Oncocyte Provides Corporate Update and Reports Fourth Quarter and Annual 2020 Financial Results

Mar 16, 2021

DetermaRx commercialization momentum continues with 36% sample growth and 58% revenue growth compared to Q3 2020

On track to launch DetermaIO™ in 2021 for immune therapy selection

Scheduled to present data at 2021 American Association for Cancer Research (AACR) Annual Meeting that supports DetermaIO's potential pan-cancer applicability

Strengthened balance sheet to support ramping commercialization of Oncocyte's broadening product portfolio

Conference call scheduled for 4:30 P.M. EDT

IRVINE, Calif., March 16, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today reported financial results for the fourth quarter and full year 2020 ended December 31, 2020, along with a corporate update.

"In a short time, we have transformed Oncocyte from a single-product, development stage company into a commercial stage oncology diagnostics company with a broadening product portfolio and multiple engines of revenue growth," said Ron Andrews, President and Chief Executive Officer of Oncocyte. "We began to build momentum in the commercialization of our expanding product portfolio targeting a multi-billion-dollar global market opportunity for diagnostic tests to help physicians make critical treatment decisions across the cancer care continuum. We launched DetermaRx™, which in Q4 generated strong unit growth and even faster revenue growth. We completed clinical studies of DetermaIO™, our flagship proprietary product for immune therapy selection, laying the groundwork to launch that product in the second half of 2021. We also are preparing for the commercial launch of a complementary targeted therapy panel later this year as well as the launch of DetermaCNI™ for research and pharma clinical trial use, also in the second half of this year. Our recent equity offering strengthened our balance sheet in preparation for our broadening commercialization efforts, including our planned expansion in medical education programs and sales coverage. We are now focused on executing several anticipated product launches throughout 2021 to ensure that we create maximum value from our product portfolio for patients and shareholders."

Commenting on the fourth quarter, Padma Sundar, Chief Commercial Officer stated, "We continue to be encouraged with the commercial success of DetermaRx in its first year. Despite the headwind of the surge in COVID-19 cases in the fourth quarter, we generated 36% sequential growth in DetermaRx orders

and 58% sequential revenue growth. In its first year as a commercial product, DetermaRx received high value Medicare coverage, including adoption into the standard of care menu for multiple hospital systems and large oncology groups. We also struck several domestic and global collaboration and distribution agreements. For example, our agreement with Burning Rock Biotech may provide access to the DetermaRx test to the estimated 250,000 patients in China who receive surgical resections for non-small cell lung cancer each year."

Mr Andrews concluded, "In Q4, we were offered the opportunity to make additional investments in new studies that allowed us to expand our indications for DetermaIO as well as expand our sales and medical education teams which increased our expense burden for the quarter. With the lineup of publications, papers and abstracts now scheduled for release over the coming months, like the AACR abstract released yesterday, we feel the ROI on the additional expenses will be significant and thus, we anticipate a rapid cadence of important data releases and new product launches in 2021. We are on track to launch DetermaIO™ for immunotherapy response prediction and DetermaTx™ for targeted therapy selection, both planned in the fourth quarter. These two expected product launches will expand the focus of Oncocyte's commercialized product portfolio to an estimated combined addressable market opportunity of over $5 billion."

"Our broadening product portfolio will also position Oncocyte as a one-stop oncology lab capable of rapidly and efficiently providing comprehensive testing across treatment decisions, not just for lung cancer but also potentially as a pan cancer test for the majority of solid tumors. With our strengthened balance sheet, we plan to continue driving rapid unit and revenue growth across our expanded product portfolio. We also plan to hire additional high-performing sales and market access staff, and to onboard additional leading cancer centers, in part with the advice and guidance of our new Medical Advisory Board. We look forward to continuing to penetrate the multi-billion-dollar market opportunity anticipated for our tests and building Oncocyte's brand as a leading partner to physicians, patients and payers in making cost effective, critical treatment decisions across the cancer care continuum."

