UK: +44 (0)207 989 0813
NA: +1 646 896 3065
AU +61 2 9280 0700
action@proactiveinvestors.com

Co-Diagnostics

06:00 20 Nov 2020

Co-Diagnostics' detection of infectious disease has led it to join the coronavirus fight with flagship test

- Develops products to detect infectious diseases in humans and animals
- Offers Logix Smart Coronavirus Disease 2019 detection test in US and globally
- Had $27.3 million in cash and investments at end-3Q 2020 to fund operations

What Co-Diagnostics does:

Co-Diagnostics Inc (NASDAQ:CODX) is a molecular diagnostics company that develops products to detect infectious diseases in humans and animals. The company also develops tools for liquid-biopsy cancer screening and agricultural uses.

The Utah-based company, which also operates a second location at the CoSara Clinical Laboratories (CSCL) in Gujarat, India, offers medical labs and facilities a proprietary platform for the development of molecular diagnostic tests. It also manufactures state-of-the-art diagnostics technology.

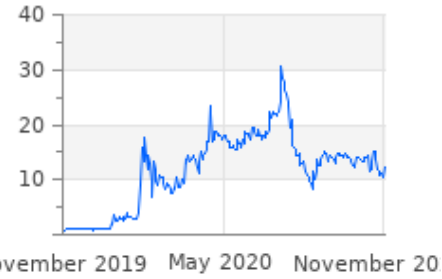
Co-Diagnostics' technology is utilized for tests designed for the detection and/or analysis of nucleic acid molecules (DNA or RNA). The company also uses its proprietary technology to design specific tests to locate genetic markers for use in industries other than infectious disease and licenses the use of those tests to specific customers.

The company's main product is its Logix Smart test that runs a foundation of its trademark CoPrimer technology and CoDx software. The company offers four tests to detect tuberculosis and viruses - Zika, Dengue, Chikungunya, and, most importantly at present, the SARS-CoV-2 virus, which causes the coronavirus (COVID-19) disease.

Co-Diagnostics also offers a host of mosquito abatement tests in the eastern US as well as the Midwest. The tests can be tailored to all regions of the country, including multiplexed tests that include either eastern equine encephalitis or western equine encephalitis.

Price:	12.14
Market Cap:	$343.19 m

1 Year Share Price Graph



Share Information

Code:		CODX
Listing:		NASDAQ
52 week	**High**	**Low**
	30.99	**0.87**
Sector:		**Pharma & Biotech**
Website:		**codiagnostics.com**

Company Synopsis:

At Co-Diagnostics, we are passionate about providing the most robust and innovative molecular tools for detection of infectious diseases in humans, mosquitoes, and animals, liquid biopsy for cancer screening, and agricultural applications, especially to those regions where pricing is paramount.

action@proactiveinvestors.com

How is it doing:

Like many diagnostic and pharmaceutical companies, Co-Diagnostics has been marshalling most of its resources to help medical professionals, regulatory officials and governmental bodies combat and stabilize the coronavirus (COVID-19) pandemic through testing, therapies and treatments.

Co-Diagnostics received an Emergency Use Authorization from the US Food & Drug Administration (FDA) in April for its COVID-19 tests. The firm currently has clients in more than 50 countries, including Australia, India, Mexico and European Community countries, plus 25 US states, and also has validations of test accuracy from regulatory bodies of numerous countries around the world.

On September 13, the group revealed it had entered into an agreement with Arches Research Inc to expand Arches'

coronavirus (COVID-19) testing services using the Logix Smart COVID-19 test kit. Arches Research, a CLIA laboratory and subsidiary of Polarity TE Inc (NASDAQ:PTE), began using Co-Diagnostics' tests for its customers earlier this year.

The announcement followed news a week earlier of additional, independent third-party validation of its COVID-19 test, supporting its performance characteristics and value in helping communities, schools, and workplaces to re-open safely and news that it was "augmenting" its test kit with a respiratory virus panel to prepare for the flu season.

On September 24, Co-Diagnostics said its Logix Smart ABC Test for Influenza A, Influenza B, and coronavirus (COVID-19) is anticipated to be ready for launch to US CLIA lab customers in the first week of October. CLIA is regulated by the Centers for Medicare & Medicaid Services, with a primary goal to ensure quality laboratory testing.

Co-Diagnostics also continues to participate in successful joint government and private collaborations in several states. In early August, the company noted that the Los Angeles Unified school district would start testing its 700,000 students and 75,000 employees for the coronavirus COVID-19, using technology developed by Co-Diagnostics.

The integrated testing program for the nation's 2nd-largest school system will be executed in part using Clinical Reference Laboratory (CRL), which recently received an Emergency Use Authorization from the US Food and Drug Administration (FDA) for a self-administered saliva test. That test will be analyzed using Co-Diagnostics' technology.

CRL is one of the largest privately-held clinical testing laboratories in the US, with dedicated facilities in North America and Europe and staff of more than 600 associates working around-the-clock performing hundreds of thousands of tests every day for clients large and small.

At the end of August, Co-Diagnostics announced that the US Patent and Trademark Office had granted increased patent protection for the company's novel CoPrimer technology used in the COVID-19 test kit and other molecular diagnostic tests.

