UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549.

Form 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2022**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from_____to_____

Commission File Number **001-38148**

CO-DIAGNOSTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Utah	**3841**	**46-2609396**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2401 S. Foothill Drive, Salt Lake City, Utah 84109
(Address of principal executive offices and zip code)

(801) 438-1036
(Registrant's telephone number including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	CODX	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $187,000,000.

As of March 14, 2023, there were 30,922,607 shares of common stock, par value $0.001 per share, outstanding.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that involve risks and uncertainties. All statements other than statements of historical fact contained in this Annual Report and the documents incorporated by reference herein, including statements regarding future events, our future financial performance, business strategy, and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors which may affect our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Moreover, we operate in a highly regulated, very competitive, and rapidly changing environment. New risks emerge from time to time, and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short term and long-term business operations, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Annual Report, and in particular, the risks discussed under "**Item 1, Business," "Item 1A, Risk Factors," and "Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations,"** and those discussed in other documents we file with the Securities and Exchange Commission (the "SEC"). In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur as described and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statement.

Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation:

- the results of clinical evaluations and the regulatory approval process;
- market acceptance of any products that may be approved for commercialization;
- our ability to protect our intellectual property rights;
- the impact of any infringement actions or other litigation brought against us;
- competition from other providers and products;
- our ability to develop and commercialize new and improved products and services;
- changes in government regulation;
- and other factors (including the risks contained in the section entitled "Risk Factors" in other documents we file with the SEC) relating to our industry, our operations and results of operations.

Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this Annual Report speak only as of the date of this Annual Report. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof.

As used in this Annual Report, the terms “we”, “us”, “our”, “Company” and “Co-Diagnostics” means Co-Diagnostics, Inc., a Utah corporation and its consolidated subsidiaries (the “Company”), unless otherwise indicated.

ITEM 1: BUSINESS

Overview

Co-Diagnostics, Inc., a Utah corporation (the “Company” or “CODX”), develops, manufactures and sells reagents used for diagnostic tests that function via the detection and/or analysis of nucleic acid molecules (DNA or RNA), including robust and innovative molecular tools for detection of infectious diseases, liquid biopsy for cancer screening, and agricultural applications. In connection with the sale of our tests we may sell diagnostic equipment from other manufacturers as self-contained lab systems (which we refer to as the “MDx Device”). We are also developing a unique, groundbreaking portable PCR device and proprietary test cups (the “Co-Dx PCR Home™ platform”) that have been designed to bring affordable, reliable polymerase chain reaction (“PCR”) to patients in point-of-care and even at-home settings. This platform is subject to U.S. Food and Drug Administration (“FDA”) review and is not available for sale at the time of this filing. There is no guarantee that our Co-Dx PCR Home platform will receive the necessary regulatory approvals for commercialization, or that, if regulatory approval is received, we will be able to successfully commercialize this platform.

Our diagnostics systems enable dependable, low-cost, molecular testing for organisms and genetic diseases by automating or simplifying historically complex procedures in both the development and administration of tests. CODX’s technical advance involves a novel, patented approach to PCR test design of primer and probe structure (“CoPrimers™”) that eliminates one of the key vexing issues of PCR amplification: the exponential growth of primer-dimer pairs (false positives and false negatives) which adversely interferes with identification of the target DNA/RNA.

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 owning 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.

In addition, continued development has demonstrated the unique properties of our CoPrimer technology that we believe makes it ideally suited for a variety of applications where specificity is key to optimal results, including multiplexing several targets, enhanced Single Nucleotide Polymorphism (“SNP”) detection and enrichment for next generation sequencing.

Our scientists use the complex mathematics of DNA/RNA PCR test design to engineer and optimize PCR tests and to automate algorithms that rapidly screen millions of possible options to pinpoint the optimum design. Dr. Brent Satterfield, our founder, developed 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 represent a major advance in PCR testing systems. CODX technologies are now protected by more than 20 granted or pending US and foreign patents, as well as certain trade secrets and copyrights. 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.

Our proprietary test design process involves identifying the optimal locations on the target genes for amplification and pair the locations with the optimized primer and probe structure to achieve outputs that meet the design input requirements identified from market research. This is done by following planned and documented processes, procedures and testing. In other words, we use the data resulting from our tests to verify whether we succeeded in designing what we intended. Verification involves a series of testing that concludes that the product is ready to proceed to validation in an evaluation either in our laboratory or in an independent laboratory setting using initial production tests to confirm that the product as designed meets the user needs.

We may either sell or lease the MDx Device to labs and diagnostic centers, through sale or lease agreements, and sell the reagents that comprise our proprietary tests to those laboratories and testing facilities.

Using our proprietary test design system and proprietary reagents, we have designed and obtained regulatory approval in the European Community and/or in India to sell PCR diagnostic tests for the detection of COVID-19, influenza, tuberculosis, hepatitis B and C, human papillomavirus, malaria, chikungunya, dengue, and the Zika virus. In the United States, we obtained Emergency Use Authorization ("EUA") for our Logix Smart™ COVID-19 detection test from the Food and Drug Administration, or FDA, and we sell that test to qualified labs. In addition, our COVID-19 detection test and certain of our other suite of COVID-19 products have been approved for sale in countries such as the United Kingdom, Australia and Mexico by the regulatory bodies in those countries and have been registered for sale in many more countries.

In addition to testing for infectious disease, the technology lends itself to identifying any section of a DNA or RNA strand that describes any type of genetic trait, which creates several significant applications. We, in conjunction with our customers, are active in designing and licensing tests that identify genetic traits in plant and animal genomes. We also have three multiplexed tests developed to test mosquitos for the identification of diseases carried by the mosquitos to enable municipalities to concentrate their efforts in managing mosquito populations on the specific areas known to be breeding the mosquitos that carry deadly viruses.

On January 23, 2020, we announced the completion of the principal design work for a PCR test for COVID-19, intended to address the potential need for detection of the virus. This test features our patented CoPrimers technology, and was designed using our proprietary software system, following the guidelines published by the World Health Organization (WHO) and Centers for Disease Control (CDC).

On February 24, 2020, we announced that this test had obtained regulatory clearance to be sold as an *in vitro* diagnostic ("IVD") for the diagnosis of COVID-19 in markets that accept CE-marking as valid regulatory approval and became available for purchase from our Utah-based ISO-13485:2016 certified facility.

We commenced sales of the COVID-19 tests in February and March of 2020 to international customers and to date have since sold over 34,000,000 of this and other COVID tests in numerous countries around the world through an expanding distributor network.

On April 6, 2020, we announced that we had received an EUA from the FDA allowing us to commence sales of our Logix Smart COVID-19 test to laboratories certified by the Center for Medicare and Medicaid Services under the Clinical Laboratories Improvements Act ("CLIA") to accept human samples for diagnostics testing throughout the United States and have sold our Logix Smart COVID-19 test to such CLIA labs since that time.

Because we believe that testing for COVID-19 will continue to be a consideration for public health worldwide, we have initiated the Co-Dx PCR Home platform to facilitate frequent testing in homes, schools, businesses, and the hospitality industry. We believe this may be accomplished through the development of a compact, relatively low-cost testing device, easy to use by non-professionals, that can provide PCR test results in around 30 minutes. The initial project built on this platform, an at-home and point-of-care COVID-19 PCR test, was ultimately facilitated by our development of a saliva or nasal swab-based PCR test that does not require the RNA/DNA extraction. While we believe the final result is believed to be approximately equivalent to those processed by a high-complexity clinical laboratory, it our COVID-19 PCR test has the advantages of increased speed and ease of handling thanks to lyophilization (or freeze-drying) of our testing reagents to allow for stability at room temperatures.

On February 15, 2021, we engaged the services of a group of professionals at Idaho Molecular, Inc ("IdMo") and Advanced Conceptions, Inc ("ACI"), with the expertise to develop the hardware for a device using our CoPrimers as the reagent chemistry. In December 2021, we announced the closing of the acquisitions of IdMo and ACI along with all existing and future assets and intellectual property related to the platform and device. It is expected that the device and test will be available to homes, schools, offices, and the travel industry among other locations, at a cost that will allow screening frequently to prevent spread of the COVID-19 virus in the future, as well as other diseases as additional single- and multiplex tests are developed and validated for use on the device. The device would also be available to test for other pathogens detectable through saliva or other samples as we develop those tests and offer them to the marketplace. All such tests will be subject to regulatory approval.

On February 22, 2023, we announced that clinical evaluations for the device and its initial test for COVID-19 had begun. Because the evaluations are dependent on identifying and enrolling a particular number of both symptomatic and asymptomatic COVID-19-positive and -negative patients at testing sites, the Company did not provide projected timelines for completion at that time.

Infectious Disease Product Offering

Using our proprietary test design system and proprietary reagents, we and CoSara Diagnostics Pvt Ltd ("CoSara"), our joint venture for manufacturing in India, design and sell PCR diagnostic tests for detection of diseases and pathogens such as COVID-19, influenza, tuberculosis, hepatitis B and C, malaria, dengue, human papillomavirus, chikungunya, and Zika virus, all of which tests have been designed and verified in our laboratories. Our tuberculosis test and Zika test received a CE Mark in 2018, and a triplex test for Zika, dengue and chikungunya received a CE Mark in 2019, qualifying the tests to be sold throughout the European community and in most countries in Central and South America. In December 2019, CoSara received a license to manufacture and sell tuberculosis, hepatitis B, hepatitis C, human papillomavirus 16/18 and malaria tests in India from the Central Drugs Standard Control Organization ("CDSCO"). In February 2020, we received a CE Mark for our Logix Smart COVID-19 test followed by an EUA by the FDA in April 2020. Also, in April 2020, our COVID-19 test was approved for manufacture and sale in India by the CDSCO and in Mexico by the INDRE, Mexico's equivalent to the United States Center for Disease Control. In August 2020, we received approval from the Australian Department of Health Therapeutic Goods Division to sell our COVID-19 test in Australia.

As explained above, our Logix Smart COVID-19 test was designed, developed, submitted for regulatory approval and ready to be used as an *in vitro* diagnostic or IVD in countries that accept a CE Mark as approval for use of the test in a period of just over 30 days. This is a real-world example of how the CODX technology can be used in an evolving epidemic or pandemic to get diagnostic tools in the hands of medical professionals in a timely manner. It can be similarly used to design a test for mutated strains of the virus should they not be detectable using currently available tests.

Caribbean and Central and South America

We began selling PCR diagnostic tests to entities located in South and Central America and the Caribbean in 2018. In some of those countries, there are limited regulatory hurdles, allowing us to begin offering our tests immediately. We have applied for and received registrations for our tests in many of those countries that require registration, and our distributors in those countries have provided us with in-country assistance in completing such registrations.

We first offered our Zika test in this region because of the demand for such a test, followed by tests for tuberculosis, and our triplex test for Zika, chikungunya, and dengue. Sales of those tests have not been material, but with the granting of a CE mark for our Logix Smart COVID-19, we experienced an increase in sales in this region.

India

In January 2017, the Company entered into an agreement to manufacture diagnostics tests for seven infectious diseases with a pharmaceutical manufacturing company in India and formed CoSara as an Indian joint venture. The agreement provided for the construction of a manufacturing plant and the manufacture of the tests named above and the joint sales and marketing of those tests in India. We have received a license for the plant in Ranoli, India to manufacture approved tests and it is being used for testing and manufacturing of our products for the Indian market.

As mentioned above, the CDSCO has given us the approval for manufacture and sale of the nine tests referred to above, and the Company's joint venture has begun manufacture and sale of those tests. The Company has commenced a reagent rental program in India with thermocyclers purchased from third-party vendors and which we refer to as our MDx Device. Each of the reagent rental placements requires the purchase of a minimum number of tests per month. The placement of thermocyclers in India has facilitated the sale of the SaraGene COVID-19 tests in India. The WHO 2019 Global Tuberculosis Report indicates that India is the country with the highest number of cases of tuberculosis in the world. WHO tuberculosis statistics for India for 2018 give an estimated incidence figure of 2.69 million cases of tuberculosis for India out of a global incidence of approximately 10.0 million.

On March 19, 2020, we announced that CoSara received authorization to begin manufacture and sale of COVID-19 tests in India. Those tests in India are branded as SaraGene COVID-19 tests and are sold exclusively by CoSara. The Indian government places restrictions on the price that could be charged for COVID-19 tests which limited the revenue in India more than we experienced in other parts of the world. At the time of this report, CoSara has received CDSCO clearance for RT-PCR tests for Mycobacterium tuberculosis, malaria, hepatitis B, hepatitis C (including viral load tests for both hepatitis B and C), human papillomavirus (HPV), a test for high-risk HPV, two COVID-19 assays, chikungunya, dengue, a dengue/chikungunya duplex test, an influenza A/influenza B/COVID-19 ("ABC") multiplex test.

Europe

Molecular diagnostics, such as our tests, are governed in Europe by the framework for IVDs, which encompasses diagnostic products such as reagents, instruments and systems intended for use in diagnosis of disease. The regulatory system for some IVDs has historically allowed for a self-certification procedure, placing heavy responsibility on manufacturers. Non self-certified products were subject to the same standards as self-certified products but were also subject to audit and review by a notified body prior to receiving approval to be CE-marked. A CE-marking is a manufacturer's declaration that a product meets the requirements of the applicable European Commission directive. Examples of current obligations include having in place a qualitative manufacturing process, user instructions that are clear and fit for purpose, and ensuring that the 'physical' features of devices and diagnostics do not pose any danger. If a product fulfils these and other related control requirements, it may be CE-marked, as an indication that the product is compliant with EU legislation and sold in the European Union. We have received CE Marks for six of our tests including for COVID-19, COVID-19 (2 gene test), ABC (a triplex test for Flu A, Flu B and COVID-19), a DS (Direct Saliva, extraction-free) COVID-19 test, tuberculosis, Zika, and our Zika, dengue, chikungunya triplex tests. Recently, the European Commission has revised its directive governing the CE- marking of IVDs, which included reclassifying which IVDs may be self-certified, and which may not. As a result of this change in directive and reclassification, substantially all of the Company's products are now subject to audit and review by a notified body, as well as a more rigorous clinical evaluation process, prior to receiving approval to be CE-marked.

We are ISO 13485:2016 certified, relating to the design and manufacture of our medical device products. The ISO certification indicates that we meet the standards required to pursue CE-marking for certain of our products and affix a CE-marking for sales of our products in countries accepting CE-marking (not in the United States).

United States

The FDA has granted permission for us to export all of our IVD products. The FDA's permission to export was granted under Section 801(e) of the Federal Food, Drug, and Cosmetic Act, as amended (the "FDC Act"). Section 801(e) of the FDA Act covers certain medical devices that have not yet received an approved Premarket Approval in the United States by the FDA, such as our products. We have not commenced any Premarket Approval steps with the FDA. Section 801(e) of the FDA Act applies to medical devices that are acceptable to the importing country and that are manufactured under the FDA's Good Manufacturing Practices. We have received EUA for our COVID-19 test, which allows sales to qualified labs in the United States, and facilitates the registration for sale in other countries as well. Under the FDA's existing policy the FDA continues to review a prioritized subset of COVID-19 tests for EUAs, and emphasizes that traditional device premarket review pathways remain open to all developers. We intend to pursue all appropriate FDA review pathways for products under development, including traditional premarket review pathways.

Under our EUA, we are actively selling our Logix Smart COVID-19 test to CLIA certified laboratories in the United States. The CLIA labs are able to use our test, or to further validate our COVID-19 tests (or other tests) as Laboratory Developed Tests (LDTs), which refers to a diagnostic test that has been validated for use in the CLIA lab. LDTs may be used by the lab only in that laboratory. CLIA laboratories develop the performance characteristics, perform the analytical validation for their LDTs and obtain licenses to offer them as diagnostic services. We are currently marketing our Logix Smart COVID-19 test to CLIA laboratories throughout the US.

Market Opportunity

The market opportunity for our tests changed radically with the emergence of the COVID-19 pandemic. Because we were able to respond rapidly and produce a quality product, we have been able to build a distribution network that extends to more than 80 countries with over 50 distributors, most of which have been the sales network that has allowed us to export products throughout the world. We believe that after the pandemic is brought under control, the network of distributors that we have built in these extraordinary times will serve us well in sales of other diagnostic tests.

The molecular diagnostics market is a fast-growing portion of the *in vitro* (test tube-based, controlled environment) diagnostics market. There are several advantages of PCR tests, such as the ones we market and sell, over other forms of diagnostic testing. These advantages include higher specificity and sensitivity, the ability to perform multiplex tests and the ability to test for drug resistance or for individual genes.

Mosquito Vector Control Services

In response to market demand, in June 2019 we introduced our first diagnostics tests to be used exclusively to test for mosquito borne pathogens in mosquito populations. Municipalities in the US and many other countries in the world are concerned about the diseases carried by mosquitos, which infect the human population. To prevent outbreaks of potentially harmful viruses such as Zika or West Nile from infecting the public, many municipalities conduct mitigation operations to eliminate the mosquito populations carrying the diseases. Because it is too expensive and potentially harmful to the environment to spray all mosquito breeding areas, municipalities identify which particular area has mosquitos that are carrying the 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 that most needed spraying. 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.

Our first vector related test was a triplex test that tests for West Nile, western equine and St. Louis encephalitis. We began shipping the tests in June 2019. We added a second test that tests mosquitos for Zika, chikungunya and dengue in a triplex test. Finally, in November 2019, we completed a test for West Nile, eastern equine and St. Louis encephalitis, specifically for use in the eastern United States. As a result, mosquito abatement districts can test for three target viruses in one test as compared to performing three different tests using other market available tests. Our products allow municipalities to obtain test results in a matter of hours, instead of the weeks they might otherwise have to wait for a central lab to process the mosquito tests.

We have sold our Vector Smart™ test products and/or related lab equipment to testing districts in different sections of the country and are marketing our products through trade shows, electronic and regular mail solicitations.

Liquid Biopsy for Cancer Screening

The enhanced specificity of our technology opens up some unique applications for liquid biopsy, demonstrating its ability to detect small quantities of mutations associated with cancer within an environment of large amounts of normal DNA, as we position the Company to take part in this historic and challenging development in human health care.

Agricultural Applications

SNP detection is also used in the agricultural industry to identify variations in crop genomes to achieve improved seed viability and other desired characteristics, including drought resistance, disease resistance, pest resistance and higher yield.

In mid-2017, the Company was first approached by a large agribusiness to evaluate our ability to multiplex certain target genomes. The results of the development project have successfully demonstrated our ability to not only multiplex the target genomes, but targeted SNP’s as well. The project was undertaken in conjunction with the manufacturer of our CoPrimers tests. The results of the project encouraged the parent of our manufacturer to seek a world-wide licensing arrangement for our CoPrimers in the agricultural industry, which was completed in October 2018. Pursuant to the exclusive license for the agronomics industry, the licensee pays us a royalty for all CoPrimers sold to the licensee’s customers. In January 2019, the licensee formally introduced the product at a large agricultural conference and has branded the product under the name “BHQ CoPrimers”.

Additional Licensing and Assay Development

We believe the unique properties of our CoPrimers technology make them ideally suited to a variety of applications where sensitivity is key to optimal results, including multiplexing several targets, enhanced SNP detection and enrichment for next generation sequencing. Our licensee for our agricultural testing requested an expansion of our license agreement to include test design services for their customers and potential customers, both in the infectious disease arena as well as for agricultural customers. The license was amended in July 2019 and we expect to derive a license fee from our licensee for its design services. If any of its customers desire to commercialize the tests designed, they will need to seek a commercial license directly from us. Because of these unique characteristics of CoPrimers, research companies and institutions have requested that we design diagnostics to locate and identify uncommon gene sequences and SNPs and create tests for the target sequences in a multiplexed reaction. This application of our technology is in its beginning stages, but we believe that the results from our initial research indicate a significant step forward in defining the capabilities of our technology, which we believe can be translated to revenue producing licensing arrangements. However, there can be no guarantee that we will be able to develop the requested capabilities, or that we will be able to successfully commercialize this application of our technology.

Competitive Advantages of Co-Diagnostics

We believe that we have the following competitive advantages:

- ***Affordability:*** Lower-cost test kits, a low-cost MDx-device, and an affordable Co-Dx PCR Home platform for at-home and point-of-care testing (the platform is subject to FDA review and not available for sale at the time of this filing).

