



Co-Diagnostics, Inc. (\$CODX)

Co-Diagnostics, Inc. is a molecular diagnostics company with a unique, patented technology platform for the development of tests to detect infectious diseases, genetic mutations associated with cancer and also for agricultural crop genomic testing applications. The company develops, manufactures and sells proprietary chemical reagent test kits for the detection and/or analysis of nucleic acid molecules (i.e. DNA or RNA). Their reagent test kits enable very rapid, low-cost, molecular testing for organisms and genetic diseases by automating historically complex procedures in both the development and administration of tests. Co-Diagnostics (i.e. 'Co-Dx') technical advancement involves a novel approach to Polymerase Chain Reaction (i.e. 'PCR') test design of primer and probe molecule structure that eliminates one of the key vexing issues of PCR amplification, the exponential growth of 'primer dimer pairs'. Primer dimers adversely affect a PCR diagnostic test's ability to identify the targeted DNA/RNA¹ sequence and are essentially the amplification of errors that can take place during the course of administering a molecular diagnostic test. Primer dimer errors can dramatically impair the accuracy of a PCR test, leading to inaccurate diagnoses in the form of 'false positives' and/or 'false negatives' which can render a company's PCR test as unreliable. Therefore, the suppression of primer dimer pairs is imperative in order to establish a highly accurate and reliable PCR test. Co-Dx technical advancement for the design of primer and probe structures utilized in PCR tests, patented as the "CoPrimers™" platform, addresses this imperative by creating reactions that are far more specific than competing PCR technologies with a 2.5-million-fold reduction in diagnostic errors owing to primer-dimer pairs^{1,2}. By enhancing the specificity of PCR diagnostics as a testing modality, CoPrimers dramatically reduce the incidence of 'false negative' results in which a sample is incorrectly assessed as testing negative for the targeted DNA/RNA sequence (n.b. when in fact, it should have tested as 'positive' for the indication). This technology platform is also enabling the company's long-term growth initiatives for the development of a point-of-care testing device (n.b. currently subject to FDA review) and a liquid biopsy panel to screen patients for the presence of a range of cancers.

As a bioengineer and mathematician with an expertise in the mathematical field of 'Cooperative Theory', Dr. Brent Satterfield, Ph.D. received the first patent relating to the CoPrimers intellectual property in 2013 and Co-Dx was founded shortly thereafter. However, this innovative methodology for creating accurate PCR tests in a fraction of the time and cost associated with legacy methods was merely Dr. Satterfield's latest achievement in the field. Previously, Dr. Satterfield pioneered the use of engineering mathematics to design new DNA testing technology and the algorithms he developed proved to be innovative, allowing for millions of possible diagnostic solutions (i.e. probe and primer structures) to be evaluated in minutes. This mathematical approach to engineering solutions for the detection and/or analysis of nucleic acid molecules was used by Dr. Satterfield to develop new diagnostic platforms for the Department of Homeland Security, the National Biodefense Analysis and Countermeasures Center, the United States Army Medical Research Institute of Infectious Disease, Sandia National Laboratories, the California Department of Public Health and others³. These algorithms were also used to develop the 'Tentacle Probes' technology, which offered a 10,000-fold



improvement in concentration-dependent specificity and up to a 200 times faster rate of reaction than could be achieved with legacy PCR probe structures available at the time. The Tentacle Probes technology was later acquired by Fluidigm Corporation⁴. Eventually, Dr. Satterfield set out to design an even faster set of probes that were also cheaper and easier to design and the CoPrimers IP represents the culmination of his effort⁵.

