

## **Press Release**

## CRITICAL OUTCOME TECHNOLOGIES REPORTS SECOND QUARTER FINANCIAL AND OPERATING RESULTS

London, Ontario (December 16, 2015): Critical Outcome Technologies Inc. (TSX Venture: COT; OTCQB: COTQF) ("COTI" or the "Company") reported its financial and operating results today for the three and six month periods ended October 31, 2015.

The major highlight for the quarter was the substantial effort involved with working through the institutional approval process at MD Anderson Cancer Centre, which led to the signing of a clinical trial agreement for COTI-2 in gynecologic cancers subsequent to the quarter end on December 8, 2015.

"The recent signing of the clinical trial agreement to begin human testing with COTI-2 was extremely rewarding following our concerted effort toward this objective in the second quarter," said Dr. Wayne Danter, President and CEO. "We look forward to expanding the cancer indications for COTI-2 to include Li-Fraumeni syndrome and head and neck cancers while we continue to work with MD Anderson Cancer Center to realize our goal of transforming cancer treatment options, not just for women with ovarian and other gynecological cancers, but for all patients afflicted with p53 mutations."

Other highlights in the quarter included conducting animal tests of COTI-2 in Li-Fraumeni syndrome leading to an application for an Orphan Drug Designation, which was submitted to the U.S. Food and Drug Administration on November 23, 2015. The Company also strengthened the Board and management support at the Annual General Meeting with the addition of an independent director with substantial experience in clinical oncology, head and neck cancer surgery, and cancer trial participation.

## **Financial Results**

The Company's operational activities during the quarter were focused in three main areas; first, the negotiation and planning of a clinical trial agreement to conduct a Phase 1 clinical trial for COTI-2; second, financing efforts to fund the Phase 1 clinical trial and the Company's operations for the next year; and, third, business development initiatives. These activities resulted in the Company incurring a net loss of \$938,861, or \$0.01 per share, for the quarter compared to a net loss of \$946,204, or \$0.01 per share, for the second quarter a year earlier. For the six months ended October 31, 2015, the Company reported a loss of \$1,923,981 or \$0.02 per common share, compared to a loss of \$1,917,000 or \$0.03 per common share on fewer shares outstanding for the same period a year earlier. Although the loss for the quarter and year-to-date were relatively flat between the comparative periods, sales and marketing expenses ("S&M") more than doubled in the respective periods compared to the prior year and this increase was offset primarily by a decrease in general and administration expenses ("G&A").

S&M expense increased by \$70,288 for the quarter and \$183,951 year over year as a ramp up in business development activities was reflected in higher professional fees and related travel costs.

G&A expenditures decreased \$36,817 in the quarter and \$300,535 year-to-date primarily related to lower professional fees and molecule amortization. A change in strategic financial advisory services was the main factor in the lower professional fees, and a review of the useful life of the molecules following the payment of the final molecule purchase contingency in May 2015 resulted in a lengthening of the

period over which the molecules were being amortized.

Research and development expenditures decreased \$6,538 for the quarter and increased \$57,344 yearto-date primarily reflecting costs related to COTI-2 including the completion of the IND approval from the FDA, the planning of the Phase 1 trial, and continued development costs for new cancer indications.

Financing

During the quarter, the Company realized approximately \$248,000 in gross proceeds through the

exercise of warrants and share options to provide further funding for operations.

More detailed operating and financial results can be found in the Company's Unaudited Condensed Interim Financial Statements and Management Discussion and Analysis for the quarter ended October 31, 2015, which can be found on SEDAR at www.sedar.com or on the Company's website at

www.criticaloutcome.com.

**About Critical Outcome Technologies Inc. (COTI)** 

COTI is a biopharmaceutical company advancing the treatment of cancer through targeted therapeutics. The Company's lead compound, COTI-2, has a novel p53-dependent mechanism of action with selective and potent anti-cancer activity. The initial indication is in gynecologic cancers (ovarian, cervical, and endometrial) that will begin a Phase 1 clinical trial at MD Anderson Cancer Center in late December 2015 or early January of 2016. The Company has secured orphan drug status for the ovarian indication in the U.S. and is planning additional studies in other cancer indications such as Li-Fraumeni, head and neck, and AML, as well as, combination therapies with other leading cancer drugs. Pre-clinical data provides evidence to suggest a potentially dramatic change in the treatment of cancers with mutations of the p53

gene.

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## **Notice to Readers**

Information contained in this press release may contain certain statements, which constitute "forwardlooking statements" within the meaning of the Securities Act (Ontario) and applicable securities laws. For example, the statement "We look forward to expanding the cancer indications for COTI-2 to include Li-Fraumeni syndrome and head and neck cancers while we continue to work with MD Anderson Cancer Center to realize our goal of transforming cancer treatment options, not just for women with ovarian and other gynecological cancers, but for all patients afflicted with p53 mutations" is a forward-looking statement. Forward-looking statements, by their nature, are not guarantees of future performance and are based upon management's current expectations, estimates, projections and assumptions. COTI operates in a highly competitive environment that involves significant risks and uncertainties, which could cause actual results to differ materially from those anticipated in these forward-looking Management of COTI considers the assumptions on which these forward-looking statements are based to be reasonable, but as a result of the many risk factors, cautions the reader that actual results could differ materially from those expressed or implied in these forward-looking statements. Information in this press release should be considered accurate only as of the date of the release and may be superseded by more recent information disclosed in later press releases, filings with the securities regulatory authorities or otherwise.