Co-Diagnostics, Inc. Announces Q3 2020 Financial Results Including YTD Net Income per Common Share of $1.07

Company also announces receipt of CE markings for both Logix Smart ABC and SARS-CoV-2 2-gene tests

SALT LAKE CITY, Nov. 16, 2020 /PRNewswire/ -- Co-Diagnostics, Inc. (Nasdaq: CODX), a molecular diagnostics company with a unique, patented platform for the development of molecular diagnostic tests, announced today financial results for the third quarter ended September 30, 2020 and provided updates on Company developments, including receipt of CE markings for both the recently developed Logix Smart ABC (Influenza A/B, SARS-CoV-2) test kit for simultaneous detection of Influenza A, Influenza B, and SARS-CoV-2 and Logix Smart SARS-CoV-2 (*genes RdRp/E*) multiplex test kit for detection of SARS-CoV-2, the virus that causes COVID-19.

Q3 2020 Highlights:

- Company continues COVID-19 test sales and reports $21.8 million of revenue in Q3;
- Quarterly net income of $15.7 million and net income per diluted common share of $0.53;
- Year-to-date net income of $29.7 million and $1.07 per diluted common share;
- Additionally, CoSara Diagnostics, the Company's India joint venture, also continues COVID-19 sales and reports $3.0 million of revenue in Q3, nearly a 3-fold increase over Q2;
- Quarterly net gain from investment in CoSara increased to $748,000 from $250,000 in Q2;
- Stockholders' equity increased to $52.7 million compared to $1.7 million at the beginning of the year.
- Continues to show strong gross margins of 73% on quarterly sales;
- Cash, cash equivalents and marketable securities were $27.3 million as of September 30, 2020, an increase of $26.4 million over 12/31/2019.

Q4 2020 Mid-Quarter Highlights:

- Company completes design work and verification for influenza A, influenza B, and COVID-19 ("ABC") multiplex panel and began distributing on a Research Use Only basis to laboratories in the first week of October;
- CE markings received for both Co-Diagnostics "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;
- Indian CDSCO approval for SARS-CoV-2 2-gene multiplex test expected to be granted soon;
- Company announced that its partner Clinical Reference Lab has begun selling its CRL Rapid Response™ COVID-19 test directly to consumers, which uses a simple saliva collection device that can be self-administered at home, work or any other setting. The test uses CoPrimer™ probes and primers developed by Co-Diagnostics with high degrees of sensitivity and specificity;
- Company receives increased patent protection from the United States Patent and Trademark Office for the novel CoPrimer™ technology used in the Company's molecular diagnostic tests;
- Company demonstrates that the CoPrimer platform technology can be used to identify the presence of SARS-CoV-2 in human saliva samples without first requiring costly and time-consuming RNA extraction, and plans development projects to incorporate extraction-free products in upcoming offerings.

"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," said Dwight Egan, Chief Executive Officer. "Development projects both completed and ongoing have helped position Co-Diagnostics 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 a expanding menu of critical diagnostic tools."

The Company will host an earnings call at 4:30 pm EDT today. Participants can register for access to the webcast here. The call will be recorded and later made available on the Company's website.

About Emergency Use Authorization:
The Co-Diagnostics SARS-CoV-2 Test has been made available under an emergency access mechanism called

an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of COVID-19. The EUAs for these tests are in effect for the duration of the COVID-19 emergency, unless terminated or revoked (after which the tests may no longer be used). An FDA cleared IVD should be used instead of an IVD under EUA, when applicable and available.

About Co-Diagnostics, Inc.:
Co-Diagnostics, Inc., a Utah corporation, is a molecular diagnostics company that develops, manufactures and markets a new, state-of-the-art diagnostics technology. The Company's technology is utilized for tests that are designed using 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 license the use of those tests to specific customers.