The CoPrimers technology platform is protected by twenty granted or pending US and foreign patents covering the company's proprietary algorithms, the physical structure of the CoPrimer molecule itself as well as all of its potential applications⁶. The initial expiry of these issued patents will not occur until 2034 when two will lapse, with additional expirations set to occur in 2036 and 2038. Additionally, the company's proprietary development software that is used to develop diagnostic tests based on CoPrimers technology is copyrighted⁷. This technology platform establishes Co-Dx as a true competitive disruptor capable of offering a compelling value proposition wherein diagnostic solutions are made more affordable for customers without compromising on the accuracy/efficacy of the diagnostic tool. Furthermore, the enhanced specificity of PCR reactions utilizing CoPrimers means that the technology is ideally suited for 'multiplexing' scenarios where multiple nucleic acid targets are to be detected and/or analyzed in a single test, including assays for detecting infectious diseases or cancer genotyping², as well as for single nucleotide polymorphism detection and next generation sequencing (n.b. SNP & NGS discussed later). Per the company's CY23 10K⁸:

"We believe our proprietary molecular diagnostics technology is paving the way for innovation in disease detection and life sciences research through our enhanced detection of genetic material. For various reasons, including ownership of our own platform, we believe we will be able to accomplish this faster and more economically than some competitors, allowing for significant margins while still positioning ourselves as a low-cost provider of molecular diagnostics and screening services. ...

Our scientists use the complex mathematics of DNA/RNA test design, to engineer and optimize a DNA/RNA test and to automate algorithms that rapidly screen millions of possible options to pinpoint the optimum design. The intellectual property we use in our business, consisting of the predictive mathematical algorithms and patented molecular structure used in the testing process, which together represents a major advance in PCR testing systems....

Ownership of our proprietary platform permits us the advantage of avoiding payment of patent royalties required by other PCR test systems, which may allow the sale of diagnostic PCR tests at a lower price than competitors, while enabling us to maintain profit margins."

Infectious Diseases

Co-Dx holds the distinction of becoming the first U.S. company to receive a CE marking for the sale of a SARS-CoV-2 in-vitro diagnostic on 2/24/20, approximately thirty days after development efforts initiated. With their initial commercial product for the detection of mosquito borne pathogens having only been introduced several months earlier in June 2019, this fledgling enterprise with twenty-five employees and ~\$215,000 of



revenue (n.b. FY19) certainly qualified as a dark horse by achieving this distinction and outpacing industry giants like Danaher, Thermo Fisher and Abbott. Co-Dx's ability to move swiftly in the development of a diagnostic tool for a novel pathogen during the earliest days of the pandemic—outpacing competitors who are orders of magnitude greater in terms of resources—validated the capability of the CoPrimers platform to accelerate the timeline for development of diagnostic tools and reduce overhead costs. With greater than 35 million PCR reagent test kits for the detection of SARS-CoV-2 sold to centralized laboratories since Q1 '20⁹, Co-Dx has begun to cultivate brand awareness in a customer segment that management views as a key channel offering durable demand for all of the company's reagent testing solutions as the anomalous market conditions of the Covid-19 pandemic subside. The sales boon experienced during the pandemic forged a global network of relationships with roughly 190 labs in the U.S., 200 labs in India and an additional 130 labs spread across 50 nations¹⁰. The surprising pace of commercial activity has also provided the company with a non-dilutive source of funding for expanding well beyond their initial test for mosquito borne pathogens and into an array of new reagent test kits for the following indications^{8,11}:

- Drug Resistant Tuberculosis ^{CS}
- Influenza A, Influenza B & SARS-CoV-2 multiplex
- Influenza multiplex (n.b. including H5N1 'Bird Flu') ^{CS}
- H1N1 (n.b. Influenza A variant 'Swine Flu') ^{CS}
- Hepatitis B ^{CS}
- Hepatitis C ^{CS}
- Human Papillomavirus ^{CS}
- Malaria ^{CS}
- Mpox & Mpox 'two-gene' (n.b. 'F8L' & 'L6R' genes)
- Mycobacterium Tuberculosis
- SARS-CoV-2 (n.b. saliva or nasopharyngeal swab) & SARS-CoV-2 'two-gene' (n.b. 'RdRp' & 'E' genes)
- STI multiplex (n.b. Chlamydia, Gonorrhea, Mycoplasma genitalium & Trichomonas vaginalis) ^{CS}
- West Nile, St. Louis Encephalitis & Eastern Equine Encephalitis multiplex (n.b. mosquitos)
- West Nile, St. Louis Encephalitis & Western Equine Encephalitis multiplex (n.b. mosquitos)
- Zika
- Zika, Dengue and Chikungunya multiplex