- ***Flexibility:*** CODX's tests have been designed to run on many customers' DNA/RNA diagnostic testing machines. Our technology is well suited to the new generation of point-of-care testing ("POCT"), compact and portable analysis machinery for field, clinical and office applications.

- ***Speed*****:** We believe our rapid assay design system software provides shorter time to product release. This has been demonstrated with the conception, design, product manufacture, clinical verification and submission for a CE Mark for our Logix Smart COVID-19 test being approximately 30 days.

- ***Accuracy***: We believe our technology allows us to build tests that are highly sensitive and specific, the two benchmarks for accuracy in PCR testing.

- ***Personalized Medicine*****:** We project that rising health care costs in developed and developing nations will increasingly require that health care systems be patient-specific to eliminate waste, misdiagnoses, and ineffectiveness. A critical component will be accurate, more affordable DNA-based diagnostics, especially in at-home and POCT settings, for which we are developing products.

- ***Low-cost Provider*****:** Our platform technology obviates the need to pay patent royalties typically required of our competitors, which use patented test platforms to design their tests.

- ***Worldwide Footprint*****:** With a dynamic technology that encompasses markets worldwide, we anticipate that we can identify the best target markets, not only in high burden developing countries but also in developed nations.

- ***Growth Industry Category*****:** We believe that real-time PCR testing is the fastest-growing segment of *in vitro* diagnostic testing.

- ***Combination Product Offering*****:** Our sensitive tests can be a well-designed match for a new generation of compact and other small POCT devices now entering the market, including our own MDx and Co-Dx PCR Home devices. Used together, we believe these affordable tests and devices have the potential to revolutionize the molecular diagnostics industry in cost, speed of test results and simplification.

- ***Multiplexing:*** Our existing multiplexed tests demonstrate that our CoPrimer-designed tests are able to test for multiple targets in the same sample without the distortion caused by false negatives and false positives that often occur in multiplexed tests.

Intellectual Property

Much of our future success and value depends on our proprietary technology, and therefore, our patent and intellectual property strategy is of critical importance. Currently, our flagship CoPrimers technology is covered by two U.S. patents titled “Cooperative primers, probes, and applications thereof” as well as by granted and pending foreign counterparts. We have another three U.S. patents directed to our earlier work in primer and assay designs. For more recent works, we have filed international and U.S. patent applications directed to “Methods and Compositions for Next Generation Sequencing (NGS) Library Preparation,” “Allele-Specific Design of Cooperative Primers for Improved Nucleic Acid Variant Genotyping,” “Methods and Compositions Related to Cooperative Primers and Reverse Transcription,” and “Systems, Methods, and Apparatus for Automated Self-Contained Biological Analysis” which is the basis of our at-home and point-of-care PCR system. We intend to continue building our patent portfolio as development continues and resources are available.

We also protect some of our technology and know-how as trade secrets and, where appropriate, we use and register trademarks to protect and strengthen our products and proprietary brands. All trademarks, trade/product names, graphics and logos of Co-Diagnostics contained herein are trademarks of Co-Diagnostics or its subsidiary, as applicable, in the U.S. and/or other countries. Solely for convenience, we may refer to trademarks in this Annual Report on Form 10-K without the ™ or ® symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted by law, our rights to our trademarks.

Major Customers

We had certain customers which were each responsible for generating 10% or more of our total revenue for the years ended December 31, 2022 and 2021, respectively. One customer accounted for approximately 37% of total revenue for the year ended December 31, 2022 and two customers together accounted for approximately 48% of total revenue for the year ended December 31, 2021. These customers may not account for the same percentage of sales in future periods. If we were to sell nothing to those customers in the future, it would have a material adverse effect on our financial condition unless we were able to replace those customers with others.

Competition

The molecular diagnostics industry is extremely competitive. There are many firms that provide some or all of the products we provide and provide many diagnostic tests that we have yet to develop. Many of these competitors are larger than us and have significantly greater financial resources. Because we are more recently established, many of our competitors have a competitive advantage in the diagnostic testing industry because they also have other lines of business in the pharmaceutical industry from which they derive revenues and for which they are well known and respected in the medical profession. We will need to overcome the disadvantage of being perceived as a start up with no significant recognition from the medical and testing professionals, although we believe this is changing as we continue to market our Logix Smart COVID-19 tests and other tests in the United States to well-known and successful laboratories. Many of these competitors already have an established customer base with industry standard technology, which we must overcome to be successful. In the diagnostic testing and POCT industries, we compete with such companies as BioMerieux, Siemens, Qiagen, Cue Health, Lumira Dx and Cepheid and with such pharmaceutical companies as Abbott Laboratories, Becton Dickinson and Johnson and Johnson.

Competition has been particularly intense in the market for COVID-19 diagnostic tests. Numerous companies in the United States and internationally have announced their intention to offer new products, services and technologies that could be used in substitution for our Logix Smart COVID-19 tests. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than our company. Existing and potential competitors in the market for COVID-19 diagnostic tests include developers of serological, antigen and molecular tests. We also compete with companies from Asia in certain markets who are willing to sell their tests for much less than we sell our tests, which creates competitive price pressure on us in certain regions, particularly Asia and Latin America.

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. The entrance of new competitors is being encouraged by governmental authorities, who are offering funding to support development of testing solutions for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements.

Government Regulation

In the United States, we are regulated by the FDA and our products must be approved, cleared, or authorized by the FDA before we are allowed to sell our tests in the United States as *in vitro* diagnostics. The FDA granted us an EUA to manufacture and sell our Logix Smart COVID-19 test to CLIA labs in the United States. We are ISO 13485:2016 certified, relating to the design and manufacture of our medical device products. Being ISO certified greatly facilitates our applications for CE-Marking, which allows us to sell any CE Marked test in most countries in Europe, South America and Asia, depending on the country and following that country's registration process. We currently have CE Markings issued for our Logix Smart COVID-19 test, tuberculosis test, our Zika virus test, a triplex test that tests for Zika, dengue, and chikungunya simultaneously, a triplex "ABC" test that identifies and distinguishes between Flu A, Flu B and Covid-19, our SARS-CoV-2 2-gene multiplex test, and our DS (Direct Saliva, extraction-free) COVID-19 test. In addition, our Logix Smart COVID-19 has received the required license to manufacture and sell in India from India's CDSCO, and The National Epidemiology Institute in Mexico evaluated our Logix Smart COVID-19 and ABC tests and approved them for sale in Mexico. We have also received approval to sell in Australia. We are in the process of registering for sale our Logix Smart COVID-19 and other tests in a number of major countries around the world.

Employees

As of December 31, 2022, we had 145 full-time and part-time employees at our executive offices and lab facilities in Salt Lake City, Utah. We have engaged independent contractors in India to promote the use of our products and develop outlets for products and employ the services of independent sales representatives on an "as needed" basis.

We consider our people and the way we work to support each other and serve our customers to be critical to our success. The key human capital measures and objectives that we focus on in managing our business are: maintaining a strong and collaborative company culture, increasing our diversity, inclusion and belonging, offering fair and competitive compensation and benefits, investing in people and organizational development, protecting and enriching employee health and wellness, and sustaining a culture of respectful and effective communications.

Organizational History and Corporate Information

We were incorporated as Co-Diagnostics, Inc., in Utah on April 18, 2013. Our principal executive office is located at 2401 S. Foothill Drive, Salt Lake City, Utah 84109. Our telephone number is (801) 438-1036. Our web address is www.codiagnostics.com. The contents of our website are not incorporated by reference in this Annual Report.

ITEM 1A. RISK FACTORS

Risks Related to Our Business and Industry

We have limited commercial history upon which to base our prospects and are not certain that we will achieve profitability in the future.

We have a limited operating history. We began operations in April 2013. Our accumulated retained earnings were $39.9 million and $54.2 million as of December 31, 2022 and 2021, respectively. We were able to achieve net income during the calendar year ending December 31, 2021 due to the high demand for our Logix Smart COVID-19 and other COVID-19 tests during the COVID pandemic. During the calendar year ending December 31, 2022 we experienced a decline in demand for our Logix Smart COVID-19 and other COVID-19 tests and operated at a net loss during the period. We do not have any way of predicting when or if we will achieve profitability again. Potential investors should be aware of the difficulties normally encountered by a new enterprise, many of which are beyond our control, including substantial risks and expenses in the course of developing new diagnostic tests, establishing or entering new markets, organizing operations and marketing procedures. The likelihood of our success must be considered in light of these risks, expenses, complications and delays, and the competitive environment in which we operate. There is, therefore, nothing at this time upon which to base an assumption that our business plan will prove successful, and we may not be able to generate significant revenue, raise additional capital or operate profitably. We will continue to encounter risks and difficulties frequently experienced by early commercial stage companies, including scaling up our infrastructure and headcount, and may encounter unforeseen expenses, difficulties or delays in connection with our growth. In addition, as a result of the start-up nature of our business, we expect to continue to sustain substantial operating expenses and may not be able to continue generating sufficient revenues to cover expenditures. Any investment in our company is therefore highly speculative and could result in the loss of any investment.

Our future success is dependent on demand for COVID-19 and other infectious disease diagnostics and upon our ability to develop and market other commercially accepted diagnostic tests and our "at-home" and POCT platforms.

Our future success will depend, in part, on the continued market for COVID-19 tests, our ability to develop and sell sufficient quantities of other diagnostics tests, and our ability to successfully obtain regulatory approval for and profitably market our Co-Dx PCR Home at-home and POCT platform. Attracting new customers and distribution networks requires substantial time and expense. Any failure to obtain regulatory approval for our product candidates and to increase sales of our diagnostic tests in sufficient quantities to achieve profitability in a timely manner would adversely affect our operating results. Many factors could affect the market acceptance and commercial success of any of our diagnostic tests and devices, including:

- Our ability to develop additional infectious disease diagnostic tests for which there is a commercial market;
- Our ability to obtain regulatory clearance to commercialize our product candidates;
- our ability to convince our potential customers of the advantages and economic value of our tests over competing technologies and diagnostic tests;
- the breadth of our test menu relative to competitors;
- changes to policies, procedures or currently accepted best practices in clinical diagnostic testing;
- the extent and success of our marketing and sales efforts; and
- our ability to manufacture in quantity our commercial diagnostic tests and meet demand in a timely fashion.

We may not realize anticipated revenue from our Logix Smart COVID-19 and other COVID-19 tests.

Currently, our business is substantially dependent on sales of our Logix Smart COVID-19 and other COVID-19 tests. Other companies are working to produce or have produced rapid tests for COVID-19 which may lead to the diversion of customers, including governmental and quasi-governmental entities, away from us and toward other companies. Moreover, the dangers posed by COVID-19 may subside over time. A number of preventative vaccines have been approved for use in human populations by regulatory agencies in the U.S. and around the world. The uptake of these vaccines will likely limit the spread of COVID-19 and potentially reduce the market size for COVID-19 testing.

We expect that, if and when the current COVID-19 pandemic subsides, there could be significantly reduced demand for testing, and thus, for our Logix Smart COVID-19 and other COVID-19 tests. We have seen a reduction in the prevalence of COVID-19 since the height of the pandemic, and in 2022 experienced a significant decrease in revenue from our COVID-19 testing products. Revenues relating to our COVID-19 testing products could decline in the future if the prevalence of COVID-19 remains low and as attention from governments and individuals to COVID-19 wanes.

Further, if the COVID-19 pandemic becomes a seasonal virus or experiences fluctuations in prevalence, we could experience fluctuations in our revenues associated with our COVID-19 tests. While there is still demand for COVID-19 testing products, there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce our COVID-19 tests in sufficient quantities to meet demand. A significant decline in demand for our COVID-19 testing products without a corresponding increase in our other businesses could have a material, adverse effect on our results of operations, cash flow and financial position.

The diagnostic market is highly competitive, and we may not be able to compete effectively against the larger, well-established companies that dominate this market or emerging and small innovative companies that may seek to obtain or increase their share of the market.

The markets for diagnostic products are intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets.

These companies enjoy significant competitive advantages over us, including:

- broad product offerings, which address the needs of health care providers in a wide range of applications;
- products that are supported by long-term clinical data;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;
- extensive intellectual property portfolios and greater resources for patent protection;

- greater financial and other resources for product research and development;
- greater experience in obtaining and maintaining FDA and other regulatory clearances and approvals for products and product enhancements;

- established manufacturing operations and contract manufacturing relationships;
- significantly greater name recognition and widely recognized trademarks; and
- established relationships with healthcare providers and payers.

Our products and any product candidates that we may introduce into the market may not enable us to overcome the competitive advantages of these large and dominant companies. In addition, even if we successfully introduce additional product candidates into the market, emerging and small innovative companies may seek to increase their market share and they may eventually possess competitive advantages, which could adversely impact our business. Our competitors may also employ pricing strategies that could adversely affect the pricing of our products.

We depend on a limited number of third-party suppliers for key raw materials used in the manufacturing of our products, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on a limited number of third-party suppliers for the raw materials required for the production of our diagnostic products and product candidates. Our dependence on a limited number of third-party suppliers involves several risks, including limited control over pricing, availability, quality, and delivery schedules for raw materials. We have no supply agreements in place with any of our suppliers and cannot be certain that our current suppliers will continue to provide us with the quantities of raw materials that we require or that satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or single sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel within a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the production of our products and product candidates and delay the development and commercialization of our product candidates, including limiting supplies necessary for commercial sale, clinical trials and regulatory approvals, which could have a material adverse effect on our business.

In order to be successful, we must expand our available product lines by commercializing new product candidates, but we may not be able to do so in a timely fashion and at expected costs, or at all.

Although we are currently manufacturing diagnostic kits for commercialization, in order to be successful, we will need to expand our product lines to include other diagnostic products. To succeed in our commercialization efforts, we must effectively continue product development and testing, find new strategic partners, obtain regulatory clearances and approvals, and enhance our sales and marketing capabilities. Because of these uncertainties, there is no assurance that we will succeed in bringing any of our current or future product candidates to market. If we fail in bringing our product candidates to market, or experience delays in doing so, we will not generate revenues as planned and will need to curtail operations or seek additional financing earlier than otherwise anticipated.

We are dependent on our senior management team, scientific team, and external advisors, and the loss of any of them could harm our business, including by adversely affecting our ability to effectuate our business strategy.

The members of our current senior management team may not be able to successfully implement our strategy. In addition, we have not entered into employment agreements with any of the members of our senior management team. There are no assurances that the services of any of these individuals will be available to us for any specified period of time. The successful integration of our senior management team, the loss of members of our senior management team, scientific team and key external advisors, or our inability to attract or retain other qualified personnel or advisors could have a material adverse effect on our business, financial condition and results of operations. We may not have a sufficient number of qualified personnel to effectuate our business strategy, which could have a material adverse effect on our business, financial condition and results of operations.

If we experience significant disruptions in our information technology systems, our business, results of operations and financial condition could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage our sales and marketing, accounting and financial functions; manufacturing processes; inventory; scientific and product development functions; and our research and development functions. As such, our information technology systems are vulnerable to damage or interruption including from earthquakes, fires, floods and other natural disasters; terrorist attacks and attacks by computer viruses or hackers; power losses; and computer systems, or Internet, telecommunications or data network failures. The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, all of which could have a material adverse effect on our reputation, business, results of operations and financial condition.

Cyber security risks and the failure to maintain the integrity of company, employee or guest data could expose us to data loss, litigation and liability, and our reputation could be significantly harmed.

We and third-party service providers collect and retain large volumes of data, including personally identifiable information regarding clinical trial participants and others, for business purposes, including for regulatory, research and development and commercialization purposes, and our collaborators' various information technology systems enter, process, summarize and report such data. We also maintain personally identifiable information about our employees. The integrity and protection of our company, employee and clinical data is critical to our business. We are subject to significant data security and privacy laws and regulations. These regulations impose significant requirements on how we maintain, use, and protect such information. Maintaining compliance with these evolving regulations and requirements could be difficult and may increase our expenses. In addition, a penetrated or compromised data system or the intentional, inadvertent or negligent release or disclosure of data could result in theft, loss or fraudulent or unlawful use of company, employee or clinical data which could harm our reputation, disrupt our operations, or result in remedial and other costs, fines or lawsuits.

Risks Related to Regulatory Approval of Our Products and Other Government Regulations

We received Emergency Use Authorization or EUA and intend to seek additional and/or amended EUAs for our COVID-19 test. The FDA may not timely grant any additional or amended EUAs, if at all. For our existing EUA and any new EUA, the FDA may revoke any EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, which would adversely impact our ability to market our COVID-19 test in the United States.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions when there are no adequate, approved and available alternatives. On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services, or U.S. HHS, issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, U.S. HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to development of *in vitro* diagnostic tests during the COVID-19 public health emergency. This guidance was updated on March 16, 2020, May 4, 2020 and May 11, 2020. It is uncertain whether the widespread availability of approved and effective vaccinations could expedite or influence any such decision making with respect to the underlying health emergency.

On April 3, 2020, we received an EUA from the FDA for our Logix Smart Coronavirus Disease 2019 (COVID-19) kit for use on individuals who are suspected of COVID-19 by their healthcare provider. We cannot predict how long the EUA for our COVID-19 test will remain in place.

There can be no assurances that the FDA will authorize any request for additional and/or amended EUAs and if we do not receive the authorization, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization. The FDA may take such a position at any time and without notice and, therefore, we cannot predict how long our EUAs will remain in place. The FDA may also revoke an EUA when the circumstances justifying its issuance no longer exist, such as when an alternative is authorized for marketing through the standard procedures, including through a 510(k) clearance.

FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures, or make it impractical or impossible for us to market our test. The revocation of an EUA, if granted, could necessitate that we pursue the lengthy and expensive 510(k) clearance process, if available, or another similarly burdensome marketing authorization process, such as a de novo classification. Indeed, FDA has recommended that manufacturers of tests subject to an EUA pursue pre-market submissions such as a 510(k), de novo classification, or pre-market approval, or PMA, as applicable, during the declared public health emergency so that their devices can remain on the market after the emergency terminates.

If either of our existing EUAs is revoked prior to us having received regulatory approval to commercialize our COVID-19 test through a traditional pathway, we may not be able to obtain required clearances or approvals in a timely manner, or at all, and one or more of our competitors may obtain the necessary clearances or approvals for their products before we do. In addition, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business. As a result, any such revocation could adversely impact our business, financial condition and results of operations.

Our long-term success depends substantially on our ability to obtain regulatory clearance or approval and thereafter commercialize our product candidates; we cannot be certain that we will be able to do so in a timely manner or at all.

The process of obtaining regulatory clearances or approvals to market a medical diagnostic from the FDA or similar regulatory authorities outside of the United States can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, or at all. The FDA's 510(k) clearance process generally takes one to six months from the date of submission, depending on whether a special or traditional 510(k) premarket notification has been submitted, but can take significantly longer. An application for premarket approval, or PMA, must be submitted to the FDA if the device cannot be cleared through the 510(k) clearance process or is not exempt from premarket review by the FDA. The PMA process almost always requires one or more clinical trials and can take two to three years from the date of filing, or even longer.

If we are required to obtain approval of any of our products through the PMA process, the costs associated with such a process will be significant, which could adversely affect our financial performance and results of operations. In addition, a submission through the PMA process would require us to delay commercialization of such product candidates until after approval is received, if ever. If we are unable to commercialize our product candidates in a timely manner, or at all, our business will be adversely affected.

Similar to our compliance with U.S. regulatory requirements, we must obtain and comply with international requirements, in order to market and sell our products outside of the United States and we may only promote and market our products, if approved, as permitted by applicable regulatory authorities. There is no guarantee that we will receive the necessary regulatory approvals for our product candidates either inside the United States or internationally. If our product candidates do not receive necessary regulatory approvals, our business could be materially and adversely affected.

Our current and future relationships with third-party payers and current and potential customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm administrative burdens and diminished profits and future earnings.