The firm said the new patent further validates the uniqueness of the CoPrimer molecule and provides even more comprehensive protection for all of its potential applications. The original patent covered certain applications of the CoPrimer molecule - which has been shown to enhance the output of polymerase chain reaction (PCR) molecular diagnostic tests by dramatically minimizing false-positive test results - and its use in PCR, but not the molecule itself.

The additional patent covers the physical structure of the CoPrimer molecule, with more broad claims and including all configurations of a molecule with such a structure.

During its 3Q 2020, Co-Diagnostics announced the receipt of CE markings for both its Logix Smart ABC and SARS-CoV-2 2-gene tests. Both tests are designed for use in saliva and other respiratory tract samples like nasal swabs, and sputum.

More recently, on November 11, 2020, the company said its whitepaper demonstrates that its CoPrimer platform technology can be used to identify the presence of SARS-CoV-2 in human saliva samples without first requiring RNA extraction of the sample, and can do so while providing low limits of detection.

And, on November 17, 2020, Co-Diagnostics announced that its Logix Smart ABC (Influenza A/B, SARS-CoV-2) test and its Logix Smart SARS-CoV-2 multi-gene test were both awarded CE marks from European regulators, which allows the products to be sold as in-vitro diagnostics.

On the financial front, on November 16, Co-Diagnostics reported stellar third-quarter results, generating $15.7 million in net income, or $0.53 per share, as well as year-to-date net income of $29.7 million, or $1.07 per share.

The company also realized revenue for the period of $21.8 million, driven by its COVID-19 test sales. CoSara Diagnostics, its India joint venture, also continued its COVID-19 sales and reported $3 million of revenue, nearly a three-fold increase over 2Q.

Co-Diagnostics ended the third quarter with $27.3 million in cash and investments.

And in a boost for shareholders, the stock was elevated to the small-cap Russell 2000 Index and broader Russell 3000 index in late June. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. About $9 trillion in assets are benchmarked against Russell's US indexes.

Inflection points:

- Boost availability of Logix Smart Coronavirus 2019 test kits
- COVID-19 tests expected to drive sales
- On track for sustainable profitablilty

What the broker says:

In a note to clients on November 17, 2020, H.C. Wainwright & Co said Co-Diagnostics' Logix Smart ABC and Logix Smart SARS-CoV-2 (genes RdRp/E) multiplex, which it considers both highly accurate and affordable, could drive future domestic and international sales, this after the company obtained CE Mark for the Logix Smart ABC (Influenza A/B, SARS-CoV-2) test kit for simultaneous detection of Influenza A, Influenza B, and SARS-CoV-2, and has begun distributing it on a Research Use Only (RUO) basis to U.S. CLIA laboratories in the first week of October 2020.

"We believe the company may seek Emergency Use Authorization (EUA) and ultimately 510(K) clearance for the ABC multiplex panel. This panel could drive both near-term and long-term sales, in our view, as patients presenting flu-like symptoms are likely to be required to test for COVID-19 even after the COVID-19 spread has largely resolved," the broker's analysts wrote.

They added: "We expect the company to continue to report top-line revenue similar to levels seen in 2Q20 and 3Q20. Our revenue projections for 4Q20 and the next 12 months (4Q20 to 3Q21) are $22M and $90M, respectively. The company's operations could be sustainably profitable, in our view, particularly given the recent resurgence of the COVID-19 pandemic."

The analysts noted that the company's saliva-based CRL Rapid Response COVID-19 test, which its partner Clinical Reference Lab has begun selling, will also help drive top-line growth in the coming quarters.

H.C. Wainwright currently has a Buy rating on stock with a $29 per share price target.

Maxim Group, meanwhile, wrote in a note to clients on November 17, 2020, that although it has lowered its price target on Co-Diagnostics (CDI) to $20 per share, they believe there is still plenty of upside left in the CDI story.

"COVID pandemic has whipsawed the markets, especially those companies right in the thick of it, like CDI. That said, the miss on revenue should not detract from the big picture for CDI. COVID testing with PCR is here to stay and what CDI should have, even without any further growth, is a baseline of $70M-$100M in revenue per year and a base to grow its agro, oncology, and infectious diseases tests (oral saliva one-step COVID, ABC for flu, and COVID combined, TB, HepB, vector borne diseases and more)," the broker said.

What the boss says:

Commenting with the company's 3Q financial results, Co-Diagnostics CEO Dwight Egan said in a statement: "Co-Diagnostics continues to see widespread uptake of our COVID-19 test domestically and abroad, and we believe our customer and distributor bases are laying the foundation for a strong future".

He added: "Development projects both completed and ongoing have helped position CoDiagnostics as a key player in the battle against the coronavirus pandemic, including receipt today of two important CE markings that will allow our ABC and COVID-19 2-gene tests to be sold as in-vitro diagnostics in areas that accept CE markings as valid regulatory

approval. The strength and flexibility of our technology platform as illustrated by our enhanced patent protection and successful proof of concept in extraction-free COVID-19 tests underscore our core competency as a forward-looking technology company with an expanding menu of critical diagnostic tools."

Contact Sean at sean@proactiveinvestors.com

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Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

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