OncoCyte Reports Third Quarter 2018 Financial Results and Progress in DetermaVu™ Development

Nov 13, 2018

Transition to New Diagnostic Testing Platform Complete

Prospective R&D Validation Study Results Expected by Late 2018 or Early 2019

Development Plan Remains On-Track, Targeting Commercial Availability in 2H 2019

Conference Call Today at 4:30 pm ET

ALAMEDA, Calif., Nov. 13, 2018 (GLOBE NEWSWIRE) -- **OncoCyte Corporation (NYSE American: OCX)**, a developer of novel, non-invasive tests for the early detection of lung cancer, today reported financial and operating results for the third quarter ended September 30, 2018 and provided a corporate update.

“During the third quarter and subsequent period, we made significant progress on our DetermaVu™ development plan by completing the transition to a new diagnostic testing platform that is yielding very consistent and reliable data,” said William Annett, President and Chief Executive Officer. “Using this equipment, we have now run over half of the 700-blood samples that are being used in our Algorithm Development Study. This study will establish a proprietary mathematical algorithm that will be used to interpret test results for DetermaVu™. Once all samples have been run, development of the algorithm will begin, and we expect its completion next month.”

“After the new algorithm is derived, we will move on to an R&D Validation Study that should determine the accuracy of DetermaVu to within approximately plus or minus eight percentage points. By about the end of 2018 or early 2019 we anticipate finishing this study and will then be able to confirm with a high degree of certainty whether we have a commercially-viable diagnostic test poised to address the multi-billion-dollar market for a liquid biopsy lung cancer diagnostic test. On successful completion of the R&D Validation study we will be on-track to complete all of the necessary pre-launch development work in the first half of 2019. If the test’s accuracy is maintained in the planned studies, we plan to make DetermaVu™ commercially available in the second half of 2019.”

Highlights

- Following rigorous testing, completed transition to a new Next Generation Sequencing diagnostic testing platform and quality control testing of new custom panel reagents
- Initiated a 700--blood sample Algorithm Development Study to develop the proprietary mathematical algorithm that will be used to interpret the results of DetermaVu™

- On-track to initiate an R&D Validation Study of 250 blinded, prospectively-collected patient blood samples with results expected by the end of this year or early 2019

Remaining Validation Pathway for DetermaVu™:

- **Approximately yearend 2018:** R&D Validation study – to confirm algorithm performance on a blinded sample set in an R&D setting
- **1H 2019:** Analytical Validation study – to establish the performance characteristics of the assay system to be validated in OncoCyte's CLIA laboratory
- **1H 2019:** CLIA Validation study – to confirm that the assay has been successfully transferred to the CLIA lab
- **1H 2019:** Clinical Validation study – approximately 300 blood sample study to establish the DetermaVu™ performance in an independent, blinded data set
- **2H 2019:** Commercial availability of DetermaVu™
- **Post-launch (2019/2020):** Clinical Utility study – follow-on real world tracking study to demonstrate a net improvement in patient outcomes and cost savings for the healthcare system

Third Quarter 2018 Financial Results

At September 30, 2018, OncoCyte had $10.8 million of cash and cash equivalents in addition to marketable equity securities valued at $0.8 million for a total of $11.6 million of liquid assets. This cash balance includes $3.3 million raised during the third quarter, net of financing expenses, from an at-market registered direct offering of common stock and warrants.

For the third quarter ended September 30, 2018, OncoCyte incurred a net loss of $3.0 million, or $0.07 per share, compared to a net loss of $6.9 million, or $0.22 per share, in the third quarter of 2017.

Operating expenses for the three months ended September 30, 2018 were $3.0 million, as reported, and were $2.6 million, on an as adjusted basis. The reconciliation between GAAP and non-GAAP operating expenses is provided in the financial tables included with this earnings release.

Research and development expenses for the third quarter ended September 30, 2018 were $1.5 million compared to $1.8 million for the same period in 2017, a decrease of $0.3 million.

General and administrative expenses for the three months ended September 30, 2018 were $1.3 million compared to $4.3 million for the same period in 2017, a decrease of $3.0 million.

Cash used in operations was $2.5 million for the third quarter of 2018, which compares to cash used in operations of $3.5 million during the third quarter of 2017, the reduced cash used in operating activities in the current quarter mostly resulting from OncoCyte's staff reductions and executive sabbatical programs implemented last quarter.

Conference Call

OncoCyte will host a conference call today, Tuesday, November 13, 2018, 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 877-407-9716; for international participants, the number is +1-201-493-6779. For all callers, please refer to Conference ID 13684100. 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 844-512-2921 toll-free (from U.S./Canada); international callers dial +1-412-317-6671. Use the Conference ID 13684100. Additionally, the archived webcast will be available at http://investors.oncocyte.com/events-and-presentations.

About DetermaVu™

DetermaVu™ is OncoCyte's confirmatory, non-invasive, liquid biopsy test intended to facilitate clinical decision making in lung cancer diagnosis. DetermaVu™ is being developed as an intermediate step to confirm the absence of cancer between imaging modalities (LDCTs) detecting suspicious lung nodules and downstream invasive procedures that determine if the nodules are malignant. OncoCyte estimates that a $4.7 billion annual market could develop in the U.S. for its confirmatory lung cancer liquid biopsy test, depending on market penetration and reimbursable pricing.