Our current and future arrangements with third-party payers and current and potential customers, including providers and physicians, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In addition, we may be subject to transparency laws and patient privacy regulations by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the Physician Payments Sunshine Act, which requires (i) manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to certain "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals, (ii) applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held in such entities by physicians and their immediate family members, with data collection beginning on August 1, 2013, (iii) manufacturers to submit reports to CMS by the 90th day of each calendar year, and (iv) disclosure of such information by CMS on a publicly available website; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers; state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

We are subject to stringent and changing data protection laws, privacy policies and data protection obligations, which continue to evolve and change over time. The actual or perceived failure by us or our third-party service providers or vendors to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

We are subject to numerous data protection laws that govern the processing of individually identifiable information and health information and other sensitive and personal information in the jurisdictions in which we operate. In many instances, these data protection laws, regulations and standards apply not only to disclosures to third parties, but also to transfers of information between or among us and other parties with which we have commercial relationships. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. These data protection laws may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that will materially and adversely affect our business, financial condition and results of operations. Failure to comply with any of these data protection laws could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. These laws and regulations include the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, or collectively referred to as the HIPAA Rules, which establish a set of national privacy and security standards to safeguard Protected Health Information, or PHI, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates and their subcontractors with whom such covered entities contract for services that involve the creation, receipt, maintenance or transmission of PHI for or on behalf of a covered entity or another business associate. HIPAA requires covered entities and business associates to, among other things, develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. As this applies to our business, we are required to maintain security standards for any PHI that we create, receive, maintain or transmit. For example, we plan to offer cloud-based portal software to help our customers more efficiently use our products. The software will maintain security safeguards that are designed to be consistent with the HIPAA Rules, but we cannot guarantee that these safeguards will not fail or that they will not be deemed inadequate in the future. In addition, we could be subject to periodic audits for compliance with the HIPAA Privacy and Security Standards by the U.S. HHS, and our customers. The U.S. HHS Office for Civil Rights may impose significant penalties on entities subject to HIPAA for a failure to comply with a requirement of the HIPAA Rules. If we are unable to properly protect the privacy and security of the PHI of our customers, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personal information, including health-related information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

Laws, regulations and standards in many other jurisdictions also apply broadly to the Processing of personal information, which impose significant compliance obligations. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any Data Protection Laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential information, whether by us, one of our service providers or another third party, could negatively affect our business, financial condition and results of operations, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose unencrypted personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify affected customers, regulators, credit reporting agencies or other affected individuals of a security breach. Such notifications are costly, and the disclosures or the failure to comply with such requirements, could lead to material adverse effects, including without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable Data Protection Laws, Data Protection Obligations or other legal obligations. In addition, although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach by our subcontractors could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and Data Protection Laws and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business.

We cannot assure you that our third-party partners and service providers with access to our or our customers', suppliers' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us or violate Data Protection Laws, or that they will not experience security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under the Data Protection Laws, which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy- and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

We may receive inquiries or be subject to investigations, proceedings or actions, by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect, including without limitation, interruptions of, or required changes to, our business practices, the diversion resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary Processing, or other remedies that adversely affect our business.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business.

While we maintain general liability insurance coverage, cyber insurance coverage and other insurance, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse effects arising out of our privacy and security practices, Processing or security breaches we may experience, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about subjects and health care providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business; affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data; result in liability; or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws (e.g., the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act, or collectively HIPAA), state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose protected health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. However, determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. Furthermore, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require continuous modifications to our compliance policies, procedures, and systems.

Many state laws govern the privacy and security of personal information and data in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (the "CCPA"), which went into effect in January 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. In addition, the California Consumer Rights Act, or CPRA, was recently enacted to strengthen elements of the CCPA and became effective on January 1, 2023. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data and expands the application of the CCPA to all human resources personal information of California-based employees. In addition, the CPRA created a new California data protection agency authorized to issue substantive regulations and is expected to result in increased privacy and information security enforcement. A number of other states have considered similar privacy proposals, and states have recently enacted their own privacy laws. For example, the Virginia Consumer Data Protection Act became effective on January 1, 2023, and Colorado and Utah enacted similar laws that will also become effective in 2023, increasing the complexity of compliance and the risk of failures to comply. These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data.

In addition to our operations in the United States, which may be subject to health care and other laws relating to the privacy and security of health information and other personal information, we may be or become subject to European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679 ("GDPR") became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10,000,000 or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20,000,000 or up to 4% of our total worldwide annual turnover, whichever

is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers.

Following the United Kingdom's withdrawal from the European Union (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover. In 2022, the government of the United Kingdom proposed and debated the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, UK GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework. However, progress on the bill stalled as the government continues to assess the most optimal approach to data protection reform.

We currently sell some of our products in the EEA, and the GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or partners.

Proposed legislation in the U.S. Congress, including changes in U.S. tax law, and the recently enacted Inflation Reduction Act of 2022 may adversely impact us and the value of common shares, pre-funded warrants, and Warrants.

Changes to U.S. tax laws (which changes may have retroactive application) could adversely affect us or holders of common shares. In recent years, many changes to U.S. federal income tax laws have been proposed and made, and additional changes to U.S. federal income tax laws are likely to continue to occur in the future.

The U.S. Congress is currently considering numerous items of legislation which may be enacted prospectively or with retroactive effect, which legislation could adversely impact our financial performance and the value of common shares. If enacted, most of the proposals would be effective for the current or later years. The proposed legislation remains subject to change, and its impact on us and the holders of common shares is uncertain.

In addition, the Inflation Reduction Act of 2022 was recently signed into law and includes provisions that will impact the U.S. federal income taxation of corporations. Among other items, this legislation includes provisions that will impose a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. It is unclear how this legislation will be implemented by the U.S. Department of the Treasury, and we cannot predict how this legislation or any future changes in tax laws might affect us or holders of common shares, pre-funded warrants or Warrants.

Risks Related to Our Intellectual Property

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to commercialize our products successfully will be harmed, and we may not be able to operate our business profitably.

Our success depends significantly on our ability to protect our proprietary rights to the technologies incorporated in our products. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office, or the USPTO, or foreign patent offices. In addition, our pending patent applications include claims to numerous important aspects of our products under development that are not currently protected by any of our issued patents. We cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The USPTO or foreign patent offices may deny or require significant narrowing of claims in our pending patent applications. Patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the USPTO or foreign patent offices could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all.

Our competitors may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may issue in the future, which could prevent or limit our ability to market our products and could limit our ability to stop competitors from marketing products that are substantially equivalent to ours. In addition, competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products but that are not covered by our patents.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time-consuming and expensive, and would divert management's attention from managing our business. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights.

We could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from marketing our commercially available products or product candidates and/or reduce the margins we may realize from our products that we may commercialize.

Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of participants in the *in vitro* diagnostics market increases and as we achieve more visibility in the marketplace and introduce products to market.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In some cases, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we were found to infringe any patents, we could be required to pay substantial damages, including triple damages if an infringement is found to be willful, and royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe those patents. If we fail to obtain any required licenses or make any necessary changes to our technologies or the products that incorporate them, we may be unable to commercialize one or more of our products or may have to withdraw products from the market, all of which would have a material adverse effect on our business, financial condition and results of operations.

We rely substantially on our trademarks and trade names. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.

We rely substantially upon trademarks to build and maintain the integrity of our brand. Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared unenforceable or determined to be violating or infringing on other intellectual property rights. We may not be able to protect or enforce our rights to these trademarks and trade names, which we rely upon to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Asserting claims against such third parties may be prohibitively expensive. In addition, there could be potential trade name or trademark infringement, or dilution claims brought by owners of other trademarks against us. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could harm our business, financial condition and results of operations.

Risks Related to Litigation from Operating Our Business

We may become subject to potential product liability claims, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the design, testing, manufacture, sale and distribution of our currently marketed products and each of our product candidates that we are seeking to introduce to the market. Someone may allege that our diagnostic tests identified inaccurate or incomplete information or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. In addition, we may be subject to product liability claims resulting from misuse or off-label use of our products and product candidates. Any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates or in our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess of this award out of our cash reserves, which could significantly harm our financial condition. A product liability claim, even one without merit, could harm our reputation in the industry, lead to significant legal fees, and result in the diversion of management's attention from managing our business.

Current or future litigation, government investigations and other legal proceedings may harm our business.

We have been, currently are and may in the future become, involved in legal proceedings that could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. The types of legal proceedings we may be or become subject to include patent and other intellectual property claims, product liability claims, employee claims, tort or contract claims, federal or state regulatory investigations, securities class actions, and other legal proceedings, investigations or claims. For example, we are currently parties to two securities class action claims and three derivative actions. On March 20, 2020, we received a voluntary request for documents from the SEC relating to disclosures regarding our COVID-19 test and other matters. Since that time we and certain of our current and former officers have been cooperating with the SEC and providing documents and information. The Company has entered into negotiations with the SEC in an attempt to reach a consensual resolution of the matters raised in the SEC's investigation. Any such resolution may include the imposition of civil penalties, injunctive and other relief against the Company, senior management and related individuals. We cannot predict the outcome of these negotiations or of the SEC's investigation at this time, however, to the best of our knowledge, we do not believe that the matter is reasonably likely to result in financial penalties having a material adverse effect on the Company. Litigation and other legal proceedings are inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for any of our products or other offerings, even if the regulatory or legal action is unfounded or not material to our operations. For additional information, see "Item 3. Legal Proceedings."

General Risk Factors

The price of our common stock may fluctuate substantially.

The market price of our common stock may be subject to wide fluctuation in response to various factors, some of which are beyond our control. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this report, are:

- sales of our common stock by our shareholders, executives, and directors;
- our ability to obtain regulatory approval to commercialize our "at-home" and POCT product candidates on a timely basis or at all;
- our ability to enter new markets;
- actual or unanticipated fluctuations in our annual and quarterly financial results;
- our ability to obtain financings to continue and expand our commercial activities, expand our manufacturing operations, conduct research and development activities including, but not limited to, human clinical trials, and other business activities;
- our ability to secure resources and the necessary personnel to continue and expand our commercial activities, develop additional diagnostic tests, conduct clinical trials and gain approval for our diagnostic tests on our desired schedule;
- commencement, enrollment or results of our clinical trials of our diagnostic tests or any future clinical trials we may conduct;
- changes in the development status of our diagnostic tests;
- any delays or adverse developments or perceived adverse developments with respect to review by the FDA or other similar foreign regulatory authorities of our planned clinical trials;
- any delay in our submission for studies or test approvals or adverse regulatory decisions, including failure to receive regulatory approval or clearance for our diagnostic tests;
- our announcements or our competitors' announcements regarding new tests, enhancements, significant contracts, acquisitions or strategic investments;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, including as a result of future issuances of securities and sales of large blocks of common stock by our shareholders;
- announcements and events surrounding financing efforts, including debt and equity securities;
- competition from existing technologies and diagnostic tests or new technologies and diagnostic tests that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new diagnostic tests, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendations and changes in recommendations, price targets and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics;
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Anti-takeover provisions in our charter documents and Utah law could discourage, delay, or prevent a change of control of our Company and may affect the trading price of our common stock.

We are a Utah corporation and the anti-takeover provisions of the Utah Control Shares Acquisition Act may discourage, delay or prevent a change of control by limiting the voting rights of control shares acquired in a control share acquisition. In addition, our Articles of Incorporation and Bylaws may discourage, delay or prevent a change in our management or control over us that shareholders may consider favorable. Among other things, our Amended and Restated Articles of Incorporation and Bylaws:

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors in response to a takeover attempt;
- provide that vacancies on our board of directors, including newly created directorships, may be filled only by a majority vote of directors then in office, except a vacancy occurring by reason of the removal of a director without cause shall be filled by vote of the shareholders;
- no right to cumulative voting;
- limit who may call special meetings of shareholders; and
- Provide for a staggered board of directors

These provisions could have the effect of delaying or preventing a change of control, whether or not it is desired by, or beneficial to, our shareholders.

We do not currently intend to pay dividends on our common stock.

We do not expect to pay cash dividends on our common stock. Any future dividend payments are within the absolute discretion of our board of directors and will depend on, among other things, our results of operations, working capital requirements, capital expenditure requirements, financial condition, contractual restrictions, business opportunities, anticipated cash needs, provisions of applicable law and other factors that our board of directors may deem relevant. We may not generate sufficient cash from operations in the future to pay dividends on our common stock.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are currently a "smaller reporting company" as defined in the Securities Exchange Act of 1934. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings, and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We incur substantial costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, insurance, accounting and other expenses, including costs associated with public company reporting. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development and commercialization activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. These laws and regulations could make it more difficult and costlier for us to obtain director and officer liability insurance for our directors and officers, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and qualified members of our board of directors, particularly to serve on our audit and compensation committees. In addition, if we are unable to continue to meet the legal, regulatory and other requirements related to being a public company, we may not be able to maintain the listing of our common stock on The NASDAQ Capital Market, which would likely have a material adverse effect on the trading price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters are located at 2401 S. Foothill Drive, Salt Lake City, Utah. Our current facility has approximately 14,000 square feet of laboratory and office space under a lease that expires in February 2024. Our recently acquired subsidiaries also lease additional laboratory and office space under month-to-month leases. We believe the facility we lease is sufficient to meet our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we are at times subject to various legal proceedings and disputes, including the proceedings specifically discussed below. We assess our liabilities and contingencies in connection with outstanding legal proceedings utilizing the latest information available. Where it is probable that we will incur a loss and the amount of the loss can be reasonably estimated, we record a liability in our consolidated financial statements. These legal reserves may be increased or decreased to reflect any relevant developments on a quarterly basis. Where a loss is not probable or the amount of loss is not estimable, we do not accrue legal reserves. While the outcome of legal proceedings is inherently uncertain, based on information currently available and available insurance coverage, our management believes that it has established appropriate legal reserves. Any incremental liabilities arising from pending legal proceedings are not expected to have a material adverse effect on our consolidated financial position, consolidated results of operations, or consolidated cash flows. However, it is possible that the ultimate resolution of these matters, if unfavorable, may be material to our consolidated financial position, consolidated results of operations, or consolidated cash flows.

Class Actions and Shareholder Derivative Suits

Gelt Securities Class Action (District of Utah)

On June 15, 2020, Gelt Trading Co. (“Gelt”) filed a lawsuit in the United States District Court for the District of Utah (“District of Utah”), against the Company and certain of our directors and officers, on behalf of itself and a putative class, seeking to recover damages for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (“Gelt Litigation”). The complaint alleges that Co-Diagnostics and the individual defendants overstated the accuracy of the Company’s Logix Smart COVID-19 test in statements on April 30, 2020 and May 1, 2020, and that plaintiff suffered losses when the Company’s stock price dropped after public reports questioned the accuracy of the Logix Smart test on May 14, 2020. On July 15, 2020, plaintiff filed an amended complaint. On March 10, 2021, the court appointed Gelt as Lead Plaintiff, and on April 7, 2021, Lead Plaintiff filed a second amended complaint (“SAC”), which asserts the same Sections 10(b) and 20(a) claims against the same defendants on largely the same theory. On May 5, 2021, the defendants moved to dismiss the SAC. On March 9, 2022, the court entered a Decision & Order denying the motion to dismiss, and on April 13, 2022, the defendants filed an answer to the SAC. On October 17, 2022, Gelt filed a motion to certify the putative class. Discovery is currently underway and the motion to certify the class is pending. The defendants believe the claims are without merit and intend to defend vigorously against them, but there can be no assurances as to the outcome.

Shareholder Derivative Lawsuits (District of Utah & Utah State Court)

On September 17, 2020, a shareholder derivative lawsuit was filed in the District of Utah by Luis Aguilera, allegedly on behalf of Co-Diagnostics, Inc., that substantially piggybacks on the Gelt Litigation referenced above. The lawsuit asserts that the defendants failed to prevent the alleged securities law violations largely asserted in the Gelt Litigation. On December 2, 2020, a second shareholder derivative lawsuit was filed in the District of Utah by Melvyn Klein asserting essentially the same claims, allegedly on behalf of Co-Diagnostics, as the Aguilera shareholder derivative action. And on April 29, 2021, the District of Utah consolidated the two shareholder derivative cases, with the Aguilera case serving as the lead case under the caption *In re Co-Diagnostics, Inc. Derivative Litigation*. On May 3, 2022, plaintiffs filed an amended complaint asserting claims for breach of fiduciary duty, unjust enrichment, and contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934. Defendants answered the amended complaint on June 24, 2022.

On November 24, 2020, an additional shareholder derivative lawsuit was filed in the District of Utah by Matthew Wallace, allegedly on behalf of Co-Diagnostics, Inc., that also piggybacks on the Gelt Litigation referenced above. It named the same defendants and asserted essentially the same claims, allegedly on behalf of Co-Diagnostics, as in the other District of Utah shareholder derivative actions referenced above. On January 25, 2021, another shareholder derivative lawsuit was filed in the District of Utah by Jason Reagan, asserting essentially the same claims as in the Wallace lawsuit. On March 18, 2021, the court consolidated the two lawsuits, with the Wallace lawsuit serving as the lead case. On April 30, 2021, plaintiffs filed an amended complaint asserting claims for breach of fiduciary duty against defendants and claims for insider trading.

On March 29, 2021, an additional shareholder derivative lawsuit was filed in the Third District Court in and for Salt Lake County, State of Utah ("Utah State Court") by Hua Ding, allegedly on behalf of Co-Diagnostics, Inc., that also piggybacks on the Gelt Litigation referenced above. It names the same defendants and asserts essentially the same claims as in *In re Co-Diagnostics, Inc. Derivative Litigation* pending in the District of Utah referenced above. On December 12, 2022, a second shareholder derivative lawsuit was filed in Utah State Court by Kathryn Matuch asserting essentially the same claims, allegedly on behalf of Co-Diagnostics, as the Ding shareholder derivative action.

The defendants believe the claims asserted in all of the shareholder derivative lawsuits referenced above are without merit and intend to defend vigorously against them, but there can be no assurances as to the outcome.

Stadium Capital Securities Class Action (Southern District of New York)

On August 16, 2022, Stadium Capital LLC ("Stadium") filed a lawsuit in the United States District Court for the Southern District of New York, against Co-Diagnostics, Inc., and certain of our officers, on behalf of itself and a putative class, seeking to recover damages for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. The complaint alleges that Co-Diagnostics and the individual defendants overstated the demand for the Company's Logix Smart COVID-19 test in statements on May 12, 2022 and June 15, 2022. The complaint alleges that plaintiff suffered losses when the Company's stock price dropped after the Company disclosed its financial results for the quarter ended June 30, 2022 in a press release on August 11, 2022. On October 31, 2022, Stadium filed a motion seeking to be appointed as Lead Plaintiff and for Kaplan Fox & Kilsheimer LLP to be appointed as lead counsel. That motion is pending before the U.S. District Court. The defendants believe the claims are without merit and intend to defend vigorously against them, but there can be no assurances as to the outcome.

Commercial Litigation

Co-Diagnostics, Inc. v. Hukui Technology, Inc., et al. (Third Judicial District Court, Salt Lake County, State of Utah, Civil No. 210902131, filed on April 21, 2021).

The Company filed a complaint against Defendants Hukui Technology, Inc., Hukui Tech, Inc., and Hukui Bio Co., Ltd (collectively, "Hukui") seeking a declaratory judgment that the Company is not obligated to any of them in any amount. On August 24, 2021, Hukui filed their Answer and Counterclaim seeking damages on a number of theories, including breach of contract for letter agreements, breach of oral agreement, promissory estoppel, unjust enrichment, and interference with economic relations. Hukui requested a money judgment against the Company in an amount to be determined at trial. On September 20, 2021, Hukui filed their Unopposed Motion for Leave to Amend Answer to the Complaint, Affirmative Defenses, and Counterclaims and, on October 14, 2021, Hukui filed their Amended Answer and Counterclaims seeking damages on declaratory judgment, as well as breach of contract for letters of authorization, breach of oral agreement, promissory estoppel, unjust enrichment, and interference with economic relations. In 2022 the parties exchanged their initial disclosures, exchanged written discovery requests, and conducted a number of depositions on each side that were concluded in January 2023. The Company believes the claims are without merit and intends to defend vigorously against them, but there can be no assurances as to the outcome.

Co-Diagnostics, Inc. v. Pantheon International Advisors Ltd. (Third Judicial District Court, Salt Lake County, State of Utah, Civil No. 210902609, filed on May 14, 2021).

The Company filed a complaint against Pantheon International Advisors ("Pantheon") asking the court to declare that the Company has no ongoing contractual business relationship with Pantheon, no monies owing, nor does Pantheon have any interest, right, title or claim to any stock issued by the Company or ownership of any kind in the Company. Pantheon was served with a 30-Day Summons on September 9, 2021 to which it failed to respond, and a default judgement against Pantheon International Advisors was entered by the Court on November 28, 2021. The time to appeal from the judgment or seek to vacate the judgment has passed.