Fourth Quarter and Recent Highlights Include:

DetermaIO

- Over the course of 2020, the test was accepted for studies in several important trials, including the NeoTrip Trial for Neoadjuvant Triple Negative Breast cancer utility. Data from these studies will be presented at major medical meetings and via peer-reviewed publications throughout 2021
- Published peer-reviewed study demonstrating that DetermaIO's gene expression analysis of the complete tumor micro-environment followed by synthesis using a proprietary algorithm may be predictive of response across multiple solid tumors
- Selection of abstract for mini-symposium presentation at AACR 2021 demonstrating potential clinical utility of DetermaIO in a third cancer – bladder cancer, in addition to NSCLC and TNBC
- Presented data at the Association for Molecular Pathology 2020 Conference, demonstrating that DetermaIO is reproducible at tissue inputs compatible with very small tissue samples, which is critical for driving broad test usage given the scarcity of tissue for competing molecular testing methods
- Presented data at the ASCO 2020 conference and the IASLC North America 2020 which demonstrated DetermaIO outperformed PD-L1 testing in predicting response to immune-checkpoint inhibitors in triple negative breast cancer and non-small cell lung cancer
- Established a Medical Advisory Board of world-renowned thought leaders in oncology to assist in accelerating our clinical development and publication efforts in immune-oncology and blood-based monitoring

DetermaRx

- Test volumes continued to grow in Q4 2020 with 36% quarter over quarter increase in testing volume to 238 samples, 58% increase in DetermaRx revenues driven by initiation of Medicare payments starting in September 2020, and 22% increase in onboarded hospitals to 82 customers; maintained physician re-order rate of approximately 60%
- Signed agreement with Multiplan networks, representing 60 million covered lives, to offer DetermaRx at a high-value reimbursement rate commensurate with Medicare
- Signed exclusive agreement with Burning Rock Biotech in China to license DetermaRx in China, the world's largest early stage lung cancer market, with an estimated 250,000 patient Total Addressable Market (TAM), reaching our goal of distribution to all major world markets within the first year of launch
- Presented new data at the IASLC 2020 World Conference on Lung Cancer showing broad adoption and real-world clinical utility of its DetermaRx test for early-stage lung cancer
- Closed second investment in Razor Genomics to complete acquisition of founding company behind DetermaRx

Pharma Services

- Initiated clinical trial processing of proprietary, blood-based monitoring assay for targeted drug response for a top 20 Pharma company
- Continued execution on FDA submission studies for a leading global diagnostic company
- Executed on site certification for two new customers, a major global pharma and leading diagnostic company, which is expected to lead to new project revenues in 2021 and beyond
- Finalizing Pharma service component of immune oncology testing for clinical trial for Fondazione Michelangelo, a leading non-profit Cancer research foundation

Fourth Quarter and Annual 2020 Financial Results

At December 31, 2020, Oncocyte had cash, cash equivalents and marketable securities of $7.8 million. In January and February 2021, Oncocyte raised an aggregate of $69 million in net proceeds from two public offerings and shares sold from its at-the-market (ATM) program. In February 2021, Oncocyte completed the acquisition of the remaining equity interests in Razor Genomics and paid the $10 million cash portion to the selling shareholders, so Oncocyte now owns all of the outstanding common stock of Razor and will consolidate Razor as of that date.

Oncocyte currently derives its revenues from the sale of its lung cancer test, DetermaRx, which was commercially launched in early 2020 and pharma services generated by its wholly owned subsidiary, Insight Genetics, which was acquired on January 31, 2020. Upon CMS and Noridian final pricing decision for the DetermaRx test, which became effective in September 2020, Oncocyte is able to recognize revenues for Medicare covered tests on an accrual basis, rather than on a cash basis, when the tests are performed.

Under U.S. accounting principles, for all payers other than Medicare, Oncocyte will be able to recognize revenues for DetermaRx 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, for all payers other than Medicare, Oncocyte expects to recognize revenue for DetermaRx tests performed on a cash basis. Accordingly, Oncocyte will incur and accrue cost of revenues and other

operating expenses related to all DetermaRx tests ordered and processed, including its pharma services performed.

Revenues for the three and twelve months ended December 31, 2020 were $0.5 million and $1.2 million respectively, generated from pharma services and DetermaRx tests completed that are covered by Medicare on an accrual basis since Oncocyte received a final pricing from CMS in September. DetermaRx revenues grew solidly in Q4 2020 versus Q3 2020, primarily due to revenue recognized for Medicare tests performed following the receipt of final CMS pricing decision in September 2020. The number of tests ordered increased significantly in the fourth quarter as compared to the third quarter of 2020 despite the COVID-19 resurgence. Pharma Services' revenues in the fourth quarter of 2020 were lower sequentially when compared to the third quarter of 2020, due to delays in project completion as a part of the COVID surge which are being carried over and are expected to be completed in the first half of 2021. Prior to January 1, 2020, Oncocyte had no revenues and no cost of revenues.

Research and development expenses for fourth quarter of 2020 were $1.8 million as compared to $2.3 million for the same period in 2019, a decrease of $0.5 million, primarily due to reduced clinical trial expenses of DetermaDx™. Research and development expenses for the year ended December 31, 2020, were $9.8 million as compared to $6.8 million for the same period in 2019, an increase of $3.0 million primarily attributable to increased investment in DetermaIO, personnel and related expenses.

