OncoCyte Confirms Launch Plans for Lung Cancer Diagnostic Test; Reports Progress Toward CLIA Lab Licensing and Second Quarter 2017 Financial Results

Aug 14, 2017

- Introduces Lung Cancer Diagnostic Branding-

-Conference Call Today at 4:30 pm ET-

ALAMEDA, Calif., Aug. 14, 2017 (GLOBE NEWSWIRE) -- **OncoCyte Corporation** (NYSE MKT:OCX), a developer of novel, non-invasive tests for the early detection of cancer, today reported the following developments:

- Financial results for the quarter ended June 30, 2017,
- Planned expansion of the senior management team by adding a Vice President of Sales and full time Chief Financial Officer,
- Branding for its lung cancer diagnostic test, and
- Progress toward CLIA lab licensing.

OncoCyte announced that it is planning to expand its senior management team. The Company is now in the final stages of hiring a Vice President of Sales. If hired, this individual will bring many years of sales and marketing leadership within the healthcare industry at leading diagnostic companies. In addition, OncoCyte has begun the process of hiring a full time Chief Financial Officer.

The Company has selected the name DetermaVu™ for its lung cancer test, a name that directly speaks to how the test will assist clinicians in determining the next steps for their patients by providing information that is not available by using only the current standard of care, a low-dose CT scan.

OncoCyte also announced that its clinical laboratory has passed the required review and inspection by the California Department of Public Health Laboratory Field Services for State Clinical Laboratory licensing and CLIA certification. OncoCyte expects to receive its California State Clinical Laboratory license and CLIA Certificate in the coming weeks.

“Our team has established a solid track record of achieving important milestones and, as a result of recent progress, we are continuing to plan for the commercial launch of our lung cancer diagnostic test in the fourth quarter of 2017,” said William Annett, Chief Executive Officer. “Upon launch, DetermaVu will be the only commercially available non-invasive liquid biopsy confirmatory lung cancer diagnostic test in

what we estimate could be a $4.7 billion annual market in the U.S. depending on market penetration and reimbursable pricing."

Other Recent Operating Highlights

- Announced positive data from the Company's lung cancer Analytical Validation Study, which established the performance characteristics of DetermaVu. The results were consistent with the data reported at the American Thoracic Society 2017 International Conference, which demonstrated sensitivity of 95%, specificity of 73%, and Area Under the Curve (AUC) of 0.92. Sensitivity and specificity are statistical measures of test performance, with sensitivity measuring the percentage of malignant nodules that are identified correctly by the test and specificity measuring the percentage of benign nodules correctly identified. The AUC of a test is a measure of overall global accuracy that combines sensitivity and specificity, with 1.0 being perfect accuracy and 0.50 being a random result. The reported score of 0.92 means that 92% of samples were correctly identified,

- Commenced its CLIA Lab Validation Study in which OncoCyte will assay approximately 120 samples previously tested in the 299-patient study presented at the ATS meeting, with the goal of demonstrating that OncoCyte's new clinical laboratory will provide the same results on clinical samples as those obtained in the R&D lab, and

- Completed a follow-on study of OncoCyte's breast cancer diagnostic test, confirming the findings of the Company's previous breast cancer study, which were presented at the San Antonio Breast Cancer Symposium in December 2016. The follow-on study, known as NICE-BC (Non-Invasive Confirmatory dEtection (of) Breast Cancer), has been submitted for presentation at a major medical conference.

Near-Term Milestones

OncoCyte's goals for the near term include the following:

- Data from OncoCyte's latest confirmatory lung cancer diagnostic research will be presented in a slide presentation at the American College of Chest Physician's CHEST 2017 annual meeting. The meeting will be held in Toronto, Ontario, Canada, from October 28 to November 1,

- An abstract concerning the lung cancer Analytical Validation Study results has been accepted for presentation at the International Association for the Study of Lung Cancer, which will take place in Chicago from September 14-16. The oral presentation will be given by Philip McQuary, Ph.D., Director, Product Development, at OncoCyte,

- William Haack, Vice President of Market Access at OncoCyte, will address the Next Generation Dx Summit 2017 on successful reimbursement strategies for diagnostic tests. Mr. Haack's presentation will focus on clinical utility studies as the key to successful reimbursement, and is being given on August 16. The Next Generation DX Summit will take place at the Grand Hyatt Washington in Washington, D.C.,

- A DetermaVu Clinical Validation Study to assess the performance of DetermaVu against clinically confirmed cancer diagnoses will be conducted. All of the samples required for this study have now been collected,

- Commercial launch of DetermaVu as a liquid biopsy lung cancer diagnostic test, if the results of the CLIA Lab Validation Study and the Clinical Validation Study results confirm that the test meets

commercial standards for sensitivity and specificity,

- Expansion of OncoCyte's commercial capabilities in sales and marketing, revenue cycle management and reimbursement,

- Seek agreements with international distributors for DetermaVu, payments for which OncoCyte anticipates will be on a cash basis, and

- Begin the execution of a comprehensive, proactive approach to pursuing coverage and reimbursement from Medicare and U.S. private payers. OncoCyte expects that U.S. revenue will be limited until if and when reimbursement is received from Medicare and/or private payers.

