



## Oncocyte Provides Corporate Update And Reports First Quarter 2020 Financial Results

May 12, 2020

*Announced Final Medicare LCD from Palmetto for DetermaRx™, Potentially Establishing Medicare Coverage for up to 70% of Eligible Early-Stage NSCLC Patients*

*Signed First Strategic International Collaboration for DetermaRx with CORE, a Leading Molecular Reference Lab in India, the Middle East and Africa*

*DetermaDx™ Clinical Validation Results On-Track for End of Q2 2020*

*Growing Pharma Services Opportunity with Full Suite of Molecular Analyses to Support Drug Development*

*Conference Call Today, May 12, at 4:30 PM EDT*

IRVINE, Calif., May 12, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today reported financial and operating results for the first quarter ended March 31, 2020, and provided a corporate update.

“Oncocyte has built remarkable momentum in 2020, and we have continued our strong execution across our programs to provide patients and doctors with actionable answers with the potential to improve outcomes,” said Ron Andrews, Chief Executive Officer of Oncocyte. “We were thrilled to announce the recent final Medicare LCD from Palmetto, establishing Medicare coverage for DetermaRx™, the first and only test for chemotherapy benefit prediction in patients with surgically resected early stage NSCLC. This is an incredibly important milestone for Oncocyte as it may lead to Medicare reimbursement for up to 70% of eligible early-stage NSCLC patients, and also is the first step in securing broader reimbursement with private payers that typically follow CMS decisions. Our onboarding of new sites continues at a rapid pace, despite the COVID-19 pandemic, and we are excited to have expanded the reach of DetermaRx to India, the Middle East and Africa.”

Mr. Andrews continued, “We have also advanced DetermaIO™, our immunotherapy response prediction test, to commercial availability for research use only, and look forward to moving forward with opportunities in pharma services for immunotherapy trials, while also uncovering the potential utility of this test more broadly for clinical use in lung cancer and other types of solid tumors. These accomplishments, in combination with our on-track progress with DetermaRx, DetermaDx™ Clinical Validation and our expanding offerings for pharma services, make it clear that Oncocyte has reached a new era in its transformation to a leader in molecular diagnostics in lung cancer.”

## Recent Corporate Highlights

### • DetermaRx

- Announced final Medicare local coverage determination (LCD) from Palmetto potentially establishing Medicare coverage for up to 70% of eligible early-stage lung cancer patients
- Announced commercial availability in January and now have 20 sites onboarded including a number of large healthcare systems
- Expanded international availability through a distribution agreement with CORE Diagnostics, providing commercial availability of DetermaRx™ in India, the Middle East and Africa
- Successfully pivoted to virtual physician engagement due to COVID-19 and continued efforts to increase adoption of DetermaRx with over 1,500 participants in online physician education programs
- ATS 2020 International Conference abstract selected for oral presentation with long-term follow-up data from a 195-patient study demonstrating the clinical utility of DetermaRx in identifying high-risk cancers that can recur rapidly if untreated, as well as the potential to safely reduce follow-up for low-risk patients to conserve healthcare resources and limit patient stress
- Abstract accepted for the 2020 ASCO Virtual Meeting detailing potential significant health economic savings provided by DetermaRx

### • DetermaIO

- Completed CLIA validation of DetermaIO
- Announced commercial launch for research use only as a reliable and robust option for academic research and biopharma companies
- Advancing pharma services opportunities, including immunotherapy trials and development of companion diagnostics in lung cancer and other solid tumors
- Abstract accepted for presentation at the 2020 ASCO Virtual Meeting highlighting the potential utility of DetermaIO in triple-negative breast cancer (TNBC), in addition to NSCLC

### • DetermaDx

- Announced successful completion of CLIA Validation Study
- Clinical Validation study on-track for completion in Q2 2020
- ATS 2020 International Conference abstract selected for oral presentation with data highlighting clinical features of the IRENE (Immune Response for Nodule Evaluation) Study population, a 2,903-patient sample biobank from 62 sites across the U.S. The study identified significant differences in the management of pulmonary nodules including different rates of invasive procedures across the academic, community and Veterans Affairs settings. These findings highlight the clinical decision challenge in managing the use of invasive biopsies for lung nodule diagnosis that DetermaDx has the potential to address.

### • Pharma Services

- Re-launch of pharma services offering with full suite of molecular analyses including tissue and blood-based technologies, proprietary platforms such as DetermaIO and TNBCType Assay, as well as custom next-generation sequencing and PCR services including whole exome sequencing, RNA-seq and targeted mutation panels
- With collaborators from MD Anderson Cancer Center, announced the peer-reviewed publication in *PLOS One* with data demonstrating the utility of the TNBCType Assay to inform triple-negative breast cancer drug development by identifying the most suitable cell lines to help biopharma and academic researchers develop new treatments

## • Financial and Corporate

- In April, Oncocyte successfully completed a \$10.7 million registered offering of common shares, priced at the market, directly with fundamentally driven, healthcare focused institutional investors. This transaction builds on the successful \$7.6 million registered offering in January, further strengthening Oncocyte's balance sheet to support the continued commercialization of DetermaRx and DetermaIO, as well as the continued development of DetermaDx and other programs.
- Moved Oncocyte's administrative and executive headquarters to Orange County, California, in January 2020 with ongoing plans to construct a clinical diagnostic and research laboratory to eventually have full service labs on the west and east coasts.