After learning that the Company had initiated suit in Utah, and after learning of Company's intent to serve it with process of that suit, on May 24, 2021, Pantheon filed a claim against the Company in the Royal Courts of Justice Group, Queens Bench Division, Claim No. QB-21-002245, stating that the Company owes Pantheon $2,860,809.79 for alleged breach of contract for failing to make payments purportedly due under a contract allegedly entered into on October 18, 2018. The Company is being represented locally in the UK by Freshfields Bruckhaus Deringer LLP in that matter. On March 4, 2022, the Company filed a jurisdictional challenge to the UK suit, alleging that there was no 2018 agreement, and that the Company is not subject to jurisdiction in the UK. The oral argument and presentation of evidence on solely the jurisdictional claim took place on November 9, 2022, with the court taking the matter of jurisdiction over the Company under advisement. The court has not yet ruled on the motion to dismiss, and it is not yet known when the court will rule upon that motion. The Company intends to vigorously defend against the UK claims and will seek to the full extent possible to enforce its rights under the Declaratory Judgment already obtained in Utah but there can be no assurances as to the outcome.

From time to time, we may become involved in litigation and other proceedings relating to claims arising out of our operations in the normal course of business and to inquiries from FINRA, NASDAQ and the U.S. Securities and Exchange Commission (the SEC). On March 20, 2020, the Company received a voluntary request for documents from the SEC relating to disclosures regarding our COVID-19 test and other matters. Since that time we and certain of our current and former officers have been cooperating with the SEC and providing documents and information. The Company has entered into negotiations with the SEC in an attempt to reach a consensual resolution of the matters raised in the SEC's investigation. Any such resolution may include the imposition of civil penalties, injunctive and other relief against the Company, senior management and related individuals. We cannot predict the outcome of these negotiations or of the SEC's investigation at this time, however, to the best of our knowledge, we do not believe that the matter is reasonably likely to result in financial penalties having a material adverse effect on the Company.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER EQUITY SECURITIES

Market Information

Our common stock has been quoted on the NASDAQ market under the symbol "CODX" since July 12, 2017.

Holders

As of March 14, 2023, the last reported sales price reported on NASDAQ for our common stock was $2.99 per share. As of March 14, 2023, we had approximately 154 record holders of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent for our common stock is VStock Transfer LLC located at 18 Lafayette Pl, Woodmere, New York 11598.

Dividends

We have never declared or paid any cash dividends on our capital stock. The payment of dividends on our common stock in the future will depend on our earnings, capital requirements, operating and financial condition and such other factors as our board of directors may consider appropriate. We currently expect to use all available funds to finance the future development and expansion of our business and do not anticipate paying dividends on our common stock in the foreseeable future.
Pursuant to Section 16-10a-640 of the Utah Revised Business Corporation Act, no distribution may be made if, after giving it effect:

(a) the corporation would not be able to pay its debts as they become due in the usual course of business; or

(b) the corporation's total assets would be less than the sum of its total liabilities plus, unless the articles of incorporation permit otherwise, the amount that would be needed, if the corporation were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of shareholders whose preferential rights are superior to those receiving the distribution.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Share Repurchase Program

Issuer Purchase of Equity Securities				
Period	**(a) Total number of shares purchased [1]**	**(b) Average price paid per share [1]**	**(c) Total number of shares purchased as part of publicly announced plans or programs [1]**	**(d) Maximum number (or approximate dollar value) of shares that may yet be purchased under the plans or programs [1]**
10/01/22 - 10/31/22	-	$ -	-	$ 17,005,627
11/01/22 - 11/30/22	4,750	$ 3.01	4,750	$ 16,991,319
12/01/22 - 12/31/22	462,582	$ 2.60	462,582	$ 15,788,134
Total	467,332	$ 2.61	467,332	$ 15,788,134

(1) In March 2022, the company announced that its board of directors authorized the repurchase of up to $30.0 million of the company's outstanding common stock. The extent to which the company repurchases its shares, and the timing of such repurchases, will depend upon a variety of factors, including trading volume, market conditions, legal requirements, business conditions and other factors. The repurchase program may be discontinued at any time, and the program does not obligate the company to acquire any specific number of shares of its common stock.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULT OF OPERATIONS

The following management's discussion and analysis of financial condition and results of operations describes the principal factors affecting the results of our operations, financial condition, and changes in financial condition. This discussion should be read in conjunction with the accompanying audited financial statements, and notes thereto, included elsewhere in this report. In addition to historical information, this Annual Report contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption "Item 1A. Risk Factors" in this Annual Report on Form 10-K.

Business Overview

Co-Diagnostics, Inc., a Utah corporation (the "Company" or "CODX"), develops, manufactures and sells reagents used for diagnostic tests that function via the detection and/or analysis of nucleic acid molecules (DNA or RNA), including robust and innovative molecular tools for detection of infectious diseases, liquid biopsy for cancer screening, and agricultural applications. In connection with the sale of our tests we may sell diagnostic equipment from other manufacturers as self-contained lab systems (which we refer to as the "MDx Device"). We are also developing a unique, groundbreaking portable PCR device and proprietary test cups (the "Co-Dx PCR Home platform") that have been designed to bring affordable, reliable polymerase chain reaction ("PCR") to patients in point-of-care and even at-home settings. This platform is subject to U.S. Food and Drug Administration ("FDA") review and is not available for sale at the time of this filing. There is no guarantee the our Co-Dx PCR Home platform will receive the necessary regulatory approvals for commercialization, or that, if regulatory approval is received, we will be able to successfully commercialize this platform.

Our diagnostics systems enable dependable, low-cost, molecular testing for organisms and genetic diseases by automating or simplifying historically complex procedures in both the development and administration of tests. CODX's technical advance involves a novel, patented approach to PCR test design of primer and probe structure ("CoPrimers") that eliminates one of the key vexing issues of PCR amplification: the exponential growth of primer-dimer pairs (false positives and false negatives) which adversely interferes with identification of the target DNA/RNA.

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 owning 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.

In addition, continued development has demonstrated the unique properties of our CoPrimer technology that we believe makes it ideally suited for a variety of applications where specificity is key to optimal results, including multiplexing several targets, enhanced Single Nucleotide Polymorphism ("SNP") detection and enrichment for next generation sequencing.

Our scientists use the complex mathematics of DNA/RNA PCR test design to engineer and optimize PCR tests and to automate algorithms that rapidly screen millions of possible options to pinpoint the optimum design. Dr. Brent Satterfield, our founder, developed 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 represent a major advance in PCR testing systems. CODX technologies are now protected by more than 20 granted or pending US and foreign patents, as well as certain trade secrets and copyrights. 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.

Our proprietary test design process involves identifying the optimal locations on the target genes for amplification and pair the locations with the optimized primer and probe structure to achieve outputs that meet the design input requirements identified from market research. This is done by following planned and documented processes, procedures and testing. In other words, we use the data resulting from our tests to verify whether we succeeded in designing what we intended. Verification involves a series of testing that concludes that the product is ready to proceed to validation in an evaluation either in our laboratory or in an independent laboratory setting using initial production tests to confirm that the product as designed meets the user needs.

We may either sell or lease the MDx Device to labs and diagnostic centers, through sale or lease agreements, and sell the reagents that comprise our proprietary tests to those laboratories and testing facilities.

Using our proprietary test design system and proprietary reagents, we have designed and obtained regulatory approval in the European Community and/or in India to sell PCR diagnostic tests for the detection of COVID-19, influenza, tuberculosis, hepatitis B and C, human papillomavirus, malaria, chikungunya, dengue, and the Zika virus. In the United States, we obtained Emergency Use Authorization ("EUA") for our Logix Smart COVID-19 detection test from the Food and Drug Administration, or FDA, and we sell that test to qualified labs. In addition, our COVID-19 detection test and certain of our other suite of COVID-19 products have been approved for sale in countries such as the United Kingdom, Australia and Mexico by the regulatory bodies in those countries and have been registered for sale in many more countries.

In addition to testing for infectious disease, the technology lends itself to identifying any section of a DNA or RNA strand that describes any type of genetic trait, which creates several significant applications. We, in conjunction with our customers, are active in designing and licensing tests that identify genetic traits in plant and animal genomes. We also have three multiplexed tests developed to test mosquitos for the identification of diseases carried by the mosquitos to enable municipalities to concentrate their efforts in managing mosquito populations on the specific areas known to be breeding the mosquitos that carry deadly viruses.

RESULTS OF OPERATIONS

Results of Operations for the Years Ended December 31, 2022 and 2021

The table below provides a comparison of our operating results for the year ended December 31, 2022 as compared to the year ended December 31, 2021.

	Years Ended December 31,		Year Change	
	2022	2021	Change	%
Revenue	$ 34,218,209	$ 97,885,603	$ (63,667,394)	-65%
Cost of revenue	5,481,092	11,574,944	(6,093,852)	-53%
Gross profit	28,737,117	86,310,659	(57,573,542)	-67%
Operating expenses				
Sales and marketing	7,344,628	13,397,813	(6,053,185)	-45%
General and administrative	14,262,963	11,550,615	2,712,348	23%
Research and development	17,438,098	14,961,916	2,476,182	17%
Depreciation and amortization	1,282,718	335,363	947,355	282%
Goodwill impairment charges	15,388,546	-	15,388,546	-
Total operating expenses	55,716,953	40,245,707	15,471,246	38%
Income (loss) from operations	(26,979,836)	46,064,952	(73,044,788)	-159%
Other income (expense)				
Interest income	704,044	45,631	658,413	1443%
Loss on disposition of assets	(138,117)	(44,355)	(93,762)	211%
Gain on remeasurement of acquisition contingencies	7,899,644	-	7,899,644	-
Loss on equity method investment in joint venture	(332,969)	(430,433)	97,464	-23%
Total other income (expense)	8,132,602	(429,157)	8,561,759	-1995%
Income (loss) before income taxes	(18,847,234)	45,635,795	(64,483,029)	-141%
Income tax provision (benefit)	(4,608,985)	8,977,231	(13,586,216)	-151%
Net income (loss)	$ (14,238,249)	$ 36,658,564	$ (50,896,813)	-139%

Revenues

For the year ended December 31, 2022, we generated $34.2 million of revenue compared to revenue of $97.9 million in the year ended December 31, 2021. The decrease in revenue of $63.7 million was primarily due to lower sales of our Logix Smart COVID-19 test throughout the world, which was developed in response to the current COVID-19 pandemic. As global attention and regulatory responses to the COVID-19 pandemic have eased, we have experienced significantly decreases in demand for our COVID-19 test. We anticipate that demand for our COVID-19 test will continue to normalize as concerns relating to COVID-19 further wane.

Cost of Revenues and Gross Profit

Cost of revenues decreased by $6.1 million from $11.6 million for the year ended December 31, 2021 to $5.5 million for the year ended December 31, 2022. The decrease in revenues combined with a larger percentage of fixed product manufacturing costs resulted in a lower cost of revenues and gross margin percentage. Our gross margin was 84.0% for the year ended December 31, 2022 compared to 88.2% for the year ended December 31, 2021.

Operating Expenses

We incurred total operating expenses of $55.7 million for the year ended December 31, 2022 compared to total operating expenses of $40.2 million for the year ended December 31, 2021. The increase in operating expenses was primarily due to the impairment of goodwill recorded in conjunction with the acquisitions of IdMo and ACI, increases in depreciation and amortization of capital and intangible assets, increased expenses related to personnel, including stock-based compensation, and increased investment in research and development, offset by decreased sales and marketing expenses, including third party sales commissions, in relation to the reduction of revenue.

Sales and marketing expenses for the year ended December 31, 2022 were $7.3 million compared to $13.4 million for the year ended December 31, 2021. The decrease of $6.1 million was primarily a result of decreased variable compensation, such as bonuses and commissions, and decreased third-party sales commissions, partially offset by increased stock-based compensation expense.

General and administrative expenses increased $2.7 million from $11.6 million for the year ended December 31, 2021 to $14.3 million for the year ended December 31, 2022. The increase in general and administrative expenses was primarily due to increased insurance expense and professional, legal, and advisory fees, as well as increased stock-based compensation expense, partially offset by decreased variable compensation expense.

Our research and development expenses increased by $2.4 million from $15.0 million for the year ended December 31, 2021, to $17.4 million for the year ended December 31, 2022. The primary increase in expenses related to increased personnel expenses in conjunction with our acquisitions of IdMo and ACI on December 31, 2021, the primary focus of which relates to the point-of-care device development, as well as increased stock-based compensation expense. Additionally, there has been an increase in professional and lab services utilized to further help us in our research and product development activities.

During the year ended December 31, 2022, the Company recognized impairment charges of $15,388,546 related to goodwill recorded in conjunction with the acquisitions of IdMo and ACI on December 31, 2021.

Other Income (Expense)

Other income was $8.1 million for the year ended December 31, 2022, compared to other expense of $0.4 million for the year ended December 31, 2021. The increase in other income of $8.6 million was primarily due to a change in the fair value of contingent consideration liabilities recorded in conjunction with the acquisitions of IdMo and ACI and driven by changes in the Company’s stock price, as well as increased interest income due to higher investment balances and interest rates in 2022 compared to 2021.

Net Income

We realized a net loss for the year ended December 31, 2022 of $14.2 million compared to net income of $36.7 million for the year ended December 31, 2021. The decrease in net income of $50.9 million was primarily the result of reduced sales of our Logix Smart COVID-19 test, increased operating expenses as discussed above, and impairment of the goodwill recorded in conjunction with the acquisitions of IdMo and ACI, partially offset by gains related to change in the fair value of acquisition related contingent liabilities. Additionally, we recorded an income tax benefit of $4.6 million during the year ended December 31, 2022, compared to income tax expense of $9.0 million for the year ended December 31, 2021.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2022, we had cash and cash equivalents of $23.0 million and marketable investment securities of $58.3 million. We consider our marketable investment securities an important part of our liquidity and focus such investments in securities that can readily be converted into cash if needed. Additionally, our total current assets at December 31, 2022, were $92.7 million compared to total current liabilities of $3.9 million.

Net cash provided by operating activities during the year ended December 31, 2022 was $6.6 million, compared to $41.1 million for the year ended December 31, 2021. The decrease in cash from operating activities was primarily due to our decreased revenue and accounts receivable.

We used $58.2 million of cash in investing activities during the year ended December 31, 2022 as compared to $4.1 million of cash from investing activities during the year ended December 31, 2021. The increase in cash used in investing activities is primarily due to purchases of marketable investment securities.

Net cash used in financing activities was $14.0 million for the year ended December 31, 2022, compared to $0.5 million of cash from financing activities for the year ended December 31, 2021. The decrease is primarily due to the repurchase of outstanding common shares during the current fiscal year.

Since commencing sales of our Logix Smart COVID-19 test in March 2020, we have used our cash generated from those sales to fund the purchase of inventories and the development of our point-of-care device, and to pay our operating expenses. We have increased our work force most significantly in research and development in order to continue development of a new device and additional tests that will enable continued use of our distributor network to sell additional products throughout the world.

We believe that our existing capital resources and the cash generated from future sales will be sufficient to meet our projected operating requirements for the next 12 months. However, our available capital resources may be consumed more rapidly than currently expected and we may need or want to raise additional financing for strategic opportunities. If needed, we expect additional investment capital to come from (i) additional issuances of our common stock with existing and new investors or (ii) the private placement of other securities with investors similar to those that have provided funding in the past. We may not be able to secure such financing in a timely manner or on favorable terms, if at all.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in Item 8 of this Annual Report on Form 10-K, within Note 2 of our consolidated financial statements in the section titled "Summary of Significant Accounting Policies", we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount, net of any allowance. The Company maintains an allowance for doubtful accounts for amounts the Company does not expect to collect. In establishing the required allowance, management considers historical losses, current market condition, customers' financial condition, the age of receivables, and current payment patterns. Account balances are written off against the allowance once the receivable is deemed uncollectible. If actual accounts receivable collections are less favorable than those projected by management at the time of the assessment, however, additional accounts receivable write-downs may be required, which could reduce our earnings.

Goodwill and Intangible Assets

The useful lives of intangible assets with definite lives are based on the expected number of years the asset will generate revenue or otherwise be used by us and the related amortization is based on the straight-line method. Goodwill, which has an indefinite life, is not amortized but instead is tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- any volatility or significant decline in our stock price and market capitalization compared to our net book value;
- loss of legal ownership or title to an asset;
- significant changes in our strategic business objectives and utilization of our assets; and
- the impact of significant negative industry or economic trends.

If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase. For goodwill, the entity has the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. The quantitative impairment test compares the fair value of a reporting unit with the carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is recorded. We completed our annual evaluation for impairment of goodwill as of December 31, 2022 and recorded a goodwill impairment charge of $15,388,546.

Accounting for Business Combinations

Under the acquisition method of accounting, the cost of an acquired business is assigned to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of the estimated fair values at the date of acquisition. We assess fair value, which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, using a variety of methods including, but not limited to, an income approach and a market approach, such as the estimation of future cash flows of the acquired business and current selling prices of similar assets. These valuations require us to make estimates and assumptions, especially with respect to intangible assets. Fair value of the assets acquired and liabilities assumed, including intangible assets, in-process research and development, and contingent payments, are measured based on the assumptions and estimations with regards to variable factors such as the amount and timing of future cash flows for the asset or liability being measured, appropriate risk-adjusted discount rates, or other factors that market participants would consider. Upon acquisition, we determine the estimated economic lives of the acquired intangible assets for amortization purposes, which are based on the underlying expected cash flows of such assets. Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that is not individually identified and separately recognized. Actual results may vary from projected results and assumptions used in the fair value assessments. If the initial accounting for a business combination is incomplete by the end of a reporting period that falls within the measurement period, we report provisional amounts in our financial statements. During the measurement period, we adjust the provisional amounts recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. We record these adjustments to the provisional amounts with a corresponding offset to goodwill. Any adjustments identified after the measurement period are recorded in the Consolidated Statements of Operations and Comprehensive Income (Loss).

Inventories

We periodically review inventory for both potential obsolescence and potential declines in anticipated selling prices. In this review, we make assumptions about the future demand for and market value of the inventory and based on these assumptions estimate the amount of any obsolete, unmarketable, slow moving or overvalued inventory. We write down the value of our inventories by an amount equal to the difference between the cost of the inventory and the net realizable value. If actual market conditions are less favorable than those projected by management at the time of the assessment, however, additional inventory write-downs may be required, which could reduce our earnings.

Income Taxes

Significant judgment is required in determining our provision for income taxes, current tax assets and liabilities, deferred tax assets and liabilities, and our future taxable income, both as a whole and in various tax jurisdictions, for purposes of assessing our ability to realize future benefit from our deferred tax assets. We recognize in the financial statements the impact of a tax position if that position is more likely than not to be sustained during an audit, including resolution of related appeals or litigation processes, if any. While we believe that we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcome of examinations by tax authorities in determining the adequacy of our provision for income taxes. See Note 12 to our Consolidated Financial Statements for more information on income taxes.

The foregoing estimates, expectations and forward-looking statements are subject to change as we make strategic operating decisions from time to time and as our revenue and expenses fluctuate from period to period.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2022 AND 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Co-Diagnostics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Co-Diagnostics, Inc (the Company) as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Goodwill and Intangible Assets

As discussed in Note 4 and in Note 7 to the consolidated financial statements, the Company acquired Idaho Molecular, Inc., and Advanced Conceptions, Inc. in December 2021. As part of the transaction, the Company acquired intangible assets totaling $27,195,000, and goodwill totaling $15,388,546. The Company assesses these assets for impairment at least annually or whenever events or changes in circumstances occur that may indicate impairment. The Company's analysis for the year ended December 31, 2022, required significant judgment to create a valuation based on future cash flows. As a result of their analysis, the Company fully impaired its goodwill, while no impairment was recorded for the intangible assets.

We identified the carrying amount of goodwill and intangible assets as a critical audit matter because management's assessment of the acquisition is highly subjective. This required an increased amount of effort, including the need to involve our internal valuation specialist, when performing audit procedures to evaluate the reasonableness of management's estimates and assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, gaining an understanding of management's process for developing the fair value estimate. We also evaluated the expertise, qualifications, and independence of management's specialist engaged to complete the evaluation. We used professionals inside our firm with specialized skills and knowledge to assess the Company's methodology. We considered the inputs, sources of data used, assumptions, and estimates used in the valuation model. We tested the mathematical accuracy of the underlying schedules used in the valuation assessment to ensure the completeness and accuracy of the reports. Finally, we considered the sensitivity of changes to key assumptions in the model.

