OncoCyte Provides Corporate Update and Reports Fourth Quarter and Full Year 2018 Financial Results

Apr 01, 2019

On track for commercial availability of DetermaVu™ in 2H 2019

Conference Call Today at 4:30 PM EDT

ALAMEDA, Calif., April 01, 2019 (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 fourth quarter and year ended December 31, 2018 and provided a corporate update.

“OncoCyte has made outstanding progress since our last quarterly update to investors, reporting positive results from our DetermaVu™ R&D Validation Study which demonstrated that DetermaVu™ is a commercially viable assay with the potential to change the treatment paradigm in lung cancer diagnostics,” said William Annett, President and Chief Executive Officer of OncoCyte. “Importantly, these results also confirmed the Company’s unique Immune System Interrogation approach provides an exquisitely sensitive and consistent signal for the diagnosis of early stage lung cancer. We are excited to investigate the broader application of this technology across multiple solid tumors moving forward and remain highly focused on executing the few remaining steps required for commercialization of DetermaVu™ later this year.”

Highlights

- Successfully transitioned to the Ion Torrent next-generation sequencing platform for robust and reproducible results
- Reported positive results from blinded, prospective R&D Validation Study demonstrating best-in-class performance with sensitivity of 90% and specificity of 75%
- R&D Validation study served as proof of concept for unique Immune System Interrogation approach with potential applicability across many types of solid tumors
- On-track to complete remaining validation studies by mid-year and make DetermaVu™ commercially available second half of 2019
- Completed a successful equity raise for gross proceeds of $40.25 million which provides the resources to execute the development and commercialization of DetermaVu™

Remaining Validation Pathway for DetermaVu™:

- **1H 2019:** Analytical Validation – with results expected shortly, this study will establish the performance characteristics of the system as established in the Clinical and Laboratory Standard Institute Guidelines that cover quantitation, precision, reproducibility and interfering substances

- **1H 2019:** CLIA Laboratory Validation study – will rerun between 100 and 120 patient samples previously run in the R&D Validation study to confirm that the same positive results are obtained on the analytically validated systems

- **Mid-year 2019:** Clinical Validation study – will run approximately 300 to 350 blinded, prospectively-collected blood samples to establish the DetermaVu™ performance in an independent, blinded data set as a final confirmation of test sensitivity and specificity in OncoCyte's CLIA lab setting

- **2H 2019:** Commercial availability of DetermaVu™

- **Post-launch (2020 initiation):** Clinical Utility study – follow-on real world evidence study to demonstrate a net improvement in patient outcomes and cost savings for the healthcare system

Fourth Quarter and Annual 2018 Financial Results

At December 31, 2018, OncoCyte had cash and cash equivalents of $8.0 million and marketable equity securities valued at $0.4 million, for a total of $8.4 million of liquid assets. The balance sheet was strengthened in February 2019 with the successful equity raise of $37.4 million in net proceeds from an underwritten public offering.

For the quarter ended December 31, 2018, OncoCyte reported a net loss of $4.5 million, or ($0.11) per share, compared to a net loss of $4.0 million, or ($0.13) per share, in the fourth quarter of 2017.

For 2018, OncoCyte reported a net loss of $15.8 million, or ($0.42) per share, compared to $19.4 million, or ($0.64) per share, in 2017.

Operating expenses for the three months ended December 31, 2018 were $4.0 million as reported, and were $3.5 million on an as adjusted basis. Operating expenses for 2018 were $15.2 million as reported and were $12.5 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 fourth quarter of 2018 were $1.2 million compared to $1.5 million for the same period in 2017, a decrease of $0.3 million. Research and development expenses for the year ended December 31, 2018 were $6.5 million, compared to $7.2 million during 2017, a decrease of $0.7 million. The decreases were primarily attributable to laboratory and other expenses related to diagnostic tests for diseases other than lung cancer as OncoCyte devoted substantially all of its research and development efforts to DetermaVu™ during 2018.

General and administrative expenses for the fourth quarter of 2018 were $2.6 million compared to $1.8 million for the same period in 2017. The $0.8 million increase was mainly attributable to personnel and related compensation, primarily related to the hiring of OncoCyte's Chief Financial Officer and its Chief Operating Officer.

General and administrative expenses for the year ended December 31, 2018 decreased to $7.0 million from $9.2 million during 2017, a decrease of $2.2 million. During the year ended December 31, 2017, OncoCyte incurred a noncash expense of $4.1 million for the issuance of new warrants to certain investors who exercised outstanding warrants. OncoCyte did not incur a similar expense during 2018. Personnel and related compensation expenses increased by $1.1 million during 2018, primarily related to the hiring of the executives noted above, an increase of $0.5 million in legal, investor relations, financing and other related expenses, and an increase of $0.3 million in noncash stock-based compensation expense due to increased stock option grants.

