OncoCyte Reports Third Quarter 2017 Financial Results

Nov 14, 2017

-Conference Call Today at 4:30 pm ET-

ALAMEDA, Calif., Nov. 14, 2017 (GLOBE NEWSWIRE) -- **OncoCyte Corporation** (NYSE American:OCX), a developer of novel, non-invasive tests for the early detection of cancer, today reported financial results for the quarter ended September 30, 2017, and provided an update on the Clinical Validation Study of DetermaVu™, the Company's liquid biopsy lung cancer diagnostic test.

"We continued to make important progress during the third quarter, including the successful completion of the Analytical Validation Study of DetermaVu™ and certification of our CLIA laboratory," said William Annett, President and Chief Executive Officer. "The consistent and significantly positive data that we have demonstrated and the numerous presentations highlighting the results are raising awareness of the potential benefits of DetermaVu™ in the early diagnosis of lung cancer."

Recent Developments

- Successfully completed the Analytical Validation and CLIA Lab Validation studies of OncoCyte's liquid biopsy lung cancer diagnostic test, confirming data that was reported in May at the American Thoracic Society 2017 International Conference (ATS), which demonstrated sensitivity of 95%, specificity of 73%, and Area Under the Curve (AUC) of 0.92,

- Received Clinical Laboratory Improvements Amendments (CLIA) certification of registration from the Centers for Medicare and Medicaid Services (CMS),

- Dr. Anil Vachani, an Associate Professor of Medicine at the Hospital of the University of Pennsylvania and the Philadelphia Veteran's Administration Medical Center, reported data on DetermaVu™ at the CHEST Annual Meeting 2017 in Toronto, Ontario, Canada, and

- Data from the Company's most recent breast cancer diagnostic study has been selected for presentation in a poster session at the 2017 San Antonio Breast Cancer Symposium (SABCS), being held from December 5-9, 2017.

Clinical Validation Study Update and Commercial Launch Plans

The Clinical Validation Study for DetermaVu™ is the final development step prior to commercial launch. This step involves assaying approximately 300 blinded prospectively collected samples to assess the performance of the full diagnostic system against clinically confirmed diagnoses.

During the process of running initial samples for the Clinical Validation Study, inconsistent analytic results were observed by OncoCyte's technical team. OncoCyte believes this was caused by a variance in a recently received lot of consumables used in the processing system that analyzes blood samples for the genetic markers that indicate whether lung nodules found in patients are benign or suspicious. To address this issue, OncoCyte has ordered and is waiting to receive new lots of consumables from the supplier. Once the new consumables are received, OncoCyte will conduct internal quality control procedures to ensure that they meet OncoCyte's requirements. Upon confirming that the new consumables will allow the analytic devices to generate data with the consistency and precision required for DetermaVu™, OncoCyte will initiate the Clinical Validation Study. Due to the time required for these steps, OncoCyte now anticipates that completion of the Clinical Validation Study necessary for the commercial launch of DetermaVu™ will be delayed into 2018, depending on the successful rectification of the causes of the inconsistent analytic results.

OncoCyte has only observed this issue in the recent lot of consumables. Earlier studies were conducted using different lots of consumables where this issue was not observed. Consequently, the previous studies were not impacted by this issue and the positive results reported to date have not changed.

Mr. Annett commented, "We remain confident in the positive results reported to date and believe that the clinical use of DetermaVu™ can make an important contribution to the management of lung cancer nodules and help to improve therapeutic outcomes for lung cancer patients."

Breast Cancer Diagnostic Update

Data from the Company's most recent breast cancer diagnostic study has been selected for presentation in a poster session at the 2017 San Antonio Breast Cancer Symposium (SABCS), which is being held from December 5-9, 2017. The data to be presented are from the Company's NICE-BC (Non-Invasive Confirmatory dEtection (of) Breast Cancer follow-on study.

Third Quarter 2017 Financial Results

For the quarter ended September 30, 2017, OncoCyte incurred a net loss of $6.9 million, or ($0.22) per share, compared to a net loss of $2.6 million, or ($0.10) per share, in the third quarter of 2016.

Operating expenses for the three months ended September 30, 2017, were $6.8 million, as reported, and were $3.2 million, on an as adjusted basis.

Research and development expenses for the quarter ended September 30, 2017, were $1.8 million compared to $1.4 million for the same period in 2016. The increase in research and development expenses for the three months ended September 30, 2017, of $0.4 million compared to the three months ended September 30, 2016, is primarily attributable to increases in salaries and compensation related expenses, development expenses primarily for our lung cancer test and stock-based compensation expenses.

General and administrative expenses for the three months ended September 30, 2017, increased by $3.2 million in comparison to the comparable period in 2016. The increase is mainly attributable to $3.0 million in shareholder noncash expense for the issuance of warrants to certain investors to exercise warrants, $0.1 million in recruiting and hiring expenses and $0.1 million in stock based compensation expenses.

At September 30, 2017, OncoCyte had cash and cash equivalents of $11.0 million and available-for-sale securities valued at $1.0 million.

Nine Month 2017 Financial Results

The net loss for the nine months ended September 30, 2017, was $15.4 million, or ($0.52) per share, compared to $8.1 million, or ($0.31) per share, in the first nine months of 2016.

Total operating expenses for the nine months ended September 30, 2017, were $15.0 million, as reported, and were $9.3 million on an as adjusted basis.