Second Quarter 2017 Financial Results

For the quarter ended June 30, 2017, OncoCyte incurred a net loss of $3.8 million, or ($0.13) per share, compared to a net loss of $2.5 million, or ($0.10) per share, in the second quarter of 2016.

Operating expenses for the three months ended June 30, 2017, were $3.6 million, as reported, and were $3.1 million, on an as adjusted basis.

Research and development expenses for the quarter ended June 30, 2017, were $2.0 million compared to $1.2 million for the same period in 2016. The increase is primarily attributable to increases of $0.3 million in development and clinical trials expenses for DetermaVu, $0.1 million in amounts charged to OncoCyte for facilities and services provided by BioTime, $0.1 million in salaries and payroll related expenses due to increased headcount, $0.1 million in stock based compensation expenses, and $0.1 million in outside service expenses and consulting fees.

General and administrative expenses of $1.1 million were substantially the same as the amount incurred during the same period of 2016.

At June 30, 2017, OncoCyte had cash and cash equivalents of $8.6 million and available-for-sale securities valued at $1.1 million. In July 2017, the Company raised $5.74 million through the exercise of stock purchase warrants by certain investors.

Six Month 2017 Financial Results

The net loss for the six months ended June 30, 2017, was $8.5 million, or ($0.29) per share, compared to $5.5 million, or ($0.22) per share, in the first six months of 2016.

Operating expenses for the six months ended June 30, 2017, were $8.1 million, as reported, and were $6.1 million, on an as adjusted basis.

Research and development expenses for the six months ended June 30, 2017, increased to $3.8 million from $2.9 million for the same period in 2016. The increase in research and development expenses of $0.9 million for the six months ended June 30, 2017, compared to six months ended June 30, 2016, is primarily attributable to increases of $0.3 million in development and clinical trial expenses for DetermaVu, $0.3 million in salaries and payroll related expenses, $0.3 million in stock based compensation expenses and $0.2 million in amounts charged to us by BioTime, Inc. for facilities and services. Those increases were offset by a decrease of $0.5 million in outside services expenses and consulting fees.

For the six months ended June 30, 2017, general and administrative expenses increased to $3.2 million from $2.1 million for the same period in 2016. The increase is mainly attributable to $1.1 million in shareholder noncash expense for the issuance of additional warrants to certain investors who agreed to exercise certain stock purchase warrants substantially before the warrant expiration date.

Conference Call

OncoCyte will host a conference call today, August 14, 2017, at 4:30 p.m. ET / 1:30 p.m. PT to discuss financial results.

The dial-in number in the U.S./Canada is 877-419-6591; international participants the number is 719-457-2648. For all callers, refer to Conference ID 6751720. To access the live webcast, go to the investor relations section on the company's website, http://investors.oncocyte.com/events-and-presentations.

A replay of the conference call will be available for seven business days beginning about two hours after the conclusion of the live call, by calling 888-203-1112 toll-free (from U.S./Canada); international callers dial 719-457-0820. Use the Conference ID 6751720. Additionally, the archived webcast will be available at http://investors.oncocyte.com/events-and-presentations.

About OncoCyte Corporation

OncoCyte is focused on the development and commercialization of novel, non-invasive blood and urine ("liquid biopsy") diagnostic tests for the early detection of cancer to improve health outcomes through earlier diagnoses, to reduce the cost of care through the avoidance of more costly diagnostic procedures, including invasive biopsy and cystoscopic procedures, and to improve the quality of life for cancer patients. While current biopsy tests use invasive surgical procedures to provide tissue samples in order to determine if a tumor is benign or malignant, OncoCyte is developing a next generation of diagnostic tests that will be based on liquid biopsies using blood or urine samples. OncoCyte's pipeline products are intended to be confirmatory diagnostics for detecting lung, breast and bladder cancer. OncoCyte's diagnostic tests are being developed using proprietary sets of genetic and protein markers that differentially express in specific types of cancer.

DetermaVu is a trademark of OncoCyte Corporation.

Forward Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates" and similar expressions) are forward-looking statements. These statements include those pertaining to the implementation and results of our future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for OncoCyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the need and ability to obtain future capital, and maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of OncoCyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in OncoCyte's Securities and Exchange Commission filings. OncoCyte disclaims any intent or obligation to update these forward-looking statements, except as required by law.