General and administrative expenses for the fourth quarter of 2020 were $3.4 million, as compared to $4.2 million for the same period in 2019, a decrease of $0.8 million. General and administrative expenses for the year ended December 31, 2020 were $16.8 million, as compared to $13.3 million for the same period in 2019, an increase of $3.5 million, primarily attributable to personnel growth and related expenses.

Sales and marketing expenses for the three and twelve months ended December 31, 2020, were $1.9 million and $6.5 million, as compared to $1.0 million and $2.2 million for the same periods in 2019, respectively. The increases in the respective periods were primarily due to personnel and related expenses for ramp up in sales and marketing activities for the commercialization efforts of DetermaRx as well as market development investments in preparation for the launch of new products in 2021.

Operating losses, as reported, for the fourth quarter of 2020 were $6.3 million, a decrease of $1.2 million from $7.5 million as compared to the fourth quarter of 2019; and operating losses, on an adjusted basis, were $6.2 million, a decrease of $0.5 million from $6.7 million as compared to the fourth quarter of 2019. Operating losses, as reported, for the year ended December 31, 2020 were $29.7 million, an increase of $7.5 million from $22.2 million as compared to the same period in 2019; and operating losses, on an adjusted basis, were $26.5 million, an increase of $7.9 million from $18.6 million as compared to the same period in 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.

For the fourth quarter ended December 31, 2020, Oncocyte reported a net loss of $6.3 million, or ($0.09) per share, as compared to $8.0 million, or ($0.15) per share, for the fourth quarter ended December 31, 2019.

For the year ended December 31, 2020, Oncocyte reported a net loss of $29.9 million, or ($0.46) per share compared to $22.4 million, or ($0.44) per share for 2019.

Cash used in operations was approximately $6.2 million for the fourth quarter of 2020 and $26.0 million for the year ended December 31, 2020.

Conference Call Information

The Company will host a conference call today, March 16, 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 13717267. 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=143840. The webcast replay will be available on the Oncocyte website for 90 days following the completion of the call.

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. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives and improve outcomes by accelerating and optimizing the diagnosis and treatment of cancer. The Company's tests and services present multiple opportunities to advance cancer care while also driving revenue growth for the Company. Oncocyte has launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection and predicts benefit from adjuvant chemotherapy. Oncocyte has also launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the company anticipates launching DetermaTx™, a test to assess mutational status of a tumor to help identify the appropriate targeted therapy, in the second half of 2021. The Company previously announced its planned acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor test, and also plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide pharmaceutical companies who are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation. Therasure is a trademark of Chronix Biomedical Inc.

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 those pertaining to financial performance and corporate updates, 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 or any distributor's 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 or any distributor's supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality 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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CONSOLIDATED BALANCE SHEETS

($ in thousands)

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 7,143	$ 22,072
Accounts receivable	203	-
Marketable equity securities	675	379
Prepaid expenses and other current assets	1,205	505
Total current assets	9,226	22,956
NONCURRENT ASSETS		
Right-of use-assets, machinery and equipment, net and construction in progress	6,524	3,728
Equity method investment in Razor	13,417	10,964

Goodwill	9,187	-
Intangibles, net	15,009	-
Deposits and other non current assets	2,056	2,211
TOTAL ASSETS	$ 55,419	$ 39,859
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to Lineage and affiliates	$ -	$ 6
Accounts payable	432	469
Accrued expenses and other current liabilities	5,752	2,610
Loan payable, current	2,390	1,125
Right-of-use and financing lease liabilities, current	422	230
Total current liabilities	8,996	4,440
NONCURRENT LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	1,508	1,905
Right-of-use and financing lease liabilities, noncurrent	4,312	2,676
Contingent consideration liabilities	7,120	-
TOTAL LIABILITIES	21,936	9,021
SHAREHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 150,000 shares authorized; 69,117 and 57,032 shares issued and outstanding at December 31, 2020 and 2019, respectively	157,160	124,583
Accumulated deficit	(123,677)	(93,745)
Total shareholders' equity	33,483	30,838
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 55,419	$ 39,859