Research and development expenses for the nine months ended September 30, 2017, were $5.7 million compared with $4.2 million for the nine months ended September 30, 2016. The increase in research and development expenses of $1.4 million is primarily attributable to increases in salaries and payroll related expenses, clinical trial expenses for OncoCyte's lung cancer test, DetermaVu™, stock based compensation expenses, charges to OncoCyte by BioTime for shared services expenses, which includes facilities, insurance and other indirect expense, and services and development expenses primarily for DetermaVu™. The increases were offset by a decrease in outside services expenses and consulting fees.

General and administrative expenses for the nine months ended September 30, 2017, increased by $4.3 million in comparison to the comparable period in 2016. The increase is mainly attributable to $4.1 million in noncash expense for the issuance of warrants to certain investors who exercised warrants, and $0.2 million in insurance expense.

Conference Call

OncoCyte will host a conference call today, November 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 888-542-1102; for international participants, the number is 719-325-2356. For all callers, please refer to Conference ID 1817036. 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 1817036. 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 research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future 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 capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, 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 accordingly as such statements 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.

Investor Contact:

EVC Group, Inc.
Matt Haines / Michael Polyviou
917-733-9297 / 212-850-5600
mhaines@evcgroup.com / mpolyviou@evcgroup.com

Financial Media Contact:

GIBSON Communications, LLC
Tom Gibson
201-476-0322
tom@tomgibsoncommunications.com

TABLES FOLLOW

ONCOCYTE CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	September 30, 2017 (unaudited)	December 31, 2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 11,024	$ 10,174
Available-for-sale securities, at fair value	1,003	2,237
Prepaid expenses and other current assets	457	285
Total current assets	12,484	12,696
NONCURRENT ASSETS		
Intangible assets, net	807	988
Equipment and furniture, net	833	688
Deposits	125	75
TOTAL ASSETS	$ 14,249	$ 14,447
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$ 2,102	$ 2,854
Accounts payable and accrued liabilities	1,498	1,219
Loan payable, current	733	-
Capital lease liability, current	304	202
Total current liabilities	4,637	4,275
LONG-TERM LIABILITIES		

Loan payable, net of issuance costs, noncurrent	1,243	-
Capital lease liability, noncurrent	321	310
TOTAL LIABILITIES	6,201	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; 31,417 and 28,737 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	59,410	45,818
Accumulated other comprehensive loss on available-for-sale securities	(645)	(654)
Accumulated deficit	(50,717)	(35,302)
Total stockholders' equity	8,048	9,862
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 14,249	$ 14,447

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**

EXPENSES:				
Research and development	$ (1,836)	$ (1,363)	$ (5,667)	$ (4,246)
General and administrative	(4,289)	(1,063)	(7,447)	(3,145)
Sales and marketing	(710)	(156)	(1,843)	(655)
Total operating expenses	(6,835)	(2,582)	(14,957)	(8,046)
Loss from operations	(6,835)	(2,582)	(14,957)	(8,046)
OTHER EXPENSES, NET				
Loss on sale of available-for-sale securities and other expenses, net	-	-	(309)	-
Interest expense, net	(71)	(13)	(149)	(19)
Total other expenses, net	(71)	(13)	(458)	(19)
NET LOSS	$ (6,906)	$ (2,595)	$ (15,415)	$ (8,065)
Basic and diluted net loss per share	$ (0.22)	$ (0.10)	$ (0.52)	$ (0.31)
Weighted average common shares outstanding: basic and diluted	30,941	26,560	29,775	25,797

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(IN THOUSANDS)

	Nine Months Ended September 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (15,415)	$ (8,065)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	237	102
Amortization of intangible assets	181	181
Stock-based compensation	1,158	619
Loss on sale of available-for-sale securities, including selling commissions	309	-
Warrants issued to certain shareholders as inducement of exercise of warrants	4,074	-
Amortization of debt issuance costs	57	-
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	(750)	1,410
Prepaid expenses and other current assets	(119)	197
Accounts payable and accrued liabilities	227	548
Net cash used in operating activities	(10,041)	(5,008)

CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of available-for-sale securities	934	-
Purchase of equipment	(85)	(19)
Security deposit	-	(54)
Net cash provided by (used in) investing activities	849	(73)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common shares and warrants	-	10,550
Financing costs paid to issue common shares and warrants	-	(800)
Proceeds from exercise of options	465	83
Proceeds from exercise of warrants	7,774	-
Proceeds from issuance of loan payable, net of financing costs	1,982	-
Repayment of capital lease obligations	(179)	(74)
Net cash provided by financing activities	10,042	9,759
NET INCREASE IN CASH AND CASH EQUIVALENTS	850	4,678
CASH AND CASH EQUIVALENTS:		
At beginning of the period	10,174	7,996
At end of the period	$ 11,024	$ 12,674

Non-GAAP Financial Measures

This earnings 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 Measure
Adjusted Operating Expenses

	Amounts In Thousands	
	For the Three Months Ended September 30, 2017 (unaudited)	**For the Nine Months Ended September 30, 2017 (unaudited)**
GAAP Operating Expenses - as reported	**$ 6,835**	**$ 14,957**
Stock-based compensation expense	(462)	(1,158)
Noncash warrant expense	(2,990)	(4,074)
Depreciation and amortization expense	(153)	(418)
Non-GAAP Operating Expenses, as adjusted	$ 3,230	$ 9,307

Source: OncoCyte Corporation