/s/ Haynie & Company
Salt Lake City, Utah
March 16, 2023

We have served as the Company's auditor since 2016.

CO-DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 22,973,803	$ 88,607,234
Marketable investment securities	58,289,066	1,255,266
Accounts receivable, net	3,453,723	20,839,182
Inventory	5,310,473	2,004,169
Income taxes receivable	1,870,419	-
Prepaid expenses and other current assets	761,186	2,338,444
Note receivable	75,000	75,000
Total current assets	92,733,670	115,119,295
Property and equipment, net	2,539,483	1,933,216
Operating lease right-of-use asset	372,115	-
Goodwill	-	14,706,818
Intangible assets, net	26,768,333	27,195,000
Investment in joint venture	672,679	1,004,953
Note receivable	-	75,000
Total assets	$ 123,086,280	$ 160,034,282
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 952,297	$ 607,506
Accrued expenses, current	934,447	3,859,652
Operating lease liability, current	297,209	-
Contingent consideration liabilities, current	1,689,471	5,767,304
Income taxes payable	-	2,213,088
Deferred revenue	-	150,000
Total current liabilities	3,873,424	12,597,550
Long-term liabilities		
Income taxes payable	1,181,284	1,067,853
Deferred tax liability	2,417,987	7,228,444
Operating lease liability	50,708	-
Contingent consideration liabilities	1,042,885	4,665,337
Total long-term liabilities	4,692,864	12,961,634
Total liabilities	8,566,288	25,559,184
Commitments and contingencies (Note 13)		
Stockholders' equity		
Convertible preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized; 34,754,265 shares issued and 30,872,607 shares outstanding as of December 31, 2022 and 33,819,862 shares issued and outstanding as of December 31, 2021	34,754	33,820
Treasury stock, at cost; 3,881,658 and 0 shares held as of December 31, 2022 and December 31, 2021, respectively	(14,211,866)	-
Additional paid-in capital	88,472,934	80,271,999
Accumulated other comprehensive income	293,140	-
Accumulated earnings	39,931,030	54,169,279
Total stockholders' equity	114,519,992	134,475,098
Total liabilities and stockholders' equity	$ 123,086,280	$ 160,034,282

See accompanying notes to consolidated financial statements.

CO-DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	Years Ended December 31,	
	2022	**2021**
Revenue	$ 34,218,209	$ 97,885,603
Cost of revenue	5,481,092	11,574,944
Gross profit	28,737,117	86,310,659
Operating expenses		
Sales and marketing	7,344,628	13,397,813
General and administrative	14,262,963	11,550,615
Research and development	17,438,098	14,961,916
Depreciation and amortization	1,282,718	335,363
Goodwill impairment charges	15,388,546	-
Total operating expenses	55,716,953	40,245,707
Income (loss) from operations	(26,979,836)	46,064,952
Other income (expense)		
Interest income	704,044	45,631
Loss on disposition of assets	(138,117)	(44,355)
Gain on remeasurement of acquisition contingencies	7,899,644	-
Loss on equity method investment in joint venture	(332,969)	(430,433)
Total other income (expense)	8,132,602	(429,157)
Income (loss) before income taxes	(18,847,234)	45,635,795
Income tax provision (benefit)	(4,608,985)	8,977,231
Net income (loss)	$ (14,238,249)	$ 36,658,564
Other comprehensive income		
Change in net unrealized gains on marketable securities, net of tax	$ 293,140	$ -
Total other comprehensive income	$ 293,140	$ -
Comprehensive income (loss)	$ (13,945,109)	$ 36,658,564
Earnings per common share:		
Basic	$ (0.45)	$ 1.27
Diluted	$ (0.45)	$ 1.23
Weighted average shares outstanding:		
Basic	31,479,028	28,874,555
Diluted	31,479,028	29,903,686

See accompanying notes to consolidated financial statements.

CO-DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Earnings	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
Balance as of December 31, 2020	-	$ -	28,558,033	$ 28,558	$ -	$49,157,236	$ -	$ 17,510,715	$ 66,696,509
Common stock issued for option exercises	-	-	189,225	189		450,209	-	-	450,398
Stock-based compensation expense	-	-	444,050	444		5,508,960	-	-	5,509,404
Common stock issued for acquisitions	-	-	4,628,554	4,629		25,155,594	-	-	25,160,223
Net income	-	-	-	-		-	-	36,658,564	36,658,564
Balance as of December 31, 2021	-	$ -	33,819,862	$ 33,820	$ -	$80,271,999	$ -	$ 54,169,279	$ 134,475,098
Common stock issued for option exercises	-	-	70,791	70	-	77,800	-	-	77,870
Common stock issued for warrant exercises	-	-	50,000	50	-	99,950	-	-	100,000
Stock-based compensation expense	-	-	725,166	725	-	7,542,498	-	-	7,543,223
Common stock issued for acquisitions	-	-	88,446	89	-	480,687	-	-	480,776
Repurchases of common stock	-	-	-	-	(14,211,866)	-	-	-	(14,211,866)
Other comprehensive income, net of tax	-	-	-	-	-	-	293,140	-	293,140
Net income	-	-	-	-	-	-	-	(14,238,249)	(14,238,249)
Balance as of December 31, 2022	-	$ -	34,754,265	$ 34,754	$(14,211,866)	$88,472,934	$ 293,140	$ 39,931,030	$ 114,519,992

See accompanying notes to consolidated financial statements.

CO-DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net income	$ (14,238,249)	$ 36,658,564
Adjustments to reconcile net income to cash used in operating activities:		
Depreciation and amortization	1,282,718	335,363
Goodwill impairment charges	15,388,546	-
Stock-based compensation expense	7,543,223	5,509,404
Change in fair value of acquisition contingencies	(7,899,644)	-
Non-cash lease expense	30,430	-
Loss from equity method investment	332,969	430,433
Loss on disposition of assets	138,117	44,355
Deferred income taxes	(4,810,457)	930,081
Bad debt expense	2,428,930	69,672
Changes in assets and liabilities:		
Accounts receivable	14,956,529	(8,740,851)
Prepaid expenses	(224,094)	(2,049,095)
Inventory	(3,525,210)	5,705,361
Deferred revenue	(150,000)	(155,307)
Income taxes payable	(2,201,250)	2,643,381
Accounts payable, accrued expenses and other liabilities	(2,483,821)	(299,937)
Net cash provided by operating activities	6,568,737	41,081,424
Cash flows from investing activities		
Purchases of property and equipment	(1,427,512)	(669,463)
Proceeds from maturities of marketable investment securities	11,255,266	3,080,180
Purchases of marketable securities	(67,995,926)	-
Investment in joint venture	-	491,739
Business combinations, net of cash acquired	-	1,196,243
Net cash (used in) provided by investing activities	(58,168,172)	4,098,699
Cash flows from financing activities		
Proceeds from exercise of options and warrants	177,870	450,398
Repurchases of common stock	(14,211,866)	-
Net cash (used in) provided by financing activities	(14,033,996)	450,398
Net increase in cash and cash equivalents	(65,633,431)	45,630,521
Cash and cash equivalents at beginning of period	88,607,234	42,976,713
Cash and cash equivalents at end of period	$ 22,973,803	$ 88,607,234
Supplemental disclosure of cash flow information		
Interest paid	$ -	$ -
Income taxes paid	$ 4,498,742	$ 5,403,769
Supplemental disclosure of non-cash investing and financing transactions		
Inventory moved to property, plant and equipment	$ 218,906	$ 285,659
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 681,327	$ -
Business acquisition measurement period adjustments	$ 1,593	$ -
Fair value of common stock issued as consideration for business acquisitions	$ 480,776	$ 25,160,223
Fair value of contingent common stock issued as consideration for business acquisitions	$ 199,359	$ 10,432,641

See accompanying notes to consolidated financial statements.

Note 1 – Overview and Basis of Presentation

Description of Business

Co-Diagnostics, Inc., a Utah corporation (the "Company" or "CODX"), is developing robust and innovative molecular tools for detection of infectious diseases, liquid biopsy for cancer screening, and agricultural applications. The Company develops, manufactures, and sells reagents used for diagnostic tests that function via the detection and/or analysis of nucleic acid molecules (DNA or RNA), including robust and innovative molecular tools for detection of infectious diseases, liquid biopsy for cancer screening, and agricultural applications. In connection with the sale of our tests we may sell diagnostic equipment from other manufacturers as self-contained lab systems.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Such estimates include receivables and other long-lived assets, legal and regulatory contingencies, income taxes, share based arrangements, and others. These estimates and assumptions are based on management's best estimates and judgments. Actual amounts and results could differ from those estimates.

Basis of Presentation

The accompanying audited consolidated financial statements of Co-Diagnostics, Inc. and its wholly owned subsidiaries have been prepared to reflect the financial position, results of operations and cash flows of the Company and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All intercompany balances and transactions have been eliminated.

Note 2 – Summary of Significant Accounting Policies

Cash and Cash Equivalents

Cash and cash equivalents consist of cash on hand, money market funds and highly liquid investments with an original maturity date of 90 days or less from the date of purchase. The fair value of cash equivalents approximated their carrying value as of December 31, 2022 and December 31, 2021. The Company has its cash and cash equivalents with a large creditworthy financial institution and the balance exceeded federally insured limits. The Company has not experienced any losses in such accounts, and management believes the Company is not exposed to any significant credit risk on cash and cash equivalents.

Marketable Investment Securities

The Company's marketable investment securities are comprised of investments in certificates of deposit and U.S. Treasury bills and notes. The Company designates investments in debt securities as available-for-sale. Available-for-sale debt securities with original maturities of three months or less from the date of purchase are classified within cash and cash equivalents. Available-for-sale debt securities with original maturities longer than three months are available to fund current operations and are classified as marketable investment securities, within current assets on the consolidated balance sheets. The Company may sell these securities at any time for use in its current operations or for other purposes, even prior to maturity. Available-for-sale debt securities are reported at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity, net of tax. Realized gains and losses on the sale of marketable securities are determined using the average cost method on a first-in, first-out basis and recorded in total other income (expense), net in the condensed consolidated statements of operations and comprehensive income.

The available-for-sale debt securities are subject to a periodic impairment review. For investments in an unrealized loss position, the Company writes down the amortized cost basis of the investment if it is more likely than not that the Company will be required or will intend to sell the investment before recovery of its amortized cost basis. For investments not likely to be sold before recovery of the amortized cost basis, the Company determines whether a credit loss exists by considering information about the collectability of the instrument, current market conditions, and reasonable and supportable forecasts of economic conditions. The Company recognizes an allowance for credit losses up to the amount of the unrealized loss when appropriate. Allowances for credit losses and write-downs are recognized in total other income (expense), net, and unrealized losses not related to credit losses are recognized in accumulated other comprehensive income (loss). There are no allowances for credit losses recorded for the periods presented.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount (net of allowance) and do not bear interest. The Company maintains an allowance for doubtful accounts for amounts the Company does not expect to collect. In establishing the required allowance, management considers historical losses, current market condition, customers' financial condition, the age of receivables, and current payment patterns. Account balances are written off against the allowance once the receivable is deemed uncollectible. Recoveries of trade receivables previously written off are recorded when collected. At December 31, 2022 total accounts receivable was $6,552,249 with an allowance for uncollectable accounts of $3,098,526 resulting in a net amount of $3,453,723. At December 31, 2021 total accounts receivable was $21,508,779 with an allowance for uncollectable accounts of $669,597 resulting in a net amount of $20,839,182.

Equity-Method Investments

Our equity method investments are initially recorded at cost and are included in other long-term assets in the accompanying consolidated balance sheet. We adjust the carrying value of our investment based on our share of the earnings or losses in the periods which they are reported by the investee until the carrying amount is zero. The earnings or losses are included in other income (expense) in the accompanying consolidated statements of operations.

Inventory

Inventory is stated at the lower of cost or net-realizable value. Inventory cost is determined on a first-in first-out basis that approximates average cost in accordance with ASC 330-10-30-12. At December 31, 2022, the Company had $5,310,473 in inventory, of which $1,327,264 was finished goods and $3,983,209 was raw materials. At December 31, 2021, the Company had $2,004,169 in inventory, of which $983,088 was finished goods and $1,021,081 was raw materials. The Company establishes reserves to reduce low-moving, obsolete, or unusable inventories to their estimated useful or scrap values.

Goodwill and Intangible Assets

Goodwill represents the excess of the purchase price and related costs over the value assigned to net tangible and identifiable intangible assets acquired in business combinations. Goodwill and indefinite-lived intangible assets are not amortized, but rather tested for impairment at least annually on December 31, or more often if and when circumstances indicate that the carrying value may not be recoverable. Finite-lived intangible assets are amortized over their useful lives.

During the year ended December 31, 2022, the Company recognized impairment charges related to goodwill of $15,388,546.

Long-lived Assets

Long-lived assets, such as property and equipment, are stated at cost less accumulated depreciation and amortization. Depreciation is provided using the straight-line method over the estimated useful lives of the property, generally from three to five years. Repairs and maintenance costs are expensed as incurred except when such repairs significantly add to the useful life or productive capacity of the asset, in which case the repairs are capitalized.

The Company reviews its long-lived assets, including property and equipment, finite-lived intangible assets, and ROU assets, for impairment whenever an event or change in facts and circumstances indicates that their carrying amounts may not be recoverable. Recoverability of these assets is measured by comparing the carrying amount to the estimated undiscounted future cash flows expected to be generated. If the carrying amount exceeds the undiscounted cash flows, the assets are determined to be impaired and an impairment charge is recognized as the amount by which the carrying amount exceeds fair value.

Business Combinations

We estimate the fair value of assets acquired and liabilities assumed in a business combination. Goodwill as of the acquisition date is measured as the excess of consideration transferred over the net of the acquisition date fair values of the assets acquired and the liabilities assumed. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Management’s estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable, and as a result, actual results may differ from estimates.

Revenue Recognition

The Company generates revenue from product sales and license sales. The Company recognizes revenue when all of the following criteria are satisfied: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as the Company satisfies each performance obligation. Based on the criteria above, the Company typically recognizes revenue upon delivery.

The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. The Company records any payments received from customers prior to the Company fulfilling its performance obligation(s) as deferred revenue.

Deferred Revenue

Deferred revenue primarily consists of payments received from customers prior to the Company fulfilling its performance obligation of providing the product. When this occurs, the Company records a contract liability as deferred revenue. Deferred revenue is recognized as revenue as the related performance obligations are satisfied.

Research and Development

Research and development costs are expensed when incurred. The Company expensed $17,438,098 and $14,961,916 of research and development costs for the years ended December 31, 2022 and 2021, respectively.

Stock-based Compensation

The Company has granted stock-based awards, including restricted stock, stock options, stock warrants and restricted stock units (“RSUs”), to its employees, certain consultants and members of its board of directors. The Company records stock-based compensation based on the grant date fair value of the awards and recognizes the fair value of those awards as expense using the straight-line method over the requisite service period of the award. The Company estimates the grant date fair value of stock options using the Black-Scholes option-pricing model. When an award is forfeited prior to the vesting date, the Company recognizes an adjustment for the previously recognized expense in the period of the forfeiture.

Income Taxes

The Company accounts for income taxes in accordance with the liability method of accounting for income taxes. Under this method, deferred income tax assets and deferred income tax liabilities represent the tax effect of temporary differences between financial reporting and tax reporting measured at enacted tax rates in effect for the year in which the differences are expected to reverse. The Company recognizes only the impact of tax positions that, based on their technical merits, are more likely than not to be sustained upon an audit by the taxing authority.

Valuation allowances are provided when it is more-likely-than-not that some or all of the deferred income tax assets may not be realized. In assessing the need for a valuation allowance, the Company has considered its historical levels of income, expectations of future taxable income and ongoing tax planning strategies.

Developing the provision for income taxes, including the effective tax rate and analysis of potential tax exposure items, if any, requires significant judgment and expertise in federal and state income tax laws, regulations and strategies, including the determination of deferred income tax assets and liabilities and any estimated valuation allowances deemed necessary to value deferred income tax assets. Judgments and tax strategies are subject to audit by various taxing authorities. The Company has uncertain income tax positions in the consolidated financial statements, and adverse determinations by these taxing authorities could have a material adverse effect on the consolidated financial positions, result of operations, or cash flows.

Net Income per Share

Basic net income or loss per common share is computed by dividing net income or loss applicable to common shareholders by the weighted average number of shares outstanding during each period.

Diluted net income or loss per share is computed by dividing net income or loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period increased by common shares that could be issued upon conversion or exercise of other outstanding securities to the extent those additional common shares would be dilutive. The dilutive effect of potentially dilutive securities is reflected in diluted net income or loss per share by application of the treasury stock method. During periods when the Company is in a net loss position, basic net loss per share is the same as diluted net loss per share as the effects of potentially dilutive securities are anti-dilutive.

Comprehensive Income

Comprehensive income is comprised of unrealized gains and losses on marketable securities, net of income taxes.

Concentrations Risk and Significant Customers

The Company had certain customers which are each responsible for generating 10% or more of the total revenue for the years ended December 31, 2022 and 2021. One customer accounted for approximately 37% and two customers together accounted for approximately 48% of total revenue for the years ended December 31, 2022 and 2021, respectively.

Three customers accounted for more than 10% of accounts receivable, and two customers each accounted for more than 10% of accounts receivable, at December 31, 2022 and 2021, respectively. These customers together accounted for approximately 61% and 66% of accounts receivable at December 31, 2022 and 2021, respectively.

Recently Issued Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") that are adopted by the Company as of the specified effective date. If not discussed, management believes that the impact of recently issued standards, which are not yet effective, will not have a material impact on the Company's financial statements upon adoption.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326) ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for certain financial instruments, which includes the Company's accounts receivable. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. The Company adopted ASU 2016-13 on January 1, 2022. The adoption did not have an impact on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which requires a lessee to recognize most leases on the balance sheet as lease liabilities with corresponding right-of-use assets. The objective of ASU 2016-02 is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The recognized lease liabilities and lease assets represent the obligation to make payments and the right to use or control the use of a specified asset for the lease term, respectively.

On January 1, 2022, the Company adopted Topic 842 using the modified retrospective approach with the effective date as the date of initial application. Consequently, results for the year ended December 31, 2022 are presented under Topic 842. No prior period amounts were adjusted and continue to be reported in accordance with previous lease guidance, ASC Topic 840, Leases. The Company elected the practical expedients available under the provisions of the new standard, including not reassessing whether expired or existing contracts are or contain leases; not reassessing the classification of expired or existing leases; and not reassessing the initial direct cost for any existing leases. Upon adoption, the Company recognized an operating lease liability of $626,699 and a corresponding operating right-of-use asset of $681,327.

Note 3 - Cash, Cash Equivalents, and Financial Instruments

The following table shows the Company's cash, cash equivalents, and marketable investment securities by significant investment category as of December 31, 2022:

	December 31, 2022					
	Adjusted Cost	Allowance for Credit Losses	Total Unrealized Gains / (Losses)	Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	$12,834,444	$ -	$ -	$12,834,444	$ 12,834,444	$ -
Level 1:						
Money market funds	146,359	-	-	146,359	146,359	-
Subtotal	146,359	-	-	146,359	146,359	-
Level 2:						
U.S. treasury securities	67,892,825	-	389,241	68,282,066	9,993,000	58,289,066
Subtotal	67,892,825	-	389,241	68,282,066	9,993,000	58,289,066
Total	$80,873,628	$ -	$ 389,241	$81,262,869	$ 22,973,803	$58,289,066

Marketable investment securities held as of December 31, 2022 mature over the next 12 months.

Note 4 – Business Combinations

On December 31, 2021, the Company completed its acquisitions of Advanced Conceptions, Inc. ("ACI") and Idaho Molecular, Inc. ("IdMo"), which were related entities developing, with the Company, an at-home/point-of-care medical diagnostic device. Upon the completion of the acquisition, all outstanding ACI and IdMo common stock was initially exchanged for approximately 3.2 million shares of the Company's common stock and contingent consideration that includes up to approximately 1.4 million shares and approximately 456,000 warrants to purchase shares of the Company's common stock. The contingent consideration is based on the achievement of certain milestones, which include regulatory approval for identified products, as well as production and net revenue targets. Upon the completion of the acquisition, both ACI and IdMo became 100% wholly-owned subsidiaries of the Company.