Note: Tests marked with ^{CS} are only available for sale by the Joint-Venture for India, CoSara. Co-Dx intends to sell all of these tests for use on the forthcoming 'PCR Pro' & 'PCR Home' platforms but securing 510(k) FDA clearance for each test has been deferred until the forthcoming platforms have been approved for sale. This is due to the fact that each diagnostic test requires a separate 510(k) regulatory submission/approval with the FDA, a costly and time-consuming process which remains imprudent until device sales may commence.

Liquid Biopsy

A Liquid biopsy solution for the detection of onco-genetic fragments within the bloodstream may offer an early-detection cancer diagnostic intended to be utilized as a frontline ‘screening’ diagnostic tool. For a fraction of the price required for more advanced and precise legacy cancer detection tools, Co-Dx believes that the liquid biopsy program might offer a highly affordable way to screen patient populations and identify individuals that may benefit from pursuing a definitive diagnosis from more advanced and costly legacy systems. While it remains a work-in-progress, the potential for the CoPrimers IP to enable a multiplex testing panel with an ability to simultaneously test for several cancer targets should be monitored closely. Management’s confidence regarding the application of the CoPrimers IP in cancer diagnostics springs from internal research efforts which determined that the IP is capable of detecting allele changes as small as a single nucleotide. During 2021, Co-Dx researchers discovered that¹²:

“These highly selective Cooperative Primers maintain excellent discrimination properties in rare mutant allele scenarios, in both monoplex and multiplex assays. With synthetic DNA samples, Cooperative Primers can detect as little as 100 copies of mutant template amongst 1 000 000 copies of wild-type template (minor allele fraction of 0.01 %). Multiplex Cooperative Primer assay was validated with cell-free DNA reference materials and consistently detected the lowest minor allele fraction available (0.1 %) for EGFR L858R, G719S and V769-D770insASV mutations, while simultaneously providing qualitative and quantitative assessment of cell-free DNA with integrated β -Actin assay. Easy to design, rapid and inexpensive, Cooperative Primer - based real time PCR assays are a promising tool for evaluation of cancer therapy response, occurrence of resistance mutations and relapse monitoring.”

Agricultural Crop Genomics

During 2017, Co-Dx formed a partnership with Bayer AG subsidiary Bayer Crop Services for the exploration of a “proof-of-concept” project covering agricultural biology molecular diagnostics as well as next generation sequencing (i.e. ‘NGS’) of plant and animal genomics. NGS describes DNA sequencing technology platforms that have revolutionized genomic research by dramatically enhancing the speed at which cellular organisms’ genomes can be sequenced. For example, it took the legacy Sanger sequencing technology over a decade to deliver a final draft of the human genome whereas NGS platforms can accomplish the task within a single day¹³. Other than a January 2020 presentation made by Bayer Crop Services in which they discuss the capabilities of CoPrimers IP in genotyping/NGS¹⁴, very little is publicly known about this relationship aside from the fact that it is “ongoing”. Given that this is an exploratory project with a multinational corporation, Co-Dx is almost certainly subject to some type of non-disclosure agreement. Regardless of why the company is reticent when it comes to the Bayer partnership, validation of the CoPrimers technology by one of the most prominent companies in the field of agricultural biology (i.e. ‘AgBio’) is encouraging.



