



## ONCOCYTE PROVIDES CORPORATE UPDATE AND REPORTS FOURTH QUARTER AND FULL YEAR 2019 FINANCIAL RESULTS

Mar 25, 2020

*Initiated Commercial Launch of DetermaRx™ in U.S.*

*Completed Acquisition of Insight Genetics*

*Initiated Research Use Launch of DetermaIO™ After Completion of CLIA Validation*

*Successful Completion of DetermaDx™ CLIA Validation*

*Conference call today, March 25, at 4:30 PM EDT*

IRVINE, Calif., March 25, 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 fourth quarter and year ended December 31, 2019, and provided a corporate update.

“We started 2020 in a strong position with significant accomplishments that support our strategy to provide actionable answers to physicians and their patients with the goal of improving outcomes and survival,” said Ron Andrews, Chief Executive Officer of Oncocyte. “I am incredibly proud to have officially transitioned to a commercial stage company with the launch of DetermaRx™, the first test for chemotherapy benefit prediction in patients with NSCLC. We have successfully onboarded all 7 of our early access partners and they have started sending patient samples to our lab and, notably, all physicians have re-ordered the test, a very important indicator of future utilization. To date, we have identified 7 ‘high-risk’ patients and believe we are already saving lives by identifying high-risk patients whose treatment course will now include adjuvant chemotherapy instead of surgical resection alone. This is a remarkable advancement for early NSCLC patients, and we are honored to be able to provide clarity for these patients and their physicians when making critical decisions after surgery. We look forward to receiving our final coverage decision from CMS and our continued progress in widespread adoption of this important test.”

Mr. Andrews continued, “While we are doing our part to minimize the COVID-19 situation in our local communities, we have been able to continue lab operations in compliance with applicable orders and mandates, and have made great strides in expanding our suite of important tests with the acquisition of Insight Genetics which includes DetermaIO™, our immunotherapy response prediction test. With the recently announced CLIA validation of DetermaIO™, and the subsequent commercial launch for research use in academic and biopharma settings, we are poised to provide a valuable and potentially transformative test that we believe, based on recently published clinical data, outperforms currently available PD-L1 and TMB immunotherapy response prediction tests. We also have continued our

progress in advancing DetermaDx™, and we were pleased to announce the completion of CLIA validation in early January, consistent with our previous guidance, and believe we are now on track with clinical validation and preparations for commercial availability. Taken together, it is clear that Oncocyte is transforming into a leader for early lung content. While cancer surgeries are being impacted by the current COVID-19 situation, our discussions with surgeons indicate that these patients will still be getting treated and surgeries will restart soon, so our focus is on being ready when that moment happens. We look forward to continued execution across our commercialization and development efforts for a milestone rich 2020.”

## Recent Corporate Highlights

- Successfully completed acquisition of Insight Genetics
  - Acquisition broadens Oncocyte’s portfolio of molecular diagnostic tests with addition of DetermaO™, a potentially transformative immunotherapy response prediction test demonstrated to outperform PD-L1 and TMB tests
  - Completed CLIA validation of DetermaO™, enabling research use launch of the test as a reliable and robust option for academic research and biopharma companies
  - Unlocks significant pharma services opportunity including immunotherapy trials and development of companion diagnostics in lung cancer and other solid tumors
  - Acquisition significantly expands Oncocyte’s suite of proprietary tests to manage key decision points potentially across multiple stages and types of cancer, as immunotherapies are currently approved for thirteen solid tumor types
- Transformed into a commercial stage company with launch of DetermaRx™
  - Announced commercial availability of DetermaRx™ in early January, transforming Oncocyte to a commercial stage company. With multiple sites already onboarded and testing beginning, the commercial team is focused on driving rapid adoption across specialty physicians
  - DetermaRx™, a CLIA-validated lung cancer treatment stratification test, broadens Oncocyte’s capabilities with an extensively validated and published molecular test that enables the identification of early-stage lung cancer patients at high risk for recurrence that are likely to benefit from chemotherapy. OncoCyte acquired the rights to commercialize this test from Razor Genomics in September 2019
  - Received regulatory approval to begin distribution of DetermaRx™ in Canada
  - Provided an educational grant in support of an accredited Continuing Medical Education (CME) Activity: Advances in™ Diagnostic Testing: Assessing Your Patient's Risk of Recurrence to Inform Treatment Decisions in Early-Stage NSCLC
- Successful Completion of CLIA Validation Study of DetermaDx™
  - Demonstrates the successful transfer of the research assay to the rigorous environment of Oncocyte’s commercial CLIA laboratory
  - Oncocyte has commenced Clinical Validation, which is expected to be completed in Q2 2020. Upon successful completion of Clinical Validation and establishment of performance parameters, Oncocyte will begin preparations for commercial availability
- Presented data at the CHEST Annual Meeting 2019 on the Immune Response for Nodule Evaluation (IRENE) clinical cohort used for the development and validation of DetermaDx™. IRENE is one of the largest reported clinical study cohorts in lung nodule management with 62 sites in the U.S. and over 3,000 enrolled patients. IRENE is uniquely representative across clinical settings with a focus on community practices, where most lung cancer patients are diagnosed and treated