### First Quarter 2020 Financial Highlights

At March 31, 2020, Oncocyte had cash, cash equivalents and marketable securities of \$16.9 million as compared to \$22.5 million at December 31, 2019. In April 2020, Oncocyte completed a \$10.7 million registered offering of common shares, priced at the market.

Prior to January 1, 2020, Oncocyte had no revenues. During the current quarter, Oncocyte commercialized DetermaRx™ and completed the acquisition of Insight Genetics, providing sources of revenue generation and other commercial opportunities for the first time since the company's inception.

Under U.S. accounting principles, Oncocyte will be able to recognize revenues on an accrual basis of accounting once it has contracts for reimbursement from third-party payers or a history of experience of cash collections for the tests performed, or both. Until that time, Oncocyte expects to recognize revenue for tests performed on a cash basis. Accordingly, Oncocyte will incur and accrue cost of revenues and other operating expenses related to its diagnostic tests, including DetermaRx™.

Beginning on January 31, 2020, Oncocyte's consolidated financial statements and results also include the results from its wholly owned subsidiary, Insight Genetics, which Oncocyte acquired on that date.

For the first quarter ended March 31, 2020, Oncocyte reported a net loss of \$7.7 million, or \$(0.13) per share, as compared to \$3.9 million, or \$(0.08) per share, for the first quarter ended March 31, 2019.

Operating losses, as reported, for the first quarter of 2020 were \$8.4 million, an increase of \$4.4 million from \$4.0 million as compared to the first quarter of 2019; and operating losses, on an adjusted basis, were \$7.4 million, an increase of \$4.2 million from \$3.2 million as compared to the first quarter of 2019.

Oncocyte has provided a reconciliation between GAAP and non-GAAP operating losses in the financial tables, included with this earnings release, which it believes is helpful in understanding its ongoing operations.

Research and development expenses for first quarter of 2020 were \$2.2 million as compared to \$1.3 million for the same period in 2019, an increase of \$0.9 million. The increase was primarily attributable to personnel and laboratory related expenses for clinical validation activities related to DetermaDx™.

General and administrative expenses for the first quarter of 2020 were \$4.6 million, as compared to \$2.4 million for the same period in 2019, an increase of \$2.2 million. The increase was mainly due to personnel and related expenses; investment banking expenses; legal, business development, investor relations expenses; and noncash stock-based compensation expenses due to additional equity grants. As noted above, Oncocyte transitioned from the Lineage Cell Therapeutics (formerly BioTime) Shared Services agreement in the latter half of 2019, and established its own administrative, human resources,

legal, finance and accounting functions and teams. This transition also includes the termination of the Shared Facilities agreement with Lineage as of December 31, 2019. In addition, Oncocyte moved its administrative and executive headquarters to Orange County, California, in January 2020 with ongoing plans to construct a clinical diagnostic and research laboratory to eventually have full service labs on the west and east coasts.

Sales and marketing expenses for the three months ended March 31, 2020, were \$1.5 million, as compared to \$0.2 million for the same period in 2019, an increase of \$1.3 million. The increase was primarily due to ramping up in sales and marketing activities, including key hires, for commercialization of DetermaRx™.

Cash used in operations was approximately \$6.9 million for the first quarter of 2020 as compared to approximately \$6.7 million during the first quarter of 2019, which is in line with Oncocyte's expectations as the first quarter of each year is generally the largest cash use quarter of the year due to the timing of payments of annual merit increases and other payments. Oncocyte also paid some nonrecurring, acquisition-related legal and other costs of approximately \$0.5 million in the first quarter of 2020.

## **Conference Call**

The Company will host a conference call today, May 12, 2020, 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 13703079. To access the live webcast, go to the investor relations section on the Company's website, or by clicking here: <http://public.viaavid.com/index.php?id=139620>.

## **About Oncocyte Corporation**

Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the cancer care continuum, with the goal of improving patient outcomes by accelerating and optimizing diagnosis and treatment. The Company recently launched DetermaRx™, a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence post-resection, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. DetermaDx™, the company's liquid biopsy test in development, utilizes a proprietary immune system interrogation approach to clarify if a patient's lung nodules are benign, which may enable them to avoid potentially risky invasive diagnostic procedures. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint immunotherapies. DetermaDx, DetermaRx and DetermaIO are trademarks of Oncocyte Corporation.