Furthermore, Co-DX relationship with the 'Lab of Government's Chemist' a.k.a. 'LGC' as an AgBio customer is a direct by-product of Bayer's endorsement of the CoPrimers technology. As the contract-manufacturer for Co-Dx's CoPrimers test designs (i.e. chemical reagent formulas), LGC Biosearch Technologies cooperates with Co-Dx and Bayer Crop Services to meet the ongoing needs of the proof-of-concept study. Although, it was only one year into the Bayer/Co-Dx partnership that the UK-based LGC determined that it wished to be both a customer and a supplier for Co-Dx as LGC secured an exclusive licensing arrangement for the world-wide rights to the application of the CoPrimers IP in the agronomics industry (i.e. plant breeding, plant genetics and soil science). LGC and Co-Dx completed the agreement in October 2018, pursuant to which LGC pays Co-Dx a royalty for all custom AgBio diagnostic solutions tailored to meet LGC clients' needs, and the "BHQ CoPrimers" product offering was introduced by LGC in January 2019. Furthermore, at LGC's request, the agreement was expanded in July 2019 to include a non-exclusive licensing of the CoPrimers IP for test design services in the infectious disease arena as well. The amended agreement also dictates that if any of LGC's customers wish to commercialize the agricultural or infectious disease tests designed for them by LGC, they will need to seek a commercial license directly from Co-Dx. With a footprint spanning over 200 countries and nearly 2400 employees on staff, LGC is a very capable partner for expanding the application of the CoPrimers IP in the areas of plant breeding, plant genetics and soil science^{8,14}.

Mosquito Vector Control

Co-Dx also offers diagnostic tools to test for mosquito borne pathogens. Municipalities within the U.S. and throughout the world are concerned about the diseases carried by mosquitoes which could potentially infect the human population. To prevent outbreaks of potentially harmful viruses such as Zika or West Nile among the public, municipalities conduct spraying operations to eliminate the mosquito populations carrying the disease. However, because it would be too expensive and harmful to the environment to spray all mosquito breeding areas, municipalities wish to identify particular areas that have mosquitoes that are carrying harmful viruses. To know where the host mosquitos with the harmful viruses are located, traps are set, mosquitos collected and then tested to find the areas where spraying is required. There are over 3,000 mosquito abatement districts throughout the United States and almost all of them conduct testing to help make the spraying more effective. Since June 2019, Co-Dx has offered three distinct triplex diagnostic tests for the mosquito vector control market, allowing mosquito abatement districts to test for three targets simultaneously and reduce their testing costs from those associated with competitors' solutions that only test for a single pathogen at a time. Co-Dx vector control products can test simultaneously for West Nile, Western Equine Encephalitis and St. Louis Encephalitis; West Nile, Eastern Equine Encephalitis and St. Louis Encephalitis; or Zika, Chikungunya and Dengue⁷. Although the vector control business is modest at <\$1MM of annual revenue, it's nonetheless another line of business for the company that demonstrates the versatility and broad application potential of the CoPrimers IP.

CoSara Diagnostics

As the second largest nation on the planet with an emerging economy, the demand for infectious disease diagnostic tools in India represents a major market opportunity. Given the tendency for India's government and citizens to favor product options that support an economically protectionist policy, Co-Dx established a partnership with the Indian conglomerate Ambalal Sarabhai Enterprises Ltd. in 2017 to offer a 'Made-in-India' solution to customers within the subcontinent. CoSara Diagnostics Pvt Ltd. ultimately launched in April 2019 following the completion of the entity's manufacturing facility in the state of Gujarat¹⁵ and is an equal partnership whereby Co-Dx licenses its CoPrimers IP to the joint venture on a royalty-free basis for the exclusive manufacturing and sale of its products within India. The legal agreement entitles Co-Dx to 50% of the first \$1MM in cumulative profits from CoSara's operations with the portion attributable to Co-Dx growing ten percent for each additional million in profits up to \$3MM in cumulative profits, after which Co-Dx will receive 80% of the profits, in perpetuity¹⁶.

Similar to the experience of Co-Dx during the pandemic, CoSara has been able to expand the company's product portfolio and the opportunity to provide highly accurate, affordable and indigenous solutions for covid diagnostics has allowed the company to establish a foothold with central lab customers and cultivate a brand reputation. India's public health agency, CDSCO, has provided CoSara with regulatory approval for the sale of 16 diagnostic kits and the boon in demand for diagnostics throughout the pandemic has allowed for CoSara to forge relationships with approximately 200 central lab customers to date. What's more, with roughly 80 of those lab customers leasing thermocycler equipment from CoSara that carries a commitment to purchase a required minimum number of tests each month⁷, CoSara has a budding subscription business model for molecular diagnostics on the subcontinent. Lastly, please note that operational performance attributable to CoSara may be found under the '*Gain (loss) on equity method investment in joint venture*' line item within the company's Income Statement filings.