TABLES FOLLOW

ONCOCYTE CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 8,644	$ 10,174
Available-for-sale securities, at fair value	1,113	2,237
Prepaid expenses and other current assets	512	285
Total current assets	10,269	12,696
NONCURRENT ASSETS		
Intangible assets, net	867	988
Equipment and furniture, net	895	688
Deposits	110	75
TOTAL ASSETS	$ 12,141	$ 14,447
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$ 2,540	$ 2,854
Accounts payable and accrued liabilities	1,316	1,219

Loan payable, current	533	-
Capital lease liability, current	297	202
Total current liabilities	4,686	4,275
LONG-TERM LIABILITIES		
Loan payable, net of issuance costs, noncurrent	1,416	-
Capital lease liability, noncurrent	400	310
TOTAL LIABILITIES	6,502	4,585
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 50,000 shares authorized; 29,520 and 28,737 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	49,985	45,818
Accumulated other comprehensive loss on available-for-sale securities	(535)	(654)
Accumulated deficit	(43,811)	(35,302)
Total stockholders' equity	5,639	9,862
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 12,141	$ 14,447

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
EXPENSES:				
Research and development	$ (1,997)	$ (1,195)	$ (3,831)	$ (2,884)
General and administrative	(1,115)	(1,067)	(3,158)	(2,081)
Sales and marketing	(477)	(270)	(1,132)	(499)
Total operating expenses	(3,589)	(2,532)	(8,121)	(5,464)
Loss from operations	(3,589)	(2,532)	(8,121)	(5,464)
OTHER INCOME (EXPENSES), NET				
Loss on sale of available-for-sale securities and other expenses, net	(150)	-	(309)	-
Interest expense, net	(65)	(11)	(79)	(7)
Total other expenses, net	(215)	(11)	(388)	(7)
NET LOSS	$ (3,804)	$ (2,543)	$ (8,509)	$ (5,471)

Basic and diluted net loss per share	$ (0.13)	$ (0.10)	$ (0.29)	$ (0.22)
Weighted average common shares outstanding: basic and diluted	29,398	25,427	29,183	25,411

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(IN THOUSANDS)

	Six Months Ended June 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,509)	$ (5,471)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	144	54
Amortization of intangible assets	121	121

Stock-based compensation	696	361
Loss on sale of available-for-sale securities, including selling commissions	309	-
Warrants issued to certain shareholders as inducement of exercise of warrants	1,084	-
Amortization of debt issuance costs	30	-
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	(313)	992
Prepaid expenses and other current assets	(194)	259
Accounts payable and accrued liabilities	61	(290)
Net cash used in operating activities	(6,571)	(3,974)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of available-for-sale securities	934	-
Purchase of equipment	(55)	(10)
Security deposit	-	(54)
Net cash provided by (used in) investing activities	879	(64)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options	257	82
Proceeds from exercise of warrants	2,031	-
Proceeds from issuance of loan payable, net of financing costs	1,982	-
Repayment of capital lease obligations	(108)	(40)
Net cash provided by financing activities	4,162	42
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,530)	(3,996)

CASH AND CASH EQUIVALENTS:		
At beginning of the period	10,174	7,996
At end of the period	$ 8,644	$ 4,000

NON-GAAP FINANCIAL MEASURES

This press release includes operating expenses prepared in accordance with accounting principles generally accepted in the United States (GAAP), and includes certain historical non-GAAP operating expenses. In particular, OncoCyte has provided non-GAAP total operating expenses, adjusted to exclude noncash stock-based compensation, depreciation and amortization and warrants expense issued to certain shareholders as an inducement of exercise of warrants. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable financial measures prepared in accordance with GAAP. However, OncoCyte believes the presentation of non-GAAP total operating expenses, when viewed in conjunction with our GAAP total operating expenses, is helpful in understanding OncoCyte's ongoing operating expenses and its programs.

Furthermore, management uses these non-GAAP financial measures in the aggregate to establish budgets and operational goals, to manage OncoCyte's business and to evaluate its performance and its programs.

ONCOCYTE CORPORATION

RECONCILIATION OF NON-GAAP FINANCIAL MEASURES

ADJUSTED OPERATING EXPENSES

	For the Three Months Ended June 30, 2017 (unaudited)	**For the Six Months Ended June 30, 2017 (unaudited)**
GAAP Operating Expenses - as reported	**$ 3,589**	**$ 8,121**
Stock-based compensation expense	(346)	(696)

Noncash warrants expense	-	(1,084)
Depreciation and amortization expense	(137)	(265)
Non-GAAP Operating Expenses, as adjusted	$ 3,106	$ 6,076

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