DetermaVu™ is a trademark of OncoCyte Corporation.

About OncoCyte Corporation

OncoCyte is focused on the development and commercialization of novel, non-invasive blood ("liquid biopsy") diagnostic tests for the early detection of lung cancer. Early detection of cancer can improve health outcomes, reduce the cost of care, and improve patients' quality of life. Liquid biopsy diagnostic tests like those OncoCyte is developing may reduce the need for costlier and riskier diagnostic procedures such as invasive biopsy and cystoscopic procedures. OncoCyte is focusing its efforts on the development of DetermaVu™ as a non-invasive confirmatory diagnostic test for lung cancer. DetermaVu™ is being developed using proprietary sets of genetic molecular markers that differentially express in lung cancer. OncoCyte also plans to conduct research to identify additional molecular markers, acquire or license markers and related technology, and develop cancer tests based on those markers.

OncoCyte 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 Contacts
Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

ONCOCYTE CORPORATION

CONDENSED BALANCE SHEETS

(IN THOUSANDS)

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,821	$ 7,600
Marketable equity securities	830	760
Prepaid expenses and other current assets	245	168
Total current assets	11,896	8,528
NONCURRENT ASSETS		
Intangible assets, net	-	746
Machinery and equipment, net	722	822
Other noncurrent assets	108	-
Deposits	179	120
TOTAL ASSETS	$ 12,905	$ 10,216

LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$ 2,110	$ 2,099
Accounts payable	194	175
Accrued expenses and other current liabilities	1,044	1,042
Loan payable, current	800	800
Capital lease liability, current	471	338
Total current liabilities	4,619	4,454
LONG-TERM LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	531	1,070
Capital lease liability, noncurrent	232	289
TOTAL LIABILITIES	5,382	5,813
STOCKHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 85,000 shares authorized; 40,664 and 31,452 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	74,343	59,968
Accumulated other comprehensive loss	-	(888)
Accumulated deficit	(66,820)	(54,677)
Total stockholders' equity	7,523	4,403
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 12,905	$ 10,216

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
EXPENSES:				
Research and development	$ 1,527	$ 1,836	$ 5,310	$ 5,667
General and administrative	1,312	4,289	4,434	7,447
Sales and marketing	184	710	1,411	1,843
Total operating expenses	3,023	6,835	11,155	14,957
Loss from operations	(3,023)	(6,835)	(11,155)	(14,957)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(50)	(71)	(167)	(149)
Unrealized gain on BioTime	102	-	71	-

marketable equity securities				
Loss on sale of available-for-sale securities and other expenses, net	-	-	(3)	(309)
Total other income (expenses), net	52	(71)	(99)	(458)
NET LOSS	$ (2,971)	$ (6,906)	$ (11,254)	$ (15,415)
Net loss per share: basic and diluted	$ (0.07)	$ (0.22)	$ (0.30)	$ (0.52)
Weighted average common shares outstanding: basic and diluted	40,227	30,941	36,901	29,775

ONCOCYTE CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(IN THOUSANDS)

	Nine Months Ended
	September 30,

	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (11,254)	$ (15,415)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	317	237
Amortization of intangible assets	121	181
Amortization of prepaid maintenance	9	-
Impairment charge for intangible assets	625	-
Stock-based compensation	1,079	1,158
Loss on sale of BioTime shares	-	309
Unrealized gain on BioTime shares	(71)	-
Warrants issued to certain shareholders as inducement of exercise of warrants	-	4,074
Amortization of debt issuance costs	62	57
Other	23	-
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	12	(750)
Prepaid expenses and other current assets	(77)	(119)
Accounts payable and accrued liabilities	(39)	227
Net cash used in operating activities	(9,193)	(10,041)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of BioTime shares	-	934
Purchase of equipment	(31)	(85)
Net cash provided by (used in) investing activities	(31)	849

CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options	58	465
Proceeds from exercise of warrants	-	7,774
Proceeds from sale of common shares	10,000	-
Financing costs to issue common shares	(65)	-
Proceeds from sale of common shares and warrants	3,592	-
Financing costs to issue common shares and warrants	(290)	-
Proceeds from issuance of loan payable, net of financing costs	-	1,982
Repayment of loan payable	(600)	-
Repayment of capital lease obligations	(250)	(179)
Net cash provided by financing activities	12,445	10,042
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,221	850
CASH AND CASH EQUIVALENTS:		
At beginning of the period	7,600	10,174
At end of the period	$ 10,821	$ 11,024

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 an impairment charge for intangible assets. 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	Amounts In Thousands
	For the Three Months Ended September 30, 2018 (unaudited)	**For the Nine Months Ended September 30, 2018 (unaudited)**
GAAP Operating Expenses - as reported	**$ 3,023**	**$ 11,155**
Stock-based compensation expense	(345)	(1,079)
Impairment charge for intangible assets	-	(625)
Depreciation and amortization expense	(119)	(447)
Non-GAAP Operating Expenses, as adjusted	$ 2,559	$ 9,004

Source: OncoCyte Corporation

Powered by SITECORE