PCR Pro & PCR Home Platforms

In addition to Co-Dx's focus on garnering relationships with central lab customers for the sale of their reagent testing kits, the company intends to expand into the 'at-home' and 'point-of-care' markets with the company's forthcoming PCR Pro & PCR Home platforms. The PCR Pro model is designed for the 'point-of-care' market, as it is capable of testing multiple samples simultaneously, whereas the PCR Home model tests a single sample. Point-of-care settings may include primary and specialist physician's offices, other outpatient clinical environments, nursing homes/skilled-care facilities, hospitals, pharmacies and more. These compact lab devices can perform PCR test(s) in approximately thirty minutes and are intended to compete directly with rapid antigen tests that presently dominate the market for at-home and point-of-care diagnostic solutions. With the ability to perform a PCR test in a period of time that is comparable to that required with an antigen test and for a similar price tag (n.b. per management), the superior accuracy of the PCR Pro & PCR Home systems will present a compelling value proposition that should allow for the product to take market share



away from existing rapid SARS-CoV-2 antigen tests. Given its portability and low-cost (n.b. per management), the PCR Pro model should also be able to expand molecular testing into marketplaces where it has previously been cost prohibitive, namely in emerging economies like India where the burden of infectious disease is very high.

Dr. Carl Wittwer and Dr. Kirk Ririe are leading the team responsible for the creation of the 'PCR Pro' & 'PCR Home' platforms. These men are considered to be extremely accomplished scientists within the field of molecular diagnostics, as they created the 'LightCycler' device (n.b. acquired by Roche) as well as the 'FilmArray' device (n.b. acquired by BioMerieux)^{17,18}. Roche and BioMerieux consistently rank among the ten largest global diagnostics companies and the achievements of Dr.'s Wittwer & Ririe have played a meaningful part in their ongoing commercial success. In engineering the PCR Pro & PCR Home platform, Co-Dx believes that they've achieved a first of its kind solution: a portable PCR diagnostic platform utilizing a saliva sample to test for pathogens with results sent instantly to your phone. The ability to utilize a patient's saliva as the sample medium for testing is enabled by the company's success with lyophilizing (i.e. freeze-drying) the company's reagents diagnostic kit and represents a more comfortable and convenient modicum for analysis by comparison to the legacy anterior and posterior nasopharyngeal swabbing techniques. An EUA application for the PCR Pro & Covid-19 test was submitted to the FDA on 12/27/23 while a formal, 510(k) application was submitted by 6/14/24^{19,20}. The timeline for other recently-issued EUAs took about six months; therefore, Co-Dx request for EUA should be answered rather soon. An EUA would enable Co-Dx to proceed with commercialization efforts while a more formal 510(k) submission is processed. While the company's initial product offering for the PCR Pro & PCR Home platform will address Covid-19, the company intends to massively expand the menu of diagnostic tests to include all of the infectious disease products presently offered for sale by Co-Dx and/or CoSara. To that end, the Bill & Melinda Gates Foundation has granted Co-Dx ~\$11.22 million for the development of Tuberculosis and Human papillomavirus tests on the new platform while the National Institutes of Health has provided ~\$1.2 million for the development of an Influenza A, Influenza B, Respiratory Syncytial Virus (i.e. 'RSV') and Covid-19⁸.

Commercial Opportunity

While pricing for the PCR Pro & PCR Home devices, along with the accompanying test cartridges, hasn't been announced, the addressable market opportunity is truly vast. According to estimates provided by the CDC and WHO, the annual incidence rate of various infectious diseases for which the company currently offers a testing product exceeds ~1.993 billion cases per year²¹. In 2023, the value of global revenue attributable to the molecular diagnostics market was estimated at ~\$15.2 billion and expected to grow at a CAGR of ~4.5% to ~\$20.7 billion in 2030²². As for liquid biopsy solutions, global revenues were estimated at ~\$10.4 billion in 2023 with expectations to expand at an impressive CAGR of ~11.6% to ~\$22.4 billion in 2030²³.