- Successfully completed a \$7.6 million registered offering of common shares, priced at the market, directly with fundamentally driven, healthcare focused institutional investors. The proceeds strengthened Oncocyte's balance sheet, which will support the strategic commercial launch of the DetermaRx™ lung cancer stratification test and the continued development of DetermaDx™
- Moved Oncocyte's administrative and executive headquarters to Orange County, California, in January 2020. Plans to construct a clinical diagnostic laboratory and a research laboratory at the new location are being implemented. The move best suited Oncocyte's need to find talented individuals to join its growing team and provides opportunities to engage with oncology patients in the community setting, as well as potentially reduce overall operating costs associated with our CLIA Lab Service

#### **Fourth Quarter and Annual 2019 Financial Highlights**

At December 31, 2019, Oncocyte had cash, cash equivalents, and marketable securities of \$22.5 million as compared to \$8.5 million at December 31, 2018. On March 20, 2020 Oncocyte put in place an at-the-market (ATM) offering for access to additional working capital.

For the fourth quarter ended December 31, 2019, Oncocyte reported a net loss of \$8.0 million, or \$(0.15) per share, as compared to \$4.5 million, or \$(0.11) per share, for the fourth quarter ended December 31, 2018.

For 2019, Oncocyte reported a net loss of \$22.4 million, or \$(0.44) per share, compared to \$15.8 million, or \$(0.42) per share for 2018.

Operating expenses, as reported, for the three months ended December 31, 2019 were \$7.5 million, an increase of \$3.5 million as compared to the same period in 2018. Operating expenses, as adjusted, for the three months ended December 31, 2019, were \$6.7 million, an increase of \$3.1 million as compared to the same period in 2018.

Operating expenses, as reported, for the year ended December 31, 2019, were \$22.2 million, an increase of \$7.0 million as compared to the same period 2018. Operating expenses, as adjusted, for the year ended December 31, 2019, were \$18.6 million, an increase of \$6.1 million as compared in 2018.

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 fourth quarter of 2019 were \$2.3 million as compared to \$1.2 million for the same period in 2018, an increase of \$1.1 million. The increase was primarily attributable to personnel and laboratory related expenses for the completion of CLIA validation of DetermaDx™. Research and development expenses for 2019 were \$6.8 million as compared to \$6.5 million for 2018, remained relatively unchanged.

General and administrative expenses for the fourth quarter of 2019 were \$4.2 million, as compared to \$2.6 million for the same period in 2018, an increase of \$1.6 million. General and administrative expenses for the year ended December 31, 2019, were \$13.3 million, as compared to \$7.0 million for 2018, an increase of \$6.3 million. The increases were primarily attributable to personnel and related expenses, including management transition costs; investment banking expenses; legal, business development, investor relations, recruiting, audit and accounting related expenses; and noncash stock-based compensation expense due to additional equity grants. As Oncocyte transitioned from Lineage Cell Therapeutics ("Lineage" formerly BioTime, Inc.) Shared Services by the second half of 2019, Oncocyte

hired its own administrative, human resources, legal, finance and accounting functions and teams. This transition also included the termination of the Shared Facilities agreement with Lineage as of December 31, 2019, in which Oncocyte leased its own facilities and laboratories and moved into its Irvine, California, headquarters in January 2020.