The fair value of assets acquired and liabilities assumed was based on a preliminary valuation, with estimates and assumptions subject to change within the measurement period. During 2022, the Company finalized negotiations that were ongoing as of December 31, 2021 with one remaining shareholder of ACI, which resulted in an increase to the purchase consideration of $580,135. Additionally, there was an increase of $101,593 in the estimated tax liabilities that resulted from the acquisition. Due to the change in purchase consideration and estimated tax liabilities, a measurement period adjustment was recorded, resulting in an increase to goodwill of $681,728.

Following the resolution with the remaining shareholder, the total number of shares exchanged as purchase consideration was approximately 3.3 million shares. Additionally, the updated purchase consideration includes contingent consideration of up to approximately 1.4 million shares and 465,000 warrants to purchase shares of the Company's common stock.

In addition, the adjustments to the provisional purchase consideration amount resulted in an increase in the gain on remeasurement of acquisition contingencies of $78,617.

The total purchase consideration, including adjustment during the measurement period, was allocated to the assets acquired and liabilities assumed as set forth below:

	Amounts Recognized as of Acquisition Date (as previously reported)	Measurement Period Adjustments	Amounts Recognized as of Acquisition Date (as adjusted)
Purchase Consideration			
Fair value of common shares issued	$ 25,160,223	$ 480,776	$ 25,640,999
Payable to shareholder	100,000	(100,000)	-
Fair value of contingent shares	8,684,669	165,957	8,850,626
Fair value of contingent warrants	1,747,972	33,402	1,781,374
Total fair value of consideration transferred	$ 35,692,864	$ 580,135	$ 36,272,999
Identifiable assets acquired and liabilities assumed			
Cash	$ 1,196,243	$ -	$ 1,196,243
Accounts receivable	31,170	-	31,170
Prepaid expenses and other current assets	70,321	-	70,321
Property and equipment	408,173	-	408,173
Technology - In-process research and development	26,101,000	-	26,101,000
Non-competition agreements	1,094,000	-	1,094,000
Accounts payable and accrued other expenses	(1,069,274)	(101,593)	(1,170,867)
Deferred tax liability	(6,845,587)	-	(6,845,587)
Total identifiable net assets	20,986,046	(101,593)	20,884,453
Goodwill	14,706,818	681,728	15,388,546
Total	$ 35,692,864	$ 580,135	$ 36,272,999

The in-process research and development is considered an indefinite-lived intangible until the completion or abandonment of the research and development activities. The non-competition agreements are being amortized over a range of 1.5 to 3 years.

Note 5 – Fair Value Measurements

The Company measures and records certain financial assets and liabilities at fair value on a recurring basis. Fair value is based on the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The following three levels of inputs are used to measure the fair value of financial assets and liabilities:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

The following table summarizes the assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 and December 31, 2021, by level within the fair value hierarchy:

	December 31, 2022			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash equivalents	$ -	$ 10,179,667	$ -	$ 10,179,667
Marketable securities (U.S. treasury bills and notes)	-	58,289,066	-	58,289,066
Total assets measured at fair value	$ -	$ 68,468,733	$ -	$ 68,468,733
Liabilities:				
Contingent consideration - common stock	$ -	$ -	$ 2,499,147	$ 2,499,147
Contingent consideration - warrants	-	-	233,209	233,209
Total liabilities measured at fair value	$ -	$ -	$ 2,732,356	$ 2,732,356

	December 31, 2021			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Marketable securities (certificates of deposit)	$ -	$ 1,255,266	$ -	$ 1,255,266
Total assets measured at fair value	$ -	$ 1,255,266	$ -	$ 1,255,266
Liabilities:				
Contingent consideration - common stock	$ -	$ -	$ 8,684,669	$ 8,684,669
Contingent consideration - warrants	-	-	1,747,972	1,747,972
Total liabilities measured at fair value	$ -	$ -	$ 10,432,641	$ 10,432,641

The Company’s financial instruments that are measured at fair value on a recurring basis consist of certificates of deposit and U.S. treasury bills and notes as of December 31, 2021 and 2022, respectively.

In connection with the acquisitions of IdMo and ACI on December 31, 2021, the Company recorded a liability for contingent consideration in the form of shares of common stock and warrants to purchase common stock. The fair value of contingent consideration is calculated using a discounted probability weighted valuation model. Discount rates used in such calculations are a significant assumption that are not observed in the market, and therefore, the resulting fair value represents a Level 3 measurement.

The changes for Level 3 items measured at fair value on a recurring basis are as follows:

Fair value as of December 31, 2021	$ 10,432,641
Change in contingent purchase consideration for measurement period adjustments	199,359
Change in fair value of contingent consideration issued for business acquisitions	(7,899,644)
Fair value as of December 31, 2022	$ 2,732,356

The fair value of the contingent consideration is based on the fair value of the contingent consideration-common stock and contingent consideration-warrants. The fair value of the contingent consideration-common stock is equal to the probability-adjusted value of the Company's common stock as of the valuation date. The fair value of the contingent consideration-warrants is equal to the probability adjusted value of a call option with terms consistent with the terms of the warrants as of the valuation date. Prior to the probability adjustments, the warrants were valued based on the following inputs:

	December 31, 2022	December 31, 2021
Stock price	$ 2.52	$ 8.93
Strike price	$ 9.13	$ 9.13
Volatility	75.00%	80.00%
Risk-free rate	4.10%	1.30%
Expected term	4.0	5.0

In order to calculate the probability-adjusted value of the contingent consideration-common stock and contingent consideration-warrants, the Company estimated the probability as of the valuation date of achieving certain milestones, which include regulatory approval for identified products, as well as production and net revenue targets. The probability of achieving the milestone related to net revenues was estimated as of the acquisition date using a Monte Carlo simulation valuation model. Significant inputs other than the fair value assumptions noted above were consistent as of the valuation date. The unobservable significant inputs to the valuation model were as follows:

	December 31, 2022	December 31, 2021
Stock price	$ 2.52	$ 8.93
Risk-free rate	4.10%	1.30%
Expected term	4.0	5.0
Weighted-average cost of capital	27.00%	27.00%
Revenue discount rate	9.50%	9.50%
Equity volatility	75.00%	80.00%
Asset volatility	80.00%	80.00%
Revenue volatility	30.00%	30.00%

Fair Value of Other Financial Instruments

The carrying amounts of certain financial instruments, including cash held in banks, accounts receivable, notes receivable, accounts payable, accrued liabilities, and other liabilities approximate fair value due to their short-term maturities and are excluded from the fair value tables above.

Note 6 – Property and Equipment

Property and equipment, net consisted of the following:

	Estimated Useful Lives in years	December 31, 2022	December 31, 2021
Lab equipment	3 - 5	$ 3,574,730	$ 2,476,813
Leasehold improvements	0 -3	224,957	3,157
Office equipment, furniture and other	2 - 5	112,044	75,401
Less accumulated depreciation and amortization		(1,372,248)	(622,155)
Fixed assets, net		$ 2,539,483	$ 1,933,216

Note 7 - Goodwill and Intangible Assets

Goodwill

Goodwill represents the excess of purchase price and related costs over the value assigned to net tangible and identifiable intangible assets acquired in business combinations. The following table presents the changes in the carrying amount of goodwill for the year ended December 31, 2022:

Balance as of December 31, 2021	$ 14,706,818
Measurement period adjustments	681,728
Goodwill impairment charges	(15,388,546)
Balance as of December 31, 2022	$ -

The Company assesses goodwill for impairment at the reporting unit level on an annual basis, or whenever events or changes in circumstances occur that indicate that the fair value of a reporting unit is below its carrying amount. The Company estimates the fair value of its reporting unit by using forecasts of discounted future cash flows and peer market multiples. If the fair value is less than the carrying value, impairment will be recognized in the amount by which the carrying value exceeds the fair value. The Company performed a qualitative and quantitative goodwill impairment assessment as of December 31, 2022. Based on the impairment assessment performed the Company concluded that it was more likely than not that the fair value of the Company's reporting unit was less than it's carrying amount. Accordingly, the Company recorded an impairment charge to reduce the carrying value of goodwill to $0.

Intangible Assets, Net

Intangible assets, net consisted of the following:

	December 31, 2022			
	Weighted-Average Useful Life (1) (in Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
In-process research and development	Indefinite	$ 26,101,000	$ -	$ 26,101,000
Non-competition agreements	2.7	1,094,000	(426,667)	667,333
Total intangible assets		$ 27,195,000	$ (426,667)	$ 26,768,333

	December 31, 2021			
	Weighted-Average Useful Life (1) (in Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
In-process research and development	Indefinite	$ 26,101,000	$ -	$ 26,101,000
Non-competition agreements	2.7	1,094,000	-	1,094,000
Total intangible assets		$ 27,195,000	$ -	$ 27,195,000

The expected future annual amortization expense of the Company's intangible assets held as of December 31, 2022 is as follows:

Year Ending December 31,	Amortization Expense
2023	364,668
2024	302,665
Total	$ 667,333

Note 8 - Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2022	December 31, 2021
Payroll liabilities	$ 428,354	$ 2,455,694
Distributor commissions	159,725	509,500
Other accrued liabilities	346,368	894,458
Total accrued expenses	$ 934,447	$ 3,859,652

Note 9 – Revenue

The following table sets forth revenue by geographic area:

	Years Ended December 31,	
	2022	2021
United States	$ 24,671,554	$ 52,185,812
Rest of World	9,546,655	45,699,791
Total	$ 34,218,209	$ 97,885,603
Percentage of revenue by area:		
United States	72%	53%
Rest of World	28%	47%

Deferred Revenue

Changes in the Company's deferred revenue balance for the years ended December 31, 2022 and 2021 were as follows:

Balance as of December 31, 2020	305,307
Revenue recognized included in deferred revenue balance at the beginning of the period	(256,110)
Increase due to prepayments from customers	79,213
Increase due to note receivable	150,000
Decrease due to refunds to customers and application to open balances	(128,410)
Balance as of December 31, 2021	$ 150,000
Revenue recognized included in deferred revenue balance at the beginning of the period	(150,000)
Balance as of December 31, 2022	$ -

Note 10 – Earnings per Share

The following table reconciles the numerator and the denominator used to calculate basic and diluted earnings per share for years ended December 31, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
Numerator		
Net income, as reported	$ (14,238,249)	$ 36,658,564
Denominator		
Weighted average shares, basic	31,479,028	28,874,555
Dilutive effect of stock options, warrants and RSUs	-	1,029,131
Shares used to compute diluted earnings per share	31,479,028	29,903,686
Basic earnings per share	$ (0.45)	$ 1.27
Diluted earnings per share	$ (0.45)	$ 1.23

For the year ended December 31, 2021, potentially dilutive securities of 154,644 were excluded from the computation of diluted earnings per share because the effect would have been anti-dilutive. The computation of diluted earnings per share for the years ended December 31, 2022 and December 31, 2021 also excludes the approximately 1.4 million shares of common stock and approximately 465,000 warrants to purchase shares of common stock mentioned in Note 4 that are contingent upon the achievement of certain milestones.

As a result of incurring a net loss for the year ended December 31, 2022, no potentially dilutive securities are included in the calculation of diluted earnings per share because such effect would be anti-dilutive. The Company had potentially dilutive securities as of December 31, 2022, consisting of: (i) 1,443,238 restricted stock units and (ii) 50,000 options.

Note 11 – Stock-Based Compensation

Stock Incentive Plans

The Company's board of directors adopted, and shareholders approved, the Co-Diagnostics, Inc. Amended and Restated 2015 Long Term Incentive Plan (the "Incentive Plan") providing for the issuance of stock-based incentive awards to employees, officers, consultants, directors and independent contractors. On August 31, 2022 the shareholders approved an increase in the number of awards available for issuance under the Incentive Plan to an aggregate of 12,000,000 shares of common stock. The number of awards available for issuance under the Incentive Plan was 6,210,790 at December 31, 2022.

Stock Options

The following table summarizes option activity during the years ended December 31, 2022 and 2021:

	Number of Options	Weighted Average Exercise Price	Weighted Average Fair Value	Weighted Average Remaining Contractual Life (Years)
Outstanding at December 31, 2020	1,300,588	$ 2.44	$ 1.24	
Granted	-	-	-	
Expired	-	-	-	
Forfeited/Cancelled	-	-	-	
Exercised	(189,225)	2.38	1.12	
Outstanding at December 31, 2021	1,111,363	$ 2.12	$ 1.31	
Granted	-	-	-	
Expired	-	-	-	
Forfeited/Cancelled	-	-	-	
Exercised	(70,791)	1.10	0.51	
Outstanding at December 31, 2022	1,040,572	$ 2.19	$ 1.37	5.88
Exercisable at December 31, 2022	1,040,572	$ 2.19	$ 1.37	5.88

The total intrinsic value of options exercised during the years ended December 31, 2022 and 2021 was approximately $0.4 million and $1.3 million, respectively. The aggregate intrinsic value of outstanding options at December 31, 2022 and 2021 was approximately $0.8 million and $7.6 million, respectively. As of December 31, 2022, there were no unvested options and no unrecognized stock-based compensation expense related to options.

Restricted Stock Units

The grant date fair value of RSUs granted is determined using the closing market price of the Company's common stock on the grant date with the associated compensation expense amortized over the vesting period of the awards. The following table sets forth the outstanding RSUs and related activity for the years ended December 31, 2022 and 2021:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2020	522,500	$ 10.49
Granted	1,217,500	9.76
Vested	(438,502)	10.10
Forfeited/Cancelled	(34,083)	9.91
Unvested at December 31, 2021	1,267,415	$ 9.94
Granted	1,925,476	5.66
Vested	(725,166)	8.66
Forfeited/Cancelled	(41,000)	8.31
Unvested at December 31, 2022	2,426,725	$ 7.06

As of December 31, 2022, there was $14.7 million of unrecognized stock-based compensation expense related to outstanding RSUs which is expected to be recognized over a weighted-average period of 2.2 years.

Warrants

The Company has issued warrants related to financings, acquisitions and as compensation to third parties for services provided. The Company estimates the fair value of issued warrants on the date of issuance as determined using a Black-Scholes pricing model. The Company amortizes the fair value of issued warrants using a vesting schedule based on the terms and conditions of each warrant if granted for services.

The following table summarizes warrant activity during the years ended December 31, 2022 and 2021:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Fair Value	Weighted Average Remaining Contractual Life (Years)
Outstanding at December 31, 2020	70,000	$ 1.83	$ 5.21	3.3
Granted	456,281	9.13	3.83	
Expired	-	-	-	
Forfeited/Cancelled	-	-	-	
Exercised	-	-	-	
Outstanding at December 31, 2021	526,281	$ 8.15	$ 4.01	4.7
Issued for adjustments to contingent purchase consideration	8,719	9.13	1.88	
Granted	-	-	-	
Expired	-	-	-	
Forfeited/Cancelled	-	-	-	
Exercised	(50,000)	2.00	1.22	
Outstanding at December 31, 2022	485,000	$ 8.81	$ 2.43	4.0

The intrinsic value of warrants exercised during the years ended December 31, 2022 and 2021 was $0.3 million and $0.0 million, respectively. The aggregate intrinsic value of outstanding warrants at December 31, 2022 was approximately $22,000.

20,000 warrants are exercisable at December 31, 2022. As discussed in Note 3 and Note 4, approximately 456,000 warrants to purchase shares of the Company's common stock were issued in connection with the acquisition of ACI and IdMo. The ability to exercise the warrants is contingent upon the achievement of certain development and revenue milestones on or before January 1, 2027. There was no unrecognized stock-based compensation expense related to warrants.

See Note 5 for additional information regarding the fair value calculation of the warrants issued during the year ended December 31, 2021.

Stock Issued for Services

The Company has issued restricted stock to third parties for services provided. The grant date fair value of the restricted stock granted is determined using the closing market price of the Company's common stock on the grant date with the associated compensation expense amortized over the vesting period of the stock awards. The Company issued 0 and 5,548 shares of restricted stock for services during the years ended December 31, 2022 and 2021, respectively, and there was no unrecognized stock-based compensation expense related to restricted stock issued.

Stock-Based Compensation Expense

The Company recognized stock-based compensation expense related to the types of awards discussed above as follows:

	Years Ended December 31,	
	2022	2021
Options	$ 78,115	$ 292,754
Restricted stock units	7,465,108	5,164,750
Stock	-	51,900
Total stock-based compensation expense	$ 7,543,223	$ 5,509,404

Note 12 – Income Taxes

The components of the provision for income taxes consists of the following for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Current:		
Federal	$ 563,821	$ 6,092,730
State	(266,248)	886,173
Total current	$ 297,573	$ 6,978,903
Deferred:		
Federal	(3,945,090)	1,394,686
State	(961,468)	603,642
Total deferred	(4,906,558)	1,998,328
Total income tax (benefit) expense	$ (4,608,985)	$ 8,977,231

A reconciliation of income tax expense at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	Year Ended December 31,	
	2022	2021
Federal income tax expense at statutory rate	21.0%	21.0%
State income tax expense, net of federal tax benefit	4.8%	3.9%
Permanent differences:		
- Foreign derived intangible income deduction	1.4%	-3.5%
- Stock based compensation	-3.6%	0.2%
- Contingent consideration remeasurement	8.8%	0.0%
- Goodwill impairment	-17.1%	0.0%
- Other permanent differences	-0.6%	0.3%
Research and development credits	11.1%	-2.6%
Change in uncertain tax positions	-2.1%	1.4%
Change in valuation allowance	0.0%	0.0%
Other	0.8%	-1.0%
Effective income tax rate	24.5%	19.7%

Net deferred tax liabilities consist of the following components as of December 31, 2022 and 2021:

	December 31,	
	2022	2021
Deferred tax assets:		
Accrued liabilities	$ 98,141	$ -
Reserves and allowances	765,004	166,050
Deferred compensation	566,076	393,871
Research and development credits	3,460,159	-
Lease liability	85,899	-
UNICAP	168,936	-
Total deferred tax assets	5,144,215	559,921
Deferred tax liabilities:		
Property and equipment, net	(609,261)	(477,542)
Intangibles, net	(6,608,914)	(6,743,972)
Prepaids	(156,053)	(560,093)
Right of use asset	(91,873)	-
Other comprehensive income	(96,101)	-
Other	-	(6,758)
Total deferred tax liabilities	(7,562,202)	(7,788,365)
Net deferred tax (liabilities)	(2,417,987)	(7,228,444)
Less valuation allowance	-	-
Net deferred tax (liabilities)	$ (2,417,987)	$ (7,228,444)

At December 31, 2022, the Company had no federal net operating loss carryforwards and no federal research and development credit carryforwards. At December 31, 2022, the Company had no state net operating loss carryforwards and $288,292 of state research and development credit carryforwards. If unused, the state research credit carryforward will expire in 2036.

ASC Topic 740-10-05 requires that the impact of a tax position be recognized in the financial statements if that position is more likely than not of being sustained on audit, based on the technical merits of the position. Our unrecognized tax benefit balances included $1,469,577 at December 31, 2022 and $1,067,853 at December 31, 2021 of tax positions that, if recognized, would impact our effective tax rate. The Company expects no material changes to the liability for unrecognized tax benefits in the next 12 months. Interest and penalties associated with uncertain tax positions are recorded as a component of income tax expense. A reconciliation of the beginning and ending amount of unrecognized benefits is as follows:

	December 31,	
	2022	2021
Unrecognized tax benefits at the beginning of the year	$ 1,067,853	$ 447,831
Gross increases - current year tax positions	1,045,590	770,069
Gross increases - prior year tax positions	34,035	-
Gross decreases - prior year tax positions	(677,901)	(150,047)
Unrecognized tax benefits at end of year	$ 1,469,577	$ 1,067,853
Interest and penalties in year-end balance	$ 34,035	$ -

The Company is subject to taxation in the United States and other state jurisdictions. The tax years from December 31, 2019 through December 31, 2022 remain open to examination for federal income tax purposes and by the other major taxing jurisdictions to which the Company is subject. The Company is not currently under examination by any taxing authority.

Note 13 – Commitments and Contingencies

Lease Obligations

The Company leases office space under a non-cancellable operating lease and leases cancellable with one month notice. The Company expenses the cancelable leases in the period incurred in accordance with the practical expedient elected. As such, one lease makes up the entirety of the right-of-use asset and lease liability disclosed.