Financials (as of 3/31/24)

In closing, a summary of the most recent capital details for the company:

- Q1 '24 Revenues: ~\$468,000; FY23 Revenues: ~\$6.81 million
- Q1 '24 Cash & Equivalents: ~\$50.4 million; Q1 '24 Current Liabilities: ~\$(5.27) million
- Q1 '24 Equity: ~\$78.35 million; Q1 '24 Long-Term Liabilities: ~\$(3.05) million
- Q1 '24 Debt/Equity: ~0.106
 - *Note: CODX doesn't have any interest-bearing debt outstanding (i.e. \$0). No bills, notes, bonds or any other form of interest-bearing obligations outstanding (i.e. \$0 interest/debt-servicing costs). In this ratio, 'debt' accounts for all liabilities on the B/S.*
- Q1 '24 Operating Cashflow ~\$(8.49) million; FY23 OCF ~\$(22.08) million
- 31,278,418 shares outstanding. No warrants and/or convertible debt issued/outstanding; basic value of shares outstanding equals the fully-diluted value of shares outstanding.
- \$30 million share buyback program created March '22. ~\$15.58mm shares of common stock repurchased at an average price of ~\$3.21/sh. 4,848,678 shares held as treasury stock. ~\$14.42 million of buyback capacity remains available under the terms of the SRP.

SWOT Analysis

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> • Differentiated technology platform; CODX owns all of the intellectual property underlying its products. • Margin potential exceeds industry's mean due to lack of licensing costs. • Academic and commercial pedigree of company's senior leadership & staff. • Commercial (CoSara & Bayer), Governmental (NIH) and NGO (Gates Foundation) partnerships. 	<ul style="list-style-type: none"> • Current sales minimal w/ negative Operating CF (i.e. "burning cash"). • Limited history of commercial operations & brand awareness. • Inexperience with manufacturing. • Scale of financial and staffing resources is relatively inferior by comparison to industry competition.
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> • 'Razor and blade' business model for new PCR Pro & PCR Home platforms; creates an install-base of customers w/ reoccurring demand for consumables. • Ownership of all IP required for the PCR Pro & PCR Home platforms allows CODX to compete on price and access 	<ul style="list-style-type: none"> • Time line for commercializing PCR Pro & PCR Home platforms indeterminate as company awaits regulatory clearance from FDA. • Failure to receive regulatory clearance • Potential for the emergence of superior diagnostic technologies.



<p>untapped demand in geographical markets where PCR testing was previously cost-prohibitive.</p> <ul style="list-style-type: none">• Growing demand for syndromic testing panels/diagnostic solutions at the point-of-care in developed world.	<ul style="list-style-type: none">• If cash reserves prove inadequate for commercializing new platforms, possibility of fundraising via equity issuance (i.e. dilution of existing shareholders' value).
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Glossary

ABC – Influenza A, Influenza B & SARS-CoV-2 diagnostic panel

CAGR – Compound Annual Growth Rate

CDC – Centers for Disease Control

CDSCO – Central Drugs Standard Control Organization (nb. India's regulatory equivalent to FDA)

DNA – Deoxyribonucleic Acid

EUA – Emergency Use Authorization

FDA – U.S. Food & Drug Administration

IP – Intellectual Property

NAAT – Nucleic Acid Amplification Tests

NGS – Next-Generation Sequencing

PCR – Polymerase Chain Reaction

RNA – Ribonucleic Acid

RT-PCR – Reverse Transcription Polymerase Chain Reaction

SARS-CoV-2 – Severe Acute Respiratory Syndrome Coronavirus 2; aka "Covid-19"

SNP – Single Nucleotide Polymorphism

SRP – Share Repurchase Program

WHO – World Health Organization

ZDC – Zika virus, Dengue Fever & Chikungunya diagnostic panel



Citations

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