Sales and marketing expenses for the three months ended December 31, 2019, were \$1.0 million, as compared to \$0.3 million for the same period in 2018, an increase of \$0.7 million. Sales and marketing expenses for 2019 were \$2.2 million, as compared to \$1.7 million for 2018, an increase of \$0.5 million. The increases were primarily due to sales and marketing efforts, including key hires and ramp-up in activities for commercialization of DetermaRx™.

## **Conference Call**

The Company will host a conference call today, March 25, 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 13700598. To access the live webcast, go to the investor relations section on the Company's website, or by clicking here:

<http://public.viavid.com/index.php?id=138611>.

## **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 patients' 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.

## **Oncocyte Forward Looking Statements**

Oncocyte cautions you that this press release contains forward-looking statements concerning, but not limited to, the commercial launch of DetermaRx, the acquisition of Insight Genetics, the commercial launch of DetermaIO for research use, and the DetermaDx clinical validation study. 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 those pertaining to the development of DetermaDx and the ongoing Clinical Validation study, the impact of the commercial launch of DetermaIO and DetermaRx, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from the acquisition of Insight Genetics, the impact on our business of the COVID-19 pandemic, 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, 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 the anticipated benefits of the acquisition, unexpected expenditures or assumed liabilities that may be incurred as a result of the acquisition, unanticipated difficulties in conforming business practices, including accounting policies, procedures and internal controls, 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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**BALANCE SHEETS**

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*(In thousands)*

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**December 31,**

**2019**

**2018**

**ASSETS**

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CURRENT ASSETS

Cash and cash equivalents	\$ 22,072	\$ 8,034
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Marketable equity securities	379	428
Prepaid expenses and other current assets	505	180
Total current assets	22,956	8,642
NONCURRENT ASSETS		
Right-of-use assets, machinery and equipment, net	3,728	614
Deposits and other noncurrent assets	2,211	262
Equity method investment in Razor	10,964	-
TOTAL ASSETS	\$ 39,859	\$ 9,518

## LIABILITIES AND SHAREHOLDERS' EQUITY

### CURRENT LIABILITIES

Amount due to Lineage and affiliates	\$ 6	\$ 2,101
Accounts payable	469	166
Accrued expenses and other current liabilities	2,610	2,109
Loan payable, current	1,125	800
Right-of-use and financing lease liabilities, current	230	385
Total current liabilities	4,440	5,561

### NONCURRENT LIABILITIES

Loan payable, net of deferred financing costs, noncurrent	1,905	347
Right-of-use and financing lease liabilities, noncurrent	2,676	187
TOTAL LIABILITIES	9,021	6,095

### SHAREHOLDERS' EQUITY

Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 85,000 shares authorized; 57,032 and 40,664 shares issued and outstanding at December 31, 2019 and 2018, respectively	124,583	74,742
Accumulated other comprehensive loss	-	-
Accumulated deficit	(93,745 )	(71,319 )
Total shareholders' equity	30,838	3,423
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 39,859</b>	<b>\$ 9,518</b>

## **ONCOCYTE CORPORATION**

### **STATEMENTS OF OPERATIONS**

*(In thousands, except per share data)*

	<b>Three Months Ended</b>			
	<b>December 31,</b>		<b>Year Ended</b>	
	<b>2019</b>	<b>2018</b>	<b>December 31,</b>	
	<b>unaudited</b>	<b>unaudited</b>	<b>2019</b>	<b>2018</b>
<b>OPERATING EXPENSES</b>				
Research and development	\$ 2,318	\$ 1,204	\$ 6,794	\$ 6,51
General and administrative	4,194	2,573	13,281	7,00