## **Oncocyte Forward Looking Statements**

Oncocyte cautions you that this press release contains 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," "may," and similar expressions) are forward-looking statements. These statements include, but are not limited to, those pertaining to the commercial launch of DetermaRx, development of DetermaDx and DetermaIO, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from acquisitions, 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, the potential impact of COVID-19 on our

financial and operational results, 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, potential interruptions to our supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize, and risks inherent in acquisitions such as failure to realize anticipated benefits, unexpected expenditures or assumed liabilities, unanticipated difficulties in conforming business practices including accounting policies, procedures and internal controls, greater than estimated allocations of resources to develop and commercialize technologies, or failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly 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, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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## **ONCOCYTE CORPORATION**

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### **CONSOLIDATED BALANCE SHEETS**

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*(\$ in thousands)*

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**March 31,**

**December  
31,**

**2020**

**2019**

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**ASSETS**

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CURRENT ASSETS

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Cash and cash equivalents	\$ 16,577	\$ 22,072
Accounts receivable	13	-
Marketable equity securities	325	379
Prepaid expenses and other current assets	1,224	505
Total current assets	18,139	22,956

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CURRENT ASSETS

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Right-of use-assets, machinery and equipment, net	\$ 4,298	\$ 3,728
Equity method investment in Razor	10,635	10,964
Goodwill	9,187	-
Intangibles, net	15,075	-
Deposits and other non current assets	2,169	2,211
TOTAL ASSETS	\$ 59,503	\$ 39,859

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**LIABILITIES AND SHAREHOLDERS' EQUITY**

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CURRENT LIABILITIES

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Amount due to Lineage and affiliates	\$ -	\$ 6
Accounts payable	1,635	469
Accrued expenses and other current liabilities	3,420	2,610
Loan payable, current	1,500	1,125
Right-of-use and financing lease liabilities, current	373	230
Total current liabilities	6,928	4,440

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**NONCURRENT LIABILITIES**

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Loan payable, net of deferred financing costs, noncurrent	1,565	1,905
Right-of-use and financing lease liabilities, noncurrent	3,097	2,676
Contingent consideration liabilities	11,130	-
Deferred tax liability	158	-
<b>TOTAL LIABILITIES</b>	<b>22,878</b>	<b>9,021</b>

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**SHAREHOLDERS' EQUITY**

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Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 85,000 shares authorized; 62,484 and 57,032 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	138,102	124,583
Accumulated other comprehensive loss	-	-
Accumulated deficit	(101,477 )	(93,745 )
Total shareholders' equity	36,625	30,838
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 59,503</b>	<b>\$ 39,859</b>

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**ONCOCYTE CORPORATION**

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**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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*(In thousands, except per share data)*

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	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
	<b>unaudited</b>	<b>unaudited</b>
<b>REVENUE</b>		
Total revenue	\$ 16	\$ -
<b>TOTAL COSTS AND OPERATING EXPENSES</b>		
Cost of revenue	\$ 173	\$ -
Research and development	2,159	1,343
General and administrative	4,625	2,449
Sales and marketing	1,490	205
Total costs and operating expenses	8,447	3,997
Loss from operations	(8,431 )	(3,997 )
<b>OTHER INCOME (EXPENSES), NET</b>		
Interest expense, net	(22 )	(19 )
Unrealized loss on marketable equity securities	(53 )	178
Pro rata loss from equity method investment in Razor	(329 )	-
Other income (expense), net	8	(26 )
Total other income (expenses), net	(396 )	133

<b>LOSS BEFORE INCOME TAXES</b>	(8,827 )	(3,864 )
Income tax benefit	1,095	-
<b>NET LOSS</b>	\$ (7,732 )	\$ (3,864 )
Net loss per share; basic and diluted	\$ (0.13 )	\$ (0.08 )
Weighted average shares outstanding; basic and diluted	61,459	46,647

**ONCOCYTE CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

*(In thousands)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
	<b>unaudited</b>	<b>unaudited</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (7,732 )	\$ (3,864 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	60	110

Amortization of intangible assets	15	-
Amortization of right-of-use assets and liabilities	152	-
Pro rata loss from equity method investment in Razor	329	-
Amortization of prepaid maintenance	36	9
Stock-based compensation	937	686
Unrealized (gain) loss on marketable equity securities	53	(178 )
Amortization of debt issuance costs	35	12
Deferred income tax benefit	(1,095 )	-
Other	-	26
Changes in operating assets and liabilities:		
Accounts receivable	8	-
Amount due to Lineage and affiliates	(6 )	(2,101 )
Prepaid expenses and other assets	(909 )	(950 )
Accounts payable and accrued liabilities	1,247	(468 )
Net cash used in operating activities	(6,870 )	(6,718 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of Insight Genetics, net of cash acquired	(6,189 )	-
Purchase of equipment	(44 )	(7 )
Security deposit and other	42	54
Net cash provided by (used in) investing activities	(6,191 )	47
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	-	943
Proceeds from sale of common shares	7,597	40,250

Financing costs to issue common shares	(1	)	(2,965	)
Common shares received and retired for employee taxes paid	(14	)	-	
Repayment of loan payable	-		(200	)
Repayment of financing lease obligations	(17	)	(134	)
Net cash provided by financing activities	7,565		37,894	
<b>NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	(5,496	)	31,223	
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH:</b>				
At beginning of the period	23,773		8,034	
At end of the period	\$ 18,277		\$ 39,257	



Source: OncoCyte Corporation