Forward-Looking Statements:
This press release contains forward-looking statements. Forward-looking statements can be identified by words such as "believes," "expects," "estimates," "intends," "may," "plans," "will" and similar expressions, or the negative of these words. Such forward-looking statements are based on facts and conditions as they exist at the time such statements are made and predictions as to future facts and conditions. Forward-looking statements in this release include statements regarding the (i) use of funding proceeds, (ii) expansion of product distribution, (iii) acceleration of initiatives in liquid biopsy and SNP detection, (iv) use of the Company's liquid biopsy tests by laboratories, (v) capital resources and runway needed to advance the Company's products and markets, (vi) increased sales in the near-term, (vii) flexibility in managing the Company's balance sheet, (viii) anticipation of business expansion, and (ix) benefits in research and worldwide accessibility of the CoPrimer technology and its cost-saving and scientific advantages. Forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances. Actual results may differ materially from those contemplated or anticipated by such forward-looking statements. Readers of this press release are cautioned not to place undue reliance on any forward-looking statements. The Company does not undertake any obligation to update any forward-looking statement relating to matters discussed in this press release, except as may be required by applicable securities laws.

CO – DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 21,230,362	$ 893,138
Marketable investment securities	6,050,000	-
Accounts receivable, net	10,640,417	131,382
Inventory	10,726,982	197,168
Prepaid expenses	384,642	362,566
Deferred tax asset	2,914,781	-
Total current assets	51,947,184	1,584,254
Property and equipment, net	538,279	196,832
Investment in joint venture	2,165,037	434,240
Total assets	$ 54,650,500	$ 2,215,326

Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 250,465	$ 5,959
Accrued expenses	786,063	200,788
Accrued expenses (related party)	120,000	120,000
Deferred revenue	657,925	1,323
Total current liabilities	1,814,453	328,070
Accrued expenses-long-term (related party)	60,000	150,000
Total liabilities	1,874,453	478,070
Commitments and contingencies (Note 8)		
Stockholders' equity		
Convertible preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 and 25,600 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	-	26
Common Stock, $0.001 par value; 100,000,000 shares authorized; 28,161,259 and 17,342,922 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	28,161	17,343
Additional paid-in capital	48,044,352	26,687,701
Accumulated earnings (deficit)	4,703,534	(24,967,814)
Total stockholders' equity	52,776,047	1,737,256
Total liabilities and stockholders' equity	$ 54,650,500	$ 2,215,326

CO – DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30, 2020		Nine Months Ended September 30, 2020	
	2020	**2019**	**2020**	**2019**
Revenue	$ 21,818,753	$ 41,434	$ 47,407,555	$ 106,408
Cost of revenue	5,821,281	20,365	12,278,326	59,626
Gross profit	15,997,472	21,069	35,129,229	46,782
Operating expenses				
Sales and marketing	798,474	262,360	1,457,148	770,539
Administrative and general	2,203,417	1,060,763	5,853,935	2,508,895

Research and development	921,889	331,027	2,072,160	990,923
Depreciation and amortization	35,490	17,006	81,456	46,768
Total operating expenses	3,959,270	1,671,156	9,464,699	4,317,125
Income (loss) from operations	12,038,202	(1,650,087)	25,664,530	(4,270,343)
Other income (expense)				
Interest income	29,992	12,207	75,740	32,255
Interest expense	-	(10)	-	(106,437)
Gain on disposition of assets	-	-	-	850
Gain (loss) on equity method investment in joint venture	748,557	(109,876)	1,016,297	(116,876)
Total other income (expense)	778,549	(97,679)	1,092,037	(190,208)
Income (loss) before income taxes	12,816,751	(1,747,766)	26,756,567	(4,460,551)
Income tax provision (benefit)	(2,914,781)	-	(2,914,781)	-
Net income (loss)	$ 15,731,532	$ (1,747,766)	$ 29,671,348	$ (4,460,551)
Earnings (loss) per common share:				
Basic	$ 0.56	$ (0.10)	$ 1.13	$ (0.27)
Diluted	$ 0.53	$ (0.10)	$ 1.07	$ (0.27)
Weighted average shares outstanding:				
Basic	28,084,267	17,328,787	26,172,439	16,809,085
Diluted	29,597,792	17,328,787	27,621,531	16,809,085

SOURCE Co-Diagnostics

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https://news.codiagnostics.com/2020-11-16-Co-Diagnostics-Inc-Announces-Q3-2020-Financial-Results-Including-YTD-Net-Income-per-Common-Share-of-1-07