Sales and marketing	1,011	270	2,164	1,68
Total operating expenses	7,523	4,047	22,239	15,2
Loss from operations	(7,523 )	(4,047 )	(22,239 )	(15,2
<b>OTHER INCOME (EXPENSES), NET</b>				
Loss on extinguishment of debt	(153 )	-	(153 )	-
Interest income (expense), net	17	(50 )	299	(216
Unrealized loss on marketable equity securities	(36 )	(498 )	(49 )	(427
Pro rata loss from equity method investment in Razor	(281 )	-	(281 )	-
Other income (expense), net	22	96	(3 )	91
Total other expenses, net	(431 )	(452 )	(187 )	(552
<b>NET LOSS</b>	\$ (7,954 )	\$ (4,499 )	\$ (22,426 )	\$ (15,7
Net loss per share; basic	\$ (0.15 )	\$ (0.11 )	\$ (0.44 )	\$ (0.42

and diluted

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Weighted average shares outstanding; basic and diluted	54,499	40,664	51,296	37,8
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## ONCOCYTE CORPORATION

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### STATEMENTS OF CASH FLOWS

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*(In thousands)*

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#### Year Ended December 31

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**2019**

**2018**

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#### CASH FLOWS FROM OPERATING ACTIVITIES:

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Net loss	\$ (22,426 )	\$ (15,754 )
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Adjustments to reconcile net loss to net cash used in operating activities:

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Depreciation expense	344	438
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Amortization of intangible assets	-	121
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Amortization of right of use assets and liabilities	7	-
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Pro rata loss from equity method investment in Razor	281	-
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Amortization of prepaid maintenance	37	18
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Impairment charge for intangible assets	-	625
Stock-based compensation	2,995	1,479
Dividend income from AgeX Therapeutics common stock received as a dividend-in-kind	-	(96 )
Unrealized loss on marketable equity securities	49	427
Amortization of debt issuance costs	59	77
Loss on extinguishment of debt	153	-
Warrants issued for advisory services	234	-
Other	107	23
Changes in operating assets and liabilities:		
Amount due to Lineage and affiliates	(2,094 )	2
Prepaid expenses and other current assets	(202 )	(11 )
Accounts payable and accrued liabilities	741	1,002
Net cash used in operating activities	(19,715 )	(11,649 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Equity method investment in Razor	(11,245 )	-
Purchase of equipment	(918 )	(31 )
Security deposit and other	(252 )	-
Net cash used in investing activities	(12,415 )	(31 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options	943	58
Proceeds from sale of common shares	48,850	10,000
Financing costs to issue common shares	(3,288 )	(65 )
Proceeds from sale of common shares and warrants	-	3,592

Financing costs to issue common shares and warrants	-	(290 )
Proceeds from refinance of bank loan	3,000	-
Payoff of principal and bank fees from refinancing of bank loan	(516 )	-
Repayment of principal of loan payable prior to refinancing	(667 )	(800 )
Repayment of financing lease obligations	(454 )	(381 )
Net cash provided by financing activities	47,868	12,114
<b>NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	15,738	434
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH:</b>		
At beginning of the year	8,034	7,600
At end of the year	\$ 23,772	\$ 8,034

### **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, an impairment charge for intangible assets, and certain warrants expense. 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

	<b>Amounts In Thousands</b>		<b>Amounts In Thousands</b>	
	<b>For the Three Months Ended</b>		<b>For the Twelve Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>	<b>(unaudited)</b>	<b>(unaudited)</b>
<b>GAAP Operating Expenses - as reported</b>	<b>\$ 7,523</b>	<b>\$ 4,047</b>	<b>\$ 22,239</b>	<b>\$ 15,202</b>
Stock-based compensation expense	(786 )	(400 )	(2,995 )	(1,479 )
Impairment charge for intangible assets	-	-	-	(625 )
Noncash warrant expense	-	-	(234 )	-
Depreciation and amortization expense	(75 )	(130 )	(381 )	(577 )

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Non-GAAP Operating Expenses, as adjusted	\$ 6,662	\$ 3,517	\$ 18,629	\$ 12,521
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Source: OncoCyte Corporation