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended December 31, (unaudited)		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
REVENUE				
Total revenue	$ 503	$ -	$ 1,216	$ -
TOTAL COSTS AND OPERATING EXPENSES				
Cost of revenue	716	-	1,855	-
Research and development	1,800	2,318	9,800	6,794
General and administrative	3,410	4,194	16,788	13,281
Sales and marketing	1,874	1,011	6,494	2,164
Change in fair value of contingent consideration	(1,030)	-	(4,010)	-
Total operating expenses	6,770	7,523	30,927	22,239
Loss from operations	(6,267)	(7,523)	(29,711)	(22,239)
OTHER INCOME (EXPENSES), NET				

Loss on extinguishment of debt	-	(153)	-	(153)
Interest income (expense), net	(77)	17	(252)	299
Unrealized gain (loss) on marketable equity securities	315	(36)	297	(49)
Pro rata loss from equity method investment in Razor	(435)	(281)	(1,547)	(281)
Other income (expense), net	(4)	22	27	(3)
Total other income (expenses), net	(201)	(431)	(1,475)	(187)
LOSS BEFORE INCOME TAXES	(6,468)	(7,954)	(31,186)	(22,426)
Income tax benefit	159	-	1,254	-
NET LOSS	$ (6,309)	$ (7,954)	$ (29,932)	$ (22,426)
Net loss per share; basic and diluted	$ (0.09)	$ (0.15)	$ (0.46)	$ (0.44)
Weighted average shares outstanding; basic and diluted	67,368	54,499	65,478	51,296

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,932)	$ (22,426)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	313	344
Amortization of intangible assets	81	-
Amortization of right-of-use assets and liabilities	1,504	7
Impairment charge for long-lived assets	422	-
Pro rata loss from equity method investment in Razor	1,547	281
Amortization of prepaid maintenance	74	37
Stock-based compensation	5,066	2,995
Unrealized (gain) loss on marketable equity securities	(297)	49
Amortization of debt issuance costs	102	59
Loss on extinguishment of debt	-	153
Warrants issued for advisory services	-	234
Change in fair value of contingent consideration	(4,010)	-
Deferred income tax benefit	(1,254)	-
Other	5	107
Changes in operating assets and liabilities:		
Accounts receivable	(182)	-
Amount due to Lineage and affiliates	(6)	(2,094)
Prepaid expenses and other assets	(267)	(202)

Accounts payable and accrued liabilities	854	741
Net cash used in operating activities	(25,980)	(19,715)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	(6,189)	-
Deposits paid for the Chronix merger agreement	(325)	-
Equity method investment in Razor	(4,000)	(11,245)
Purchase of furniture and equipment	(1,227)	(918)
Security deposit and other	(7)	(252)
Net cash used in investing activities	(11,748)	(12,415)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	1,445	943
Proceeds from sale of common shares	18,343	48,850
Financing costs to issue common shares	(58)	(3,288)
Proceeds from sale of common shares under at-the-market transactions	2,462	-
Financing costs for at-the-market sales	(74)	-
Common shares received and retired for employee taxes paid	(14)	-
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	(375)	(667)
Repayment of financing lease obligations	(71)	(454)
Proceeds from PPP loan	1,141	-
Net cash provided by financing activities	22,799	47,868
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(14,929)	15,738

CASH, CASH EQUIVALENTS AND RESTRICTED CASH:				
At beginning of the period		23,772		8,034
At end of the period	$	8,843	$	23,772

Non-GAAP Financial Measures

This earnings release includes loss from operations prepared in accordance with accounting principles generally accepted in the United States (GAAP) and includes certain historical non-GAAP adjustments to operating expenses. In particular, Oncocyte has provided non-GAAP total loss from operations, adjusted to exclude noncash stock-based compensation, depreciation and amortization expenses, an impairment charge for certain long-lived assets, an unrealized gain for change in fair value of contingent consideration and a severance charge. 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 loss from operations, when viewed in conjunction with our GAAP total loss from operations, is helpful in understanding Oncocyte's ongoing operations 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 Loss from Operations

	Amounts In Thousands		**Amounts In Thousands**	
	For the Three Months Ended		**For the Twelve Months Ended**	
	December 31, (unaudited)		**December 31,**	
	2020	**2019**	**2020**	**2019**

GAAP loss from operations - as reported	**$ (6,267)**	**$ (7,523)**	**$ (29,711)**	**$ (22,239)**
Stock-based compensation expense	984	786	5,066	2,995
Impairment charge for long-lived assets	-	-	422	-
Noncash warrant expense	-	-	-	234
Depreciation and amortization expense	140	75	461	381
Change in fair value of contingent consideration	(1,030)	-	(4,010)	-
Severance charge	-	-	1,260	-
Non-GAAP loss from operations, as adjusted	$ (6,173)	$ (6,662)	$ (26,512)	$ (18,629)

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Source: Oncocyte Corporation

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