

October 29, 2015

### Cologuard® Growth Trajectory Increases to 34,000 Completed Tests, Generates \$12.6M in Revenue in Third Quarter 2015

MADISON, Wis.--(BUSINESS WIRE)-- Exact Sciences Corp. (Nasdaq:EXAS) today announced that the company continued its strong performance during the third quarter ended Sept. 30, 2015, completing 34,000 Cologuard tests, an increase of 60 percent from the second quarter, which resulted in \$12.6 million in revenues. The cumulative number of ordering physicians grew to 21,000 during the quarter, an increase of 42 percent.

"We remain pleased with the growing traction that Cologuard is gaining in the colon cancer screening market," said Kevin T. Conroy, chairman and CEO of Exact Sciences. "Cologuard's continued growth is built on its outstanding performance characteristics, our sales and marketing strategy, physician awareness, patient preference and accessibility."

The patient compliance rate at the end of the third quarter remained strong at 73 percent. The compliance rate is derived from the number of valid test results generated from collection kits shipped to patients 60 or more days prior to Sept. 30, 2015. Exact Sciences Laboratories, through its customer care center, is helping to drive patient compliance by systematically contacting patients for whom Cologuard has been ordered and encouraging them to complete their screening.

Cologuard's strong patient compliance is having an impact on people who previously had not been screened for colon cancer. Data presented this month at the American College of Gastroenterology's annual scientific meeting showed that 42 percent of initial Cologuard users between 50-74 years of age, the primary targets for screening, reported no previous colorectal cancer screening.

Patients are also quickly showing a preference for Cologuard. An independently-conducted, peer-reviewed study published this month in *Family Medicine and Community Health* showed that 75 percent of the prospectively-recruited patients found Cologuard "more suitable" than a colonoscopy. The self-administered study, conducted by the Case Western Reserve University School of Medicine, evaluated perceptions of patients undergoing both a colonoscopy and a Cologuard test. Eighty-four percent of patients said they'd be likely or somewhat likely to repeat Cologuard testing, if recommended.

A recently-published, peer-reviewed study of Cologuard use among Alaska Native people also confirms its performance across all stages of colorectal cancer and showcased how the at-home test can improve access to screening. In the study of 661 average-risk Alaska Native people, Cologuard detected 100 percent (10/10) of colorectal cancers and 52 percent (24/46) of significant premalignant lesions (adenomas > 1cm) in people between the ages of 40-85. The detection rate of Cologuard increased to 80 percent for the largest pre-cancers ( > 3cm), which are most likely to progress to cancer. The study, "Stool DNA Testing for Screening Detection of Colorectal Neoplasia in Alaska Native People," is published in the *Mayo Clinic Proceedings*.

As part of the study, which mirrored a previously-published (New Engl J Med April 2014) 10,000-patient prospective study of Cologuard, patients underwent both Cologuard and fecal immunochemical testing (FIT) prior to a pre-scheduled screening colonoscopy. The Alaska Native people study results improved on the previously-published results, showing a higher rate of sensitivity for colorectal cancer and pre-cancer, and an increased specificity. FIT detected 80 percent (8/10) of colorectal cancers and only 30 percent of significant premalignant lesions (adenomas > 1 cm). Cologuard achieved a specificity of 93 percent and FIT achieved a specificity of 96 percent.

#### **Financial Results**

Exact Sciences reported total revenues of \$12.6 million for the third quarter of 2015 and total revenues of \$25.0 million for the nine months ended Sept. 30, 2015. Cologuard received approval from the U.S. Food and Drug Administration in August 2014 and a final National Coverage Decision from the Center for Medicare and Medicaid Services in October 2014.

For the third quarter of 2015, Exact Sciences reported a net loss of (\$42.9) million, or (\$0.45) a share. The company had a net loss of (\$32.1) million, or (\$0.39) a share, for the same period of 2014. The company's net loss for the first nine months of 2015 was (\$117.8) million, or (\$1.30) a share. The company had a net loss of (\$67.6) million, or (\$0.86) a share, for the same period of 2014.

Operating expenses for the quarter ending Sept. 30, 2015, were \$48.4 million, compared to \$31.3 million for the third quarter of 2014. Operating expenses for the nine months ended Sept. 30, 2015, were \$126.8 million. The company had operating expenses of \$67.3 million for the same period of 2014.