For the year ended December 31, 2022, components of lease expense are summarized as follows:

	Year Ended December, 2022
Operating lease costs	$ 346,349
Short-term lease costs	384,902
Total lease costs	$ 731,251

Short-term lease costs under month-to-month lease agreements are paid to related parties.

As of December 31, 2022, the maturities of the Company’s lease liabilities are as follows:

	Year Ending December 31,
2023	$ 303,059
2024	50,773
2025	-
2026	-
2027	-
Thereafter	-
Total lease payments	353,832
Less: imputed interest	5,915
Present value of operating lease liabilities	347,917
Less: current portion	297,209
Long-term portion	$ 50,708

Other information related to operating leases was as follows:

	Year Ended December 31, 2022
Cash paid for operating leases included in operating cash flows	$ 700,821
Remaining lease term of operating leases	1 year
Discount rate of operating leases	3.1%

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred.

The Company is a defendant in two class action claims and three derivative actions claiming that the Company promulgated false and misleading press releases to increase the price of our stock to improperly benefit the officers and directors of the Company. The plaintiffs demand compensatory damages sustained as a result of the Company's alleged wrongdoing in an amount to be proven at trial. The Company believes these lawsuits are without merit and intends to defend the cases vigorously. The Company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in these cases. As of the date of this report, the Company does not believe it is probable that these cases will result in an unfavorable outcome; however, if an unfavorable outcome were to occur in these cases, it is possible that the impact could be material to the Company's results of operations in the period(s) in which any such outcome becomes probable and estimable.

Note 14 – Share Repurchase Program

In March 2022, the Company's board of directors authorized a share repurchase program that would allow the Company to repurchase up to $30.0 million of CODX common stock. The repurchase program does not obligate the Company to acquire any particular number of common shares, and the repurchase program may be suspended or discontinued at any time at the Company's discretion. The timing and amount of any share repurchases under the share repurchase program will be determined by Co-Diagnostics' management at its discretion based on ongoing assessments of the capital needs of the business, the market price of the Company's common stock, corporate and regulatory requirements, and general market conditions.

For accounting purposes, common stock repurchased under the stock repurchase program is recorded based upon the transaction date of the applicable trade. Such repurchased shares are held in treasury and are presented using the cost method. These shares are not retired and are considered issued but not outstanding. The following table shows the changes in treasury stock for the periods presented:

	Year Ended December 31, 2022
Balance, beginning of period	-
Repurchases of common stock	3,881,658
Balance, end of period	3,881,658

Note 15 – Subsequent Events

None.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain a set of disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in rules and forms adopted by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. Based on the evaluation, management has concluded that our disclosure controls and procedures are effective as of December 31, 2022 to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Changes in Internal Control Over Financial Reporting

There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a- 15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of 2022 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022. In making its evaluation, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013).

Based on this evaluation, management determined that our internal control over financial reporting was effective as of December 31, 2022.

This Annual Report does not include an attestation report by our independent registered public accounting firm regarding internal control over financial reporting since we are a non-accelerated filer. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit non-accelerated filers to provide only management's report in the 10-K.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are intended to be designed to provide reasonable assurance of achieving their objectives. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost–effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth the names, ages and positions of our executive officers and directors as of March 16, 2023. The following is information on the business experience of each director and executive officer now serving and a discussion of the qualifications, attributes and skills that led to the board of directors' conclusion that each one is qualified to serve as a director or as an executive officer as the case may be. Executive officers serve at the discretion of the board of directors.

Name	Age	Position
Dwight Egan	69	Chief Executive Officer, President and Chairman of the Board
Brian Brown	47	Chief Financial Officer and Secretary
Eugene Durenard	53	Director
James Nelson	70	Director
Richard Serbin	78	Director
Ted Murphy	58	Director

The following is a brief summary of the background of each of our directors:

Edward Murphy has been a member of our board of directors since June 2019. Since December 1999, Mr. Murphy has served as a senior vice president and a partner of Dover Investments Ltd., a private investment firm. Throughout his career, Mr. Murphy's duties have included investment analysis of various types of investment projects in real estate and financial services. Currently, Mr. Murphy serves on the board of directors of several Canadian publicly reporting companies that have interests in various industries. He has been a Director at Empire Minerals Corporation Inc. since January 2016, at Digicrypts Blockchain Solutions Inc. from June 2011 to November 2022, at Lakefield Marketing Corporation since February 2018, CEO/CFO and Director of Credo Resources Inc. since September 2019, at the Mosport Park Entertainment Corporation since April 30, 1997, at Essex Oil Ltd. Since July 2021, and at Darkhorse Technologies Ltd. since November 2021. He served as a Director at Aurquest Resources from May 2003 to December 2017. Mr. Murphy's experience in the capital markets outside the United States and his involvement in investment analysis is a benefit to the board of directors.

Richard Serbin has been a member of our board of directors since May 2017. Mr. Serbin currently serves as a consultant to many companies in the healthcare industry. He was the President of Corporate Development and In-House Legal Counsel at Life Science Institute, LLC, from June 1, 2013 to July 15, 2014. He was appointed to the Advisory Board of Cure Pharmaceutical in January 2017 and has been a Member of Advisory Board at Prime Access, Inc. since September 2015. Mr. Serbin has been a Director at Rapid Nutrition Plc since November 18, 2014. He served as Director at Viropro Inc. from May 2013 to June 2014. He was Head of Business Advisory Board at Mazal Plant Pharmaceuticals Inc. from October 2006 to September 2007 and also served as its Member of Business Advisory Board. He served as Chief Executive Officer of Optigenex Inc. from July 2002 to September 15, 2005 and a director from July 2004 to September 2005. From January 1999 until July 2002 Mr. Serbin served as a consultant to various pharmaceutical companies. He served as the President of Bradley Pharmaceuticals. He served as Vice President of Corporate Development at Ortho Pharmaceuticals, a Johnson & Johnson subsidiary, and practiced Patent and FDA law at Revlon Johnson & Johnson and Schering-Plough. He served as Patent Attorney for Schering Plough Corporation and Chief FDA Counsel for Revlon Corporation and Johnson and Johnson Corporation. Subsequently, he worked at Revlon Corporation, as its Chief Food, Drug and Cosmetic Counsel. He founded Radius Scientific Corporation. He was J&J's Vice President of Corporate Development, and later led a successful public offering venture based on technology developed at Stanford Medical School. Mr. Serbin spent a large portion of his career focusing on international markets and clients. While at J&J, Mr. Serbin served on the board of directors of 16 US and international subsidiary companies, including Ethicon, Ortho, J&J Consumer Products, Pittman-Moore, Mc Neil, and J&J Development Corporation. He worked on multiple international acquisitions and strategic relationships, and sat on the board of directors of several of its international subsidiaries, including those in India, Hong Kong, Japan, Taiwan, Germany, and England. Mr. Serbin has a B.S. and a B. Pharmacy from Rutgers University and Rutgers University College of Pharmacy, a J.D. degree from Seton Hall Law School and a Master's Degree in Trade Regulations and Law from NYU Law School. Mr. Serbin's experience in business, law and medicine and knowledge gained as an advisor to the healthcare industry is critical to our board of directors as we continue to commercialize our products.

Dwight Egan serves as our President and Chief Executive Officer and has been an officer and director of the Company since April 2013. Mr. Egan has been engaged in private investment business from February 1999 to the present. He was a senior executive at Data Broadcasting Corporation, a leading provider of wireless, real-time financial market data, news and sophisticated fixed- income portfolio analytics to 27,000 individual and professional investors from 1995 to 1999. He co-founded and served as CEO and Chairman of the Board of Broadcast International, Inc. from 1984 to 1995, when Data Broadcasting Corporation acquired Broadcast International and created *CBS MarketWatch*, a leading financial news site and participated in its initial public offering. Mr. Egan's prior experience in executive leadership positions with public companies and working with capital markets qualifies him to serve as our Chairman, President and Chief Executive Officer.

Eugene Durenard has been a member of our board of directors since June 2019. Dr. Durenard is the Founder and CEO of Hyperbolic Holdings, a Swiss-based holding, management consulting and strategy advisory company specialized in healthcare. Dr. Durenard brings investment and entrepreneurial experience spanning 20 years. For the last 7 years he has been working with family offices on direct investments and philanthropy focused on life sciences. He serves on the advisory board of several private companies in the biotech and MedTech sectors. After an initial career in proprietary research and trading at Salomon Brothers and Credit Suisse in London, he co-founded Orion Investment Management in Bermuda specializing in quantitative asset and liability management for institutions and private clients. He subsequently sold it to Capital G Bank and co-headed their asset management. Dr. Durenard spent several years establishing personal connections with representatives of 40+ clusters of life science innovation, families operating healthcare businesses and industry leaders globally. He regularly visits labs and incubators, meets with leading scientists and innovators in order to keep abreast of current trends and developments. His advice is based on a thorough analysis that combines in-depth knowledge of science, competitive forces and financial expertise. He has published several articles in asset-liability management industry magazines as well as the book "Professional Automated Trading — Theory and Practice" (Wiley 2013). He has a PhD in Mathematics from Harvard University. Dr. Durenard brings a thorough multi-asset class investment and entrepreneurial experience spanning 25 years to the Company's board of directors.

James Nelson has been a member of our board of directors since June 2019. Mr. Nelson is the retired Chairman and CEO of Sunworks, Inc., a NASDAQ traded commercial, agriculture, and residential solar Integrator which he helped found in October 2010. Mr. Nelson spent most of his career working in private equity as a general partner with Peterson Partners and with Millennial Capital Partners. In addition to his investment and financial responsibilities, he served as CEO of two of his firms' portfolio companies. Prior to his years in private equity, Mr. Nelson served as Vice President of Marketing at Banana Republic, where he managed company-wide marketing, as well as the company's international expansion initiative. He was also general manager for Banana Republic's catalog division. He was Vice President of Marketing and Corporate Development at Saga Corporation, a multi-billion-dollar food service company. Mr. Nelson began his executive career over 35 years ago at Bain and Company, a business strategy consulting firm, where he managed teams of consultants on four continents. Mr. Nelson received his MBA from Brigham Young University, where he graduated summa cum laude and was named the Outstanding Master of Business Administration Graduate. Mr. Nelson's advice to the board of directors from his experiences as a chief executive officer and strategic advisor is useful to the board of directors.

The following is a brief summary of the background of each of our executive officers.

Dwight Egan - See narrative description above.

Brian Brown became our Chief Financial Officer in February 2021. From July 2020 until February 2021, Mr. Brown served as the Chief Financial Officer of A-Core Concrete Cutting, Inc. where his duties included overseeing the company's accounting and finance departments, mergers and acquisitions and responsibility for financial forecasting and budgeting. From January 2020 to July 2020, Mr. Brown was an independent consultant. From August 2019 to December 2019, Mr. Brown served as the Vice President of Accounting, Treasury and Investor Relations at Sportsman's Warehouse Holdings, Inc., a public company reporting on Nasdaq Global Select under the symbol SPWH, where his duties included overseeing the company's accounting, treasury and investor relations departments, preparing the company's annual, quarterly and current reports with the SEC, overseeing all aspects of the company's annual audit, including, but not limited to, the preparation and review of audit support schedules, preparation of financial statements and footnotes, and providing support to the company's independent auditors. From October 2009 to August 2019, Mr. Brown served as the Director of Finance of Sportsman's Warehouse Holdings, Inc. where he assisted with the company's initial public offering in April 2014 as well as effecting private and secondary public offerings, acquisitions of a group of retail stores and preparing the company's periodic and current reports with the SEC and complying with the Sarbanes Oxley Act. From May 2005 to October 2009, Mr. Brown served as the Corporate Controller of Franklin Covey Products where he developed and maintained the company's internal controls over financial reporting structure in accordance with the control standards required under Section 404 of the Sarbanes Oxley Act. From July 2001 to May 2005, Mr. Brown served as an Assurance Senior at KPMG, LLP where he provided audit services to various clients in multiple industries. Mr. Brown holds a Bachelor of Arts in Accounting and Masters of Professional Accountancy from the University of Utah. Mr. Brown is a licensed CPA in Utah.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our directors or executive officers has been involved in any bankruptcy or criminal proceedings (other than traffic and other minor offenses) or been subject to any of the items set forth under Item 401(f) of Regulation S-K, nor have there been any judgments or injunctions brought against any of our directors or executive officers during the last ten years that we consider material to the evaluation of the ability and integrity of any director or executive officer.

Board and Committee Matters

Our board of directors has five members. The Chairman of the Board and our Chief Executive Officer, Dwight Egan, is a member of the board and is a full-time employee of the Company. Eugene Durenard, Edward Murphy, James Nelson and Richard Serbin are non-employee directors, and the board has determined that these persons (who constitute a majority of the board) are "independent directors" under the criteria set forth in Rule 5605(a)(2) of the Nasdaq Listing Rules. The board met eleven times during the year ended December 31, 2022. All directors attended more than seventy-five percent (75%) of the meetings of the board and committee meetings of which such director was a member held during 2022.

We maintain an audit committee of the board, a compensation committee of the board and a corporate governance/nominating committee of the board, each of which is discussed below. Our board has determined that Messrs. Durenard, Nelson, Murphy and Serbin are "independent" under the definition of independence in the Marketplace Rules of the NASDAQ listing requirements. Our board of directors may from time to time establish other standing committees. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues.

The following table sets forth a description of the three permanent board committees and the chairpersons and members of those committees, all of whom are independent directors:

Committee	Independent Chairperson	Independent Members		
Audit Committee	Eugene Durenard	Edward Murphy	James Nelson	Richard S. Serbin
Compensation Committee	Richard S. Serbin	Edward Murphy	Eugene Durenard	James Nelson
Governance Committee	James Nelson	Edward Murphy	Eugene Durenard	Richard S. Serbin
Nominating Committee	Edward Murphy	James Nelson	Eugene Durenard	Richard S. Serbin

Audit Committee and Financial Expert

Our audit committee currently is comprised of Messrs. Durenard, Nelson, Murphy and Serbin with Mr. Durenard serving as chairperson of the audit committee. The functions of the audit committee include engaging an independent registered public accounting firm to audit our annual financial statements, reviewing the independence of our auditors, the financial statements and the auditors' report, and reviewing management's administration of our system of internal control over financial reporting and disclosure controls and procedures. The board of directors has adopted a written audit committee charter. A current copy of the audit committee charter is available to security holders on our website at www.codiagnostics.com. Our board has determined that all our directors that are serving on the audit committee are "independent" under the definition of independence in the Marketplace Rules of the NASDAQ listing standards. The Audit Committee met five times during the year ended December 31, 2022. All committee members attended more than seventy-five percent (75%) of the meetings of the Audit Committee held during 2022.

Our board of directors has determined that Mr. Durenard meets the requirements of an "audit committee financial expert" as defined in applicable SEC regulations.

Compensation Committee

Our compensation committee currently includes Messrs. Serbin, Nelson, Murphy and Durenard with Mr. Serbin serving as chairperson of the compensation committee. The functions of the compensation committee include reviewing and approving corporate goals relevant to compensation for executive officers, evaluating the effectiveness of our compensation practices, evaluating and approving the compensation of our chief executive officer and other executives, recommending compensation for board members, and reviewing and making recommendations regarding incentive compensation and other employee benefit plans. The board of directors has adopted a written compensation committee charter. A current copy of the compensation committee charter is available to shareholders on our website at www.codiagnostics.com. Our board has determined that all of our directors serving on the compensation committee are "independent" under the definition of independence in the Marketplace Rules of the NASDAQ listing standards. The Compensation Committee did not meet as a separate committee in 2022, but rather, because the committee is comprised of all four independent directors, committee matters were addressed as necessary in meetings of the board. during the year ended December 31, 2022.

Corporate Governance Committee

Our Corporate Governance Committee currently includes Messrs. Nelson, Murphy, Durenard and Serbin with Mr. Nelson serving as chairperson of the Corporate Governance Committee. Among other items, the committee is tasked by the board of directors to: develop and recommend to the board the Corporate Governance Guidelines of the Company and oversee compliance therewith and evaluate and provide successor planning for the Chief Executive Officer and other executive officers. A current copy of the Corporate Governance committee charter is available to shareholders on our website at www.codiagnostics.com. Our board has determined all directors serving on the Corporate Governance committee are "independent" under the definition of independence in the Marketplace Rules of the NASDAQ listing standards. The Corporate Governance Committee did not meet as a separate committee in 2022, but rather, because the committee is comprised of all four independent directors, committee matters were addressed as necessary in meetings of the board the year ended December 31, 2022.

Nominating Committee

Our Nominating Committee was split from the Corporate Governance Committee in 2022 and currently includes Messrs. Nelson, Murphy, Durenard and Serbin with Mr. Murphy serving as chairperson of the Nominating Committee. The Nominating Committee has been established by the board, among other things to: assist the board in effecting board organization, membership and function including identifying qualified board nominees; assist the board in effecting the organization, membership and function of board committees including the composition of board committees and recommending qualified candidates therefor; evaluate and provide successor planning for the Chief Executive Officer and other executive officers; and develop criteria for board membership, such as independence, term limits, age limits and ability of former employees to serve on the board and the evaluation of candidates' qualifications for nominations to the board and its committees as well as removal therefrom. The Nominating Committee did not meet as a separate committee in 2022, but rather, because the committee is comprised of all four independent directors, committee matters were addressed as necessary in meetings of the board for the year ended December 31, 2022.

Board Nominations

In considering board candidates, the board seeks individuals of proven judgment and competence who have strong reputations in their respective fields. Although we do not have a formal diversity policy, the board considers such factors as experience, education, employment history, special talents or personal attributes, anticipated participation in board activities, and geographic and diversity factors. The process for identifying and evaluating nominees would include detailed consideration of the recommendations and opinions of members of our board, our executive officers, and our stockholders. There would be no difference in the process of evaluation of candidates recommended by a stockholder and those recommended by other sources.

Our Amended and Restated Bylaws (the "Bylaws") set forth procedures for shareholders to recommend nominees to the Company's board. Nominations of persons for election to the board of directors to be considered by the stockholders may be made at an annual meeting of stockholders (i) pursuant to the Company's notice of meeting, (ii) by or at the direction of the board of directors, or (iii) by any stockholder of the Company who (A) was a stockholder of record at the time of giving of the notice, (B) is entitled to vote with respect to such matter at the meeting, and (C) complies with the notice procedures set forth in the Bylaws.

The following is a summary of key provisions from our Bylaws. For nominations to be properly brought before an annual meeting by a stockholder, the stockholder making such nominations must have given timely notice in writing to the secretary of the Company. To be timely, a stockholder's notice shall be delivered to the secretary at the principal executive offices of the Company not later than the close of business on the 75th day nor earlier than the close of business on the 125th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, notice by the stockholder to be timely must be so delivered not later than the close of business on the later of (x) the 75th day prior to the scheduled date of such annual meeting or (y) the 15th day following the day on which public announcement of the date of such meeting is first made by the Company. To be in proper form, a stockholder's notice to the secretary must: set forth, as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (A) the name and address of such stockholder, as they appear on the Company's books, and of such beneficial owner, if any, (B) the class or series and number of shares of the Company that are, directly or indirectly, owned beneficially and of record by such stockholder and such beneficial owner, if any, as of the date of such notice, and (C) any other information relating to such stockholder and beneficial owner, if any, that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in a contested election pursuant to Section 14 of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (the "Exchange Act"). In addition, shareholders who intend to solicit proxies in support of director nominees other than the company's nominees must also comply with the additional requirements of Rule 14a-19(b).

The notice shall set forth, as to each person, if any, whom the stockholder proposes to nominate for election or reelection as a director (A) all information relating to such person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14 of the Exchange Act (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected) and (B) a description of all direct and indirect compensation and other monetary agreements, arrangements and understandings during the past three years, and any other relationships, between or among such stockholder and beneficial owner, if any, and their respective affiliates and associates, or others acting in concert therewith, on the one hand, and each proposed nominee, and his or her respective affiliates and associates, or others acting in concert therewith, on the other hand, including, without limitation all information that would be required to be disclosed pursuant to Rule 404 promulgated under Regulation S-K if the stockholder making the nomination and any beneficial owner on whose behalf the nomination is made, if any, or any affiliate or associate thereof or person acting in concert therewith, were the "registrant" for purposes of such rule and the nominee were a director or executive officer of such registrant; and with respect to each nominee for election or reelection to the board of directors, include the completed and signed questionnaire, representation, and agreement required by the Bylaws. The Company may require any proposed nominee to furnish such other information as may reasonably be required by the Company to determine the eligibility of such proposed nominee to serve as an independent director of the Company or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee.

