET

The molecular diagnostics market is the fastest-growing segment of the \$33 billion US in vitro (test-tube based, controlled environment) diagnostics market. In vitro diagnostics is expected to grow to a \$75 billion industry in 2020 *Source: In Vitro Diagnostics (IVD) Market by Product (instruments, Reagents, Software, Service by Technology Immunoassay, Clinical Chemistry, Molecular Diagnostics, Hematology by Application (Diabetes, Cancer, Cardiology, Autoimmune Diseases - Forecast to 2020 Markets and Markets Research Paper July 2015*. The molecular diagnostics market is poised to reach USD \$9.3 billion by 2020 from USD \$5.9 billion in 2015, at a CAGR of 9.3% from 2015 to 2020. *Source: "Molecular Diagnostics Market by Application (Infectious Disease (HIV, HPV, TB), Oncology, Genetics, Microbiology), Technology (PCR, Microarray, DNA Sequencing), End User (Hospital, Laboratories), Product (Instruments, Reagent, Software) - Forecast to 2020*

The Co-Diagnostics development platform represents the latest and most efficient iteration of the gold standard of molecular diagnostics – PCR (polymerase chain reaction). The formalization of PCR technology earned a Nobel prize for its creators in 1985.

REVENUE MODEL

The Company will generate revenue directly from licensing agreements and shared-revenue contracts with biotech companies (speed-to-market test development, companion diagnostics), diagnostics product distributors, CLIA-certified clinical reference and research labs, HMO's, pharmacies, clinics and others looking for a low-cost, accurate, adaptable molecular diagnostics system. It anticipates creating an India sales force with a JV partner (see below) and, wherever advantageous, contracting with distributors to promote its TB and other infectious disease tests, as well as additional tests under development targeted to developing nations; and to the private market, governments, charitable foundations and others. It currently has licensing agreements for the development of cancer drug companion diagnostics.

The India Initiative India will in the next decade become the largest healthcare market in the world. The Company is forming a joint venture India subsidiary with Synbiotics Limited, an established manufacturing/distributing in-country partner, to focus on five identified domestic markets – mid-size labs in 3 categories, chain labs and public hospitals (PPP/Tender program) – and to be a manufacturing resource for tests to be distributed and sold beyond India. Under the direction of India bio-industry veterans, the joint venture will coordinate test manufacturing and form its own sales force to address these markets.

The Zika Virus Initiative Coordinating with its majority-owned subsidiary, Zika Diagnostics Inc., the Company has developed a \$10 Zika virus test, compatible with an affordable analytical device, for the

Americas and beyond. Company principals met in October 2016 with government healthcare professionals in Guyana, where the presentation of a highly cost-effective Zika test-and-device kit (under \$15,000, including 1,000 initial tests) was met with great enthusiasm. Company CEO Dwight Egan and his entourage also met with the Brazilian ambassador to Guyana and presented the kit at the Trinidad/Tobago headquarters of CARPHA – a health care consortium representing 28 countries in the Caribbean region (including Guyana). At CARPHA's request, the Company has created several proposals, ready for submission both to CARPHA and to charitable institutions with interest in the region.

The Company also anticipates coordinating clinical trials for its Zika test at Roosevelt Hospital, Guatemala City; at Hospital Israelita Albert Einstein in São Paulo; and at Woodlands Hospital, Georgetown, Guyana.

CORPORATE STRATEGY

- 1) Expand and continue to improve on very affordable, accurate PCR diagnostics testing platform under the brand CoDx™
- 2) Create an ever-expanding product line of diagnostic tests, with initial focus on infectious diseases
- 3) Sell to multiple prospective markets:
 - a) Molecular diagnostics distributors: labs, private organizations and government agencies addressing healthcare needs in developed and developing nations. In India, establish a dedicated sales force, reinforced where necessary with regional distributors.
 - b) Clinical reference labs as an affordable test development alternative in creating their own DNA- based
 - c) Health maintenance organizations
 - d) Co-Diagnostics' platform and development tools to other PCR diagnostics companies
 - e) Pharmaceutical companies looking for accurate companion diagnostics as they introduce new drugs to market
- 4) Seek strategic partnerships with medium-to-large-cap biotech companies that can provide broader distribution and a potential merger
- 5) Examine and develop other market opportunities, ie., veterinary medicine, agriculture and bio-security