Exact Sciences ended the third quarter of 2015 with cash, cash equivalents and marketable securities of \$343.5 million, compared to \$282.8 million at Dec. 31, 2014.

#### **Third-Quarter Conference Call & Webcast**

Company management will host a conference call and webcast on Thursday, Oct. 29, 2015, at 10 a.m. ET to discuss third-quarter results. The webcast will be available at <a href="https://www.investorExactSciences.com">www.investorExactSciences.com</a>. Domestic callers should dial 877-212-6082 and international callers should dial +1 707-287-9332. An archive of the webcast and a replay of the conference call will be available at <a href="https://www.exactsciences.com">www.exactsciences.com</a> or by calling 855-859-2056 domestically or +1 404-537-3406 internationally. The access code for the conference call and replay is 62540786. The conference call, webcast and replay are open to all interested parties.

#### **About Exact Sciences Corp.**

Exact Sciences Corp. is a molecular diagnostics company focused on the early detection and prevention of the deadliest forms of cancer. The company has exclusive intellectual property protecting its noninvasive, molecular screening technology for the detection of colorectal cancer. Cologuard is included in the colorectal cancer screening guidelines of the American Cancer Society and stool DNA is included in the U.S. Multi-Society Task Force on Colorectal Cancer. For more information, please follow us on Twitter @ExactSciences or find us on Facebook.

Certain statements made in this presentation contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this presentation regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected numbers of completed and reported Coloquard tests, anticipated patient compliance rates, expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning payor reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products: the acceptance of our products by patients and health care providers; the willingness of health insurance companies and other payors to reimburse us for our performance of the Coloquard test; the amount and nature of competition from other cancer screening products and procedures; our ability to maintain regulatory approvals and comply with applicable regulations; our success establishing and maintaining collaborative and licensing arrangements; recommendations and/or guidelines issued by the U.S. Preventive Services Task Force, the American Cancer Society, or other organizations regarding cancer screening or our products and services; our ability to successfully develop new products; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

# EXACT SCIENCES CORPORATION Selected Unaudited Financial Information Condensed Consolidated Statements of Operation Data (Amounts in thousands, except per share data)

Three Months Ended September 30,				September 30,					
2015	2014			2015	2014				
\$ 12,632	\$	-	\$	25,017	\$	-			
-		-		-		294			
12,632		_		25,017		294			

Laboratory service revenue License fees

Cost of sales	7,528	924	16,834	924	
Gross margin	5,104	(924)	8,183	(630)	
Operating Expenses:					
Research and development	9,863	9,073	24,549	23,677	
General and administrative	15,432	8,994	42,086	19,810	
Sales and marketing	23,079	13,217	60,196	23,839	
	48,374	31,284	126,831	67,326	
Loss from operations	(43,270)	(32,208)	(118,648)	(67,956)	
Investment income	365	160	780	392	
Interest income (expense)	(40)	(12)	56	(40)	
Net loss	\$ (42,945)	\$ (32,060)	\$(117,812)	\$(67,604)	
Net loss per share - basic and diluted	\$ (0.45)	\$ (0.39)	\$ (1.30)	\$ (0.86)	
Weighted average common shares outstanding - basic and diluted	94,444	82,941	90,696	78,702	

## EXACT SCIENCES CORPORATION Selected Unaudited Financial Information Condensed Consolidated Balance Sheet Data (Amounts in thousands)

	September 30, 2015		December 31, 2014	
Assets		_		
Cash and cash equivalents	\$	31,522	\$	58,131
Marketable securities		311,987		224,625
Accounts receivable		4,209		1,376
Inventory, net		6,032		4,017
Prepaid expenses and other current assets		5,602		3,528
Property and equipment, net		32,075		19,947
Other long-term assets		2,562		1,200
Total assets	\$	393,989	\$	312,824
Liabilities and stockholders' equity				
Total current liabilities	\$	23,514	\$	17,521
Long-term debt		3,535		1,000
Other long-term liabilities		4,455		3,599
Long-term accrued interest		-		106
Lease incentive obligation, less current portion		1,199		1,614
Total stockholders' equity		361,286		288,984
Total liabilities and stockholders' equity		393,989	\$	312,824

View source version on <u>businesswire.com</u>: <u>http://www.businesswire.com/news/home/20151029005484/en/</u>

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Source: Exact Sciences Corp.