Sales and marketing expenses for the fourth quarter of 2018 were $0.3 million compared to $0.6 million for the same period in 2017, a decrease of $0.3 million. Sales and marketing expenses for the full-year 2018 were $1.7 million compared to $2.4 million during 2017, a decrease of $0.7 million. These decreases were primarily due the decrease in consulting, marketing, and related expenses as OncoCyte concentrated its resources on the development of DetermaVu™ rather than on marketing related activities.

Conference Call

The Company will host a conference call today, April 1, 2019, at 4:30 pm EDT / 1:30 pm PDT to discuss the results along with recent corporate developments.

The dial-in number in the U.S./Canada is 877-407-9716; for international participants, the number is 201-493-6779. For all callers, please refer to Conference ID 13689139. To access the live webcast, go to the investor relations section on the Company's website, http://investors.oncocyte.com/events-and-presentations.

About DetermaVu™

DetermaVu™ is being developed as an intermediate step to confirm the absence of cancer after imaging modalities (LDCTs) that detect suspicious lung nodules and before 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™ has the potential to dramatically reduce U.S. healthcare costs by billions of dollars each year by eliminating unnecessary biopsies, which, according to a recent Medicare study, cost on average $14,634 each. In addition, DetermaVu™ can provide great benefit to patients by avoiding invasive biopsies and the complications that arise in up to 24% of those procedures, and deaths that occur in up to 1% of cases.

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.

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ONCOCYTE CORPORATION

BALANCE SHEETS

(IN THOUSANDS)

	December 31, 2018	December 31, 2017
ASSETS		

CURRENT ASSETS		
Cash and cash equivalents	$ 8,034	$ 7,600
Marketable equity securities	428	760
Prepaid expenses and other current assets	180	168
Total current assets	8,642	8,528
NONCURRENT ASSETS		
Intangible assets, net	-	746
Machinery and equipment, net	614	822
Deposits and other noncurrent assets	262	120
TOTAL ASSETS	$ 9,518	$ 10,216
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$ 2,101	$ 2,099
Accounts payable	166	175
Accrued expenses and other current liabilities	2,109	1,042
Loan payable, current	800	800
Capital lease liability, current	385	338
Total current liabilities	5,561	4,454
NONCURRENT LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	347	1,070
Capital lease liability, noncurrent	187	289
TOTAL LIABILITIES	6,095	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 December 31, 2018 and December 31, 2017, respectively	74,742	59,968
Accumulated other comprehensive loss	-	(888)
Accumulated deficit	(71,319)	(54,677)
Total stockholders' equity	3,423	4,403
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 9,518	$ 10,216

ONCOCYTE CORPORATION

STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended December 31, (unaudited)		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
OPERATING EXPENSES:				
Research and development	$ 1,204	$ 1,507	$ 6,514	$ 7,174

General and administrative	2,573	1,785	7,007	9,232
Sales and marketing	270	600	1,681	2,443
Total operating expenses	4,047	3,892	15,202	18,849
Loss from operations	(4,047)	(3,892)	(15,202)	(18,849)
OTHER EXPENSES, NET				
Interest expense, net	(50)	(68)	(216)	(217)
Unrealized loss on marketable equity securities	(498)	-	(427)	-
Other income (expense), net	96	-	91	(309)
Total other expenses, net	(452)	(68)	(552)	(526)
NET LOSS	$ (4,499)	$ (3,960)	$ (15,754)	$ (19,375)
Basic and diluted net loss per share	$ (0.11)	$ (0.13)	$ (0.42)	$ (0.64)
Weighted average shares outstanding: basic and diluted	40,664	31,440	37,850	30,195

STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Year Ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (15,754)	$ (19,375
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	438	338
Amortization of intangible assets	121	242
Amortization of prepaid maintenance	18	-
Impairment charge for intangible assets	625	-
Stock-based compensation	1,479	1,630
Loss on sale of BioTime shares	-	309
Dividend income from AgeX Therapeutics common stock received as dividend-in-kind	(96)	-
Unrealized loss on marketable equity securities	427	-
Warrants issued to certain shareholders as inducement to exercise of warrants	-	4,074
Amortization of debt issuance costs	77	83
Other	23	-
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	2	(753
Prepaid expenses and other current assets	(11)	115

Accounts payable and accrued liabilities	1,002	(48
Net cash used in operating activities	(11,649)	(13,385
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of BioTime shares	-	934
Purchase of equipment	(31)	(91
Net cash provided by (used in) investing activities	(31)	843
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	58	610
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	(800)	(133
Repayment of capital lease obligation	(381)	(265
Net cash provided by financing activities	12,114	9,968
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	434	(2,574
CASH AND CASH EQUIVALENTS:		
At beginning of the year	7,600	10,174
At end of the year	$ 8,034	$ 7,600

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 December 31, 2018 (unaudited)	**For the Year Ended December 31, 2018 (unaudited)**
GAAP Operating Expenses - as reported	**$ 4,047**	**$ 15,202**
Stock-based compensation expense	(400)	(1,479)
Impairment charge for intangible assets	-	(625)
Depreciation and amortization expense	(130)	(577)
Non-GAAP Operating Expenses, as adjusted	$ 3,517	$ 12,521

Source: OncoCyte Corporation

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