Communication with the Board

We have not, to date, developed a formal process for shareholder communications with the board of directors. We believe our current informal process, in which any communication sent to the board of directors, either generally or in care of the chief executive officer, secretary or other corporate officer or director, is forwarded to all members of the board of directors, has served the board's and the shareholders' needs.

Conflicts of Interests

On an annual basis, each director and executive officer is obligated to complete a director and officer questionnaire that requires disclosure of any transactions with our company, including related person transactions reportable under SEC rules, in which the director or executive officer, or any member of his or her immediate family, have a direct or indirect material interest. Under our company's standards of conduct for employees, all employees, including the executive officers, are expected to avoid conflicts of interest. Pursuant to our code of ethics for the chief executive officer and senior finance officers (as discussed below), such officers are prohibited from engaging in any conflict of interest unless a specific exception has been granted by the board. All of our directors are subject to general fiduciary standards to act in the best interests of our company and our shareholders. Conflicts of interest involving an executive officer or a director are generally resolved by the board.

Role of the Board in Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of the risks that we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors is responsible for satisfying itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of the board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for us. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors oversight of the performance of our internal audit function. Our Corporate Governance/Nominating Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs have the potential to encourage excessive risk-taking or promote behaviors contra to our Code of Business Conduct.

Code of Ethics

We have adopted a code of ethics for our principal executive officer, principal financial officer, controller, or persons performing similar functions. A copy of the code of ethics is included on our website at www.codiagnostics.com.

Family Relationships

There are no family relationships among our directors and executive officers.

ITEM 11. EXECUTIVE COMPENSATION

We are a "smaller reporting company" as defined in the rules and regulations of the SEC. As a smaller reporting company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not smaller reporting companies. Accordingly, this Report includes reduced disclosure about our executive compensation arrangements.

Summary Compensation Table

The table below summarizes the total compensation paid or earned by each of the named executive officers in their respective capacities for the fiscal years ended December 31, 2022 and 2021. We have omitted in this report certain columns otherwise required to be included because there was no compensation made with respect to such columns, as permitted by applicable SEC regulations.

Name and Principal Position	Year	Salary	Bonus (1)	Stock Awards (2)	All Other Comp (3)	Total Compensation
Dwight Egan	2022	$ 366,146	$ 146,245	$ 1,454,750	$ -	$ 1,967,141
President & Chief Executive Officer	2021	$ 350,000	$ 638,459	$ 1,208,750	$ 26,793	$ 2,224,002
Brian Brown	2022	$ 280,875	$ 106,647	$ 1,190,250	$ -	$ 1,577,772
Chief Financial Officer and Secretary	2021	$ 209,731	$ 475,014	$ 1,441,600	$ 26,793	$ 2,153,138

(1) Bonuses for the year ended December 31, 2021 include accrued bonus payments of $281,597 to Mr. Egan and $223,248 to Mr. Brown that were paid in February 2022.

(2) The amounts reported in this column represent the aggregate grant date fair value of the restricted stock units, or RSUs, granted under our 2015 Plan as computed in accordance with FASB ASC Topic 718. Note that the amounts reported in this column reflect the accounting value for these equity awards and do not correspond to the actual economic value that may be received from the equity awards as the RSUs vest over three years.

(3) Company profit sharing payments to the Company's 401 K Plan.

Narrative Disclosure to Summary Compensation Table: We do not have written employment agreements with any of our executive officers. All of our executive officers serve on an at-will basis. The base salaries for our named executive officers were determined by our compensation committee after reviewing a number of factors, including: the responsibilities associated with the position, the seniority of the executive's position, the base salary level in prior years, and our financial position; and for executive officers other than our Chief Executive Officer, recommendations made by our Chief Executive Officer. By utilizing a combination of objective and subjective performance factors critical to our success, the board will award cash bonuses intended to incentivize our executive officers to achieve results that benefit them and the Company. Performance factors include the achievement of predetermined financial performance objectives, adherence to financial discipline measures and achievement of business development, product development and long-term business stability. The board may modify or re-weight the objectives during the course of the fiscal year, if necessary, to reflect changes in our business plan.

Outstanding Equity Awards at Fiscal Year-End 2022

The following table contains certain information concerning outstanding equity awards for the Named Executive Officers as of December 31, 2022.

	Option Awards				Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (1)	Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Dwight Egan	50,000	-	$ 2.63	09/20/28	-	-	-	-
	50,000	-	$ 1.10	09/02/29	-	-	-	-
	-	-	-	-	25,000(2)	$ 63,000	-	-
	-	-	-	-	62,500(4)	$ 157,500	-	-
	-	-	-	-	229,167(5)	$ 577,501	-	-
Brian Brown	-	-	-	-	10,000(3)	$ 25,200	-	-
	-	-	-	-	50,000(4)	$ 126,000	-	-
	-	-	-	-	187,500(5)	$ 472,500	-	-

(1) Based on $2.52 per share, which was the closing price of our common stock on December 31, 2022.
(2) Consists of restricted stock units granted on 11/23/2020, which vest in 6 installments commencing on 5/23/2021 and continuing every six months thereafter.
(3) Consists of restricted stock units granted on 2/22/2021, which vest in 6 installments commencing on 5/23/2021 and continuing every six months thereafter.
(4) Consists of restricted stock units granted on 8/12/2021, which vest in 6 installments commencing on 11/23/2021 and continuing every six months thereafter.
(5) Consists of restricted stock units granted on 6/6/2022, which vest in 6 installments commencing on 11/23/2022 and continuing every six months thereafter.

Potential Payments Upon Termination or Change of Control

There is no compensation payable to the named executive officers upon voluntary termination, retirement, involuntary not-for-cause termination, termination following a change of control or in the event of disability or death of the executive.

Director Compensation

We use a combination of cash and stock-based incentive compensation to attract and retain qualified candidates to serve on its board of directors. In setting director compensation, we consider the significant amount of time that directors expend in fulfilling their duties as well as the skill level required by our members of the board.

The table below summarizes the compensation paid or accrued by us to each of our non-employee directors for the fiscal year ended December 31, 2022.

Name	Fees Earned or Paid in Cash	Stock Awards: Value of Restricted Stock Units (1)	Total
Richard Serbin (2)	$ 87,500	$ 429,100	$ 516,600
James Nelson (3)	$ 87,500	$ 429,100	$ 516,600
Edward Murphy (4)	$ 87,500	$ 429,100	$ 516,600
Eugene Durenard (5)	$ 87,500	$ 429,100	$ 516,600

(1) The amounts reported in this column represent the aggregate grant date fair value of the restricted stock units, or RSUs, granted under our 2015 Plan as computed in accordance with FASB ASC Topic 718. Note that the amounts reported in this column reflect the accounting value for these equity awards and do not correspond to the actual economic value that may be received from the equity awards. The RSUs vested immediately upon grant.
(2) As of December 31, 2022, Mr. Serbin had 70,833 RSU awards outstanding.
(3) As of December 31, 2022, Mr. Nelson had 70,833 RSU awards outstanding.
(4) As of December 31, 2022, Mr. Murphy had 70,833 RSU awards outstanding.
(5) As of December 31, 2022, Mr. Durenard had 70,833 RSU awards outstanding.

Our non-employee directors receive cash compensation of $100,000 per year, paid quarterly. In 2021, the non-employee directors also each received 37,500 RSU's vesting 1/3rd equally in January 2021, 2022, and 2023. In 2022, they also received 70,000 RSU's vesting 1/6th equally in November 2022, 2023, and 2024 and May 2023, 2024, and 2025. In addition, non-employee directors may be entitled to receive special awards of stock options or RSUs from time to time as determined by the board. The chairman of the board and the chairperson of each of the audit, corporate governance/nomination, and compensation committees receive no additional fees for serving in such capacities. There is no additional compensation for meeting attendance. Directors who are employees of the Company receive no additional compensation for serving as directors. All stock options granted to outside directors are immediately exercisable and expire ten years from the date of grant or 30 days after the date they cease to be directors. Directors are reimbursed for ordinary expenses incurred in connection with attending board and committee meetings.

Equity Incentive Plans

Under our Amended and Restated 2015 Long-term Incentive Plan (the "2015 Plan"), the board of directors may issue incentive stock-based awards to employees, directors and consultants of the company. Options awarded generally expire ten years after being granted. Any stock-based awards granted vest in accordance with the vesting schedule determined by the board of directors. Should an employee's director's or consultant's relationship with the company terminate before the vesting period is completed, the unvested portion of each grant is forfeited. We continue to maintain and grant awards under the 2015 Plan which will remain in effect until its expiration by its terms.

The purpose of our incentive plan is to advance the interests of our stockholders by enhancing our ability to attract, retain and motivate persons who are expected to make important contributions to the company by providing them with both equity ownership opportunities and performance-based incentives intended to align their interests with those of our stockholders. These plans are designed to provide us with flexibility to select from among various equity-based compensation methods, and to be able to address changing accounting and tax rules and corporate governance practices by optimally utilizing stock-based awards.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information, as of March 14, 2023, with respect to the holdings of (1) each person who is the beneficial owner of more than 5% of our Common Stock, (2) each of our directors, (3) each named executive officer, and (4) all of our current directors and executive officers as a group.

Beneficial ownership of the common stock is determined in accordance with the rules of the Securities and Exchange Commission and includes any shares of common stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days of March 14, 2023. Applicable percentage ownership in the following table is based on 30,922,607 shares of common stock plus, for each individual, any securities that individual has the right to acquire within 60 days of March 14, 2023.

The information in the table below is based on information known to us or ascertained by us from public filings made by the stockholders. Except as otherwise indicated in the table below, addresses of the director, executive officers and named beneficial owners are in care of Co-Diagnostics, Inc., 2401 S. Foothill Drive, Suite D, Salt Lake City, Utah 84109.

	Number of Shares Beneficially Owned	Percentage of Class (1)
5% Stockholders		
Vanguard Group (1)	1,781,283	5.8%
Named Executive Officers and Directors		
Dwight Egan (2)	193,197	*
Brian Brown	73,236	*
Edward Murphy (3)	99,167	*
Eugene Durenard	36,667	*
James Nelson (4)	86,667	*
Richard Serbin (5)	59,612	*
All Directors and Executive Officers as a Group (6 persons)	548,546	1.7%

*Represents beneficial ownership of less than 1%.

(1) Information obtained from Schedule 13G/A filed with the SEC on February 9, 2023. Vanguard Group has an address of 100 Vanguard Blvd, Malvern, PA, 19355.
(2) Includes exercisable options to acquire 100,000 shares of common stock.
(3) Includes exercisable options to acquire 50,000 shares of common stock.
(4) Includes exercisable options to acquire 50,000 shares of common stock.
(5) Includes exercisable options to acquire 20,445 shares of common stock.

Equity Compensation Plan Information

Plan Category	(a) Number of Shares to be Issued upon Exercise of Outstanding Options and Rights	(b) Weighted-average Exercise Price of Outstanding Options and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Referenced in Column (a))
Equity compensation plans approved by stockholders	3,467,297(1)	$ 2.19(2)	6,210,790
Equity compensation plans not approved by stockholders	-	$ -	-
Total	3,467,297(1)	$ 2.19(2)	6,210,790

(1) Includes options and restricted stock units outstanding under our 2015 Equity Incentive Plan.

(2) Represents weighted-average exercise price per share of common stock acquirable upon exercise of outstanding stock options.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The Company employs two persons who are related to current or former executive officers. Seth Egan is the Company's Director of Sales and Marketing, and is the son of Dwight Egan, the Company's President and Chief Executive Officer. Andrew Benson is the Company's Director of Investor Relations, and is the son of Reed Benson, the Company's former Chief Financial Officer and Secretary. During the year ended December 31, 2022, the total compensation paid to or earned by these persons, including salaries, bonuses, and the grant date fair value of equity awards which vest over three years, was $962,800 and $489,000, respectively.

Policy for Review of Related Party Transactions

The review of transactions with related persons policy is set forth in our Corporate Governance Committee Charter. The Corporate Governance Committee is to oversee the administration of any related party transactions policy in effect with respect to transactions in which the Company is a participant and involving directors, nominees for director, executive officers of the Company or holders of more than 5% of the Company's common stock or immediate family members of any such person.

Director Independence

For information regarding the independence of our directors, see "Directors, Executive Officers and Corporate Governance" in Part III, Item 10 of this Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table presents aggregate fees for professional services rendered by our independent auditors for the respective periods.

	Years Ended December 31,	
	2022	2021
Audit fees	$ 136,600	$ 113,100
Audit related fees	-	-
Other consulting fees	-	-
Tax fees	-	-
Total fees	$ 136,600	$ 113,100

Audit fees consist of fees for professional services provided in connection with the audit of our annual consolidated financial statements, review of our quarterly consolidated financial statements and our offerings.

The audit committee has adopted a policy that requires advance approval of all services performed by the independent auditor when fees are expected to exceed $15,000. The audit committee has delegated to the audit committee chairperson, Mr. Durenard, the authority to approve services, subject to ratification by the audit committee at its next committee meeting. All fees incurred were pre-approved by the audit committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) *Financial Statements.* The Consolidated Financial Statements filed as part of this Annual Report on Form 10-K are included in Part II, Item 8 of this Annual Report on Form 10-K.

(2) *Financial statement schedules.* There are no financial statements schedules included because they are either not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

(3) Exhibits. The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
2.1*+	Agreement and Plan of Merger by and between Co-Diagnostics, Inc, IDMO Acquisition Corp., Idaho Molecular Inc., and Company Representative dated as of December 21, 2021.		Form 8-K (Exhibit 2.1)	12/23/21	001-38148
2.1.2	Amendment to Agreement and Plan of Merger by and among Co-Diagnostics, Inc., Idaho Molecular, Inc., and Kirk Ririe, as Company Representative		Form 8-K (Exhibit 2.2)	06/16/22	001-38148
2.2*+	Agreement and Plan of Merger by and between Co-Diagnostics, Inc, ACI Acquisition Corp., Advanced Conceptions, Inc., and Company Representative dated as of December 21, 2021		Form 8-K (Exhibit 2.2)	12/23/21	001-38148
2.2.1	Amendment to Agreement and Plan of Merger by and among Co-Diagnostics, Inc., Advanced Conceptions, Inc., and Richard Abbott, as Company Representative		Form 8-K (Exhibit 2.1)	06/16/22	001-38148
3.1	Articles of Incorporation		Draft Registration Statement (Exhibit 3.1)	01/12/17	377-01467
3.1.1	Amendment to the Articles of Incorporation		Draft Registration Statement (Exhibit 3.1.1)	01/12/17	377-01467
3.1.2	Articles of Amendment to Articles of Incorporation		Form 8-K (Exhibit 3.2)	01/03/19	001-38148
3.1.3	Articles of Amendment		Form 10-K (Exhibit 3.1.3)	03/24/22	001-38148
3.1.3	Articles of Amendment	X			
3.2	Amended and Restated Bylaws of Co-Diagnostics, Inc.		Form 8-K (Exhibit 3.1)	04/01/22	001-38148
4.1	Description of Registrant's securities	X			
10.1	Exclusive Agreement between Co-Diagnostics, Inc. and DNA Logix, Inc., dated April 18, 2014		Draft Registration Statement (Exhibit 10.2)	01/12/17	377-01467
10.2#	Co-Diagnostics, Inc. Amended and Restated 2015 Long Term Incentive Plan		Form S-8/A	11/20/20	333-237684
10.3	Form of Indemnification Agreement		Form S-1/A (Exhibit 10.13.8)	05/24/17	333-217542
10.4	Shareholders' Agreement between Co-Diagnostics and Synbiotics Limited, dated January 27, 2017		Form S-1 (Exhibit 10.16)	04/28/17	333-217542
10.5	Amended Exclusive License Agreement between Co-Diagnostics, Brent Satterfield, and DNA Logix, Inc., dated January 1, 2017		Form S-1 (Exhibit 10.17)	04/28/17	333-217542
10.6	Warrant Agreement between Co-Diagnostics, Inc and VStock Transfer, LLC. Dated December 31, 2021 (ACI Warrant)		Form 10-K (Exhibit 10.6)	03/24/22	001-38148

10.7	Warrant Agreement between Co-Diagnostics, Inc and VStock Transfer, LLC. Dated December 31, 2021 (IDMO Warrant)		Form 10-K (Exhibit 10.7)	03/24/22	001-38148
10.8	Form of Securities Purchase Agreement, dated February 27, 2020		Form 8-K (Exhibit 10.1)	02/27/20	001-38148
10.9	Lease Agreement 2401 Foothill Drive		Form 10-K (Exhibit 10.9)	03/24/22	001-38148
10.9.1	Amendment #1 to Lease		Form 10-K (Exhibit 10.9.1)	03/24/22	001-38148
10.9.2	Amendment #2 to Lease		Form 10-K (Exhibit 10.9.2)	03/24/22	001-38148
14.1	Code of Ethics for Senior Financial Officers		Form 10-K (Exhibit 14.1)	03/30/20	001-38148
21.1	Subsidiaries of Registrant	X			
23.1	Consent of Haynie & Company	X			
31.1	Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101 SCH	Inline XBRL Taxonomy Extension Schema Document (A)	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (A)	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (A)	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (A)	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (A)	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X			
(A)	IXBRL (INLINE EXTENSIBLE BUSINESS REPORTING LANGUAGE) information is furnished and not filed for purposes of Section 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.	X			

[#]Management Contract or Compensatory Plan or Arrangement

*Schedules and exhibits to these Exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

+ Portions of Exhibit 2.1 and Exhibit 2.2 have been omitted as they contain information that (i) is not material and (ii) is the type of information the issuer both customarily and actually treats as private and confidential.

Item 16. Form 10-K Summary.

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CO-DIAGNOSTICS, INC.

Date: March 16, 2023

By: */s/ Dwight Egan*
Dwight Egan
Chief Executive Officer, President and Director
(Principal Executive Officer)

By: */s/ Brian Brown*
Brian Brown
Chief Financial Officer
(Principal Financial and Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ Dwight Egan Dwight Egan	Chief Executive Officer, President and Director (Principal Executive Officer)	March 16, 2023
/s/ Brian Brown Brian Brown	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2023
/s/ Eugene Durenard Eugene Durenard	Director	March 16, 2023
/s/ Edward Murphy Edward Murphy	Director	March 16, 2023
/s/ James Nelson James Nelson	Director	March 16, 2023
/s/ Richard Serbin Richard Serbin	Director	March 16, 2023

Exhibit 21.1

List of Subsidiaries

LIST OF SUBSIDIARIES

Co-Diagnostics, Inc. (the “Company”) has the following direct and indirect subsidiaries:

Subsidiary Name	Jurisdiction of Formation	Percentage of Ownership
DNA Logix, Inc.	Utah	100%
Idaho Molecular, Inc.	Idaho	100%
Advanced Conceptions, Inc.	Utah	100%

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements No. 333-226835 and 333-249651 on Form S-3 and 333-237684 and 333-269350 Form S-8 of Co-Diagnostics, Inc. of our report dated March 16, 2023, relating to our audits of the consolidated financial statements which appear in this Annual Report on Form 10-K of Co-Diagnostics, Inc. for the years ended December 31, 2022 and 2021.

/s/ Haynie & Company
Salt Lake City, Utah
March 16, 2023

EXHIBIT 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND RULE 13A-14 OF THE EXCHANGE ACT OF 1934

CERTIFICATION

I, Dwight Egan, certify that:

1. I have reviewed this annual report on Form 10-K of Co-Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2023

/s/ Dwight Egan

Dwight Egan
Chief Executive Officer, President and Principal Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND RULE 13A-14 OF THE EXCHANGE ACT OF 1934

CERTIFICATION

I, Brian Brown, certify that:

1. I have reviewed this annual report on Form 10-K of Co-Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2023

/s/ Brian Brown

Brian Brown
Chief Financial Officer and Principal Financial and Accounting Officer

EXHIBIT 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S. C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Co-Diagnostics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dwight Egan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2023

/s/ Dwight Egan
Dwight Egan
Chief Executive Officer, President and Principal Executive Officer

EXHIBIT 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S. C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Co-Diagnostics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Brown, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 16, 2023

/s/ Brian Brown
Brian Brown
Chief Financial Officer and Principal Financial and Accounting Officer