Oncocyte Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

Mar 10, 2022

DetermaRx Revenues and Test Volume Grew 104% and 54%, respectively, in Q4 versus Q3 2021

Development and Co-Marketing Agreement with Thermo Fisher Scientific to Provide Platform and Channel Partner for Delivering Determa Product Line to Laboratories in Europe and other International Markets

Data Showing Utility of DetermaCNI Blood-Only Monitoring Test to Detect Recurrence Following Surgery in Epithelial Ovarian Cancer Published in Peer-Review Journal

TheraSure Transplant Monitor LDT Testing on Track for Commercial Launch 1H2022

New Data on DetermaIO Clinical Test for Immunotherapy Response in Triple Negative Breast Cancer Presented at San Antonio Breast Cancer Symposium 2021

Conference Call to be held today at 4:30pm ET/1:30 pm PDT

IRVINE, Calif., March 10, 2022 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company with the mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey, today reports financial results for the fourth quarter 2021 ended December 31, 2021, along with a corporate update.

“Our fourth quarter and the first two months of 2022 were a productive period for Oncocyte. A key accomplishment was forming a strategic collaboration with Thermo Fisher for two distributed *in vitro* diagnostic (IVD) assays on their Ion Torrent™ Genexus™ System” said Ron Andrews, President and CEO of Oncocyte. “By leveraging Thermo Fisher’s proven global capabilities and installed base, we will be able to expand the commercial availability of our proprietary tests as IVD assays beyond the U.S. market.”

Mr. Andrews continued, “During the fourth quarter, DetermaRx™ returned to double-digit quarter over quarter growth as the COVID-19 pandemic receded, and surgical procedures began to recover. In addition to significantly growing our testing volume, we continue to deliver on two metrics used to measure test adoption during the current market environment – new hospital onboards increased by 16% and ordering physicians grew by 17% quarter over quarter. We have now established a solid install base of 429 physicians and are poised to grow our sample volume and revenue once early-stage lung cancer surgeries return to pre-pandemic levels.”

“The recent publication of data showing that DetermaCNI™ detects cancer recurrence with higher sensitivity than the standard of care, propels an important component of our strategy: to provide

physicians with a blood-based monitoring test to help them better understand how well a therapy is working. The published data are indicative of the potential value of DetermaCNI in the monitoring of therapeutic response, and given the data published to date in multiple tumor types, we believe this test may ultimately become a valuable treatment monitoring tool that will complement our treatment decision test menu. There is currently a blanket reimbursement approach by CMS for these types of monitoring tests at high value rates. Our recent publications build upon the evidence we need to secure Medicare approval for this very lucrative market."

"In Transplant rejection monitoring, we are on track to launch our TheraSure™ Transplant Monitor as a lab-developed test (LDT) in the U.S. by the end of March from our Nashville CLIA lab. We continue to believe that our patented digital PCR method can deliver unique capabilities, including absolute quantification and better turn-around time more cost effectively than current methods. We remain in discussions with multiple global digital PCR platform companies, and are confident we will partner with a world-class company as a development and channel partner as we decentralize this important test to transplant centers in the US and Europe."

"In November, we initiated the clinical launch of our DetermaIO™ test via an early access program (EAP), an important milestone to inform immunotherapy decisions, which strengthens Oncocyte's differentiated position in precision diagnostics. Physicians are recognizing the importance of DetermaIO as the first commercially available test to evaluate the tumor and its microenvironment (TIME) in a manner that has been shown to inform response to immunotherapy. The tumor microenvironment plays a critical role in treatment response and resistance," continued Mr. Andrews. "We believe that the combination of DetermaIO with our comprehensive genomic profiling test DetermaTx™, expected to be launched in mid-Q2, will offer the most complete precision diagnostic solution to inform cancer treatment decisions for the 1.8 million patients diagnosed with cancer in the United States each year, a total addressable market of $5 billion. We anticipate that the launch of DetermaCNI as a research use only test to monitor these patients will enable Oncocyte to become the only company to provide upfront testing to inform immunotherapy treatment via TIME assessment as well as monitor patients on treatment for early detection of progression."

"Looking ahead to 2022, our goals are to concentrate on market-focused initiatives that support clinical utility and adoption of our comprehensive testing portfolio. We expect to launch three major products across oncology and transplant, expanding indications and securing reimbursement over the course of the year. We are well positioned to achieve the promise of the Determa platform, and to help physicians address the unanswered questions in treating patients across all stages of cancer," concluded Mr. Andrews.

Fourth Quarter and Recent Highlights Include:

- Announced co-development and co-marketing with Thermo Fisher to for two distributed *in vitro* diagnostic (IVD) assays on Thermo Fisher Scientific's Ion Torrent Genexus System. The agreement also grants Oncocyte rights to develop future companion diagnostics on the Genexus System.

- Oral presentation at the European Society for Medical Oncology (ESMO) on randomized clinical trial data definitively established DetermaIO as a predictive biomarker of immunotherapy response. In the triple negative breast cancer (TNBC) NeoTRIPaPDL1 study, DetermaIO outperformed 80 other immune signatures.

- Published a peer-reviewed study in the journal *Cancers* with investigators from leading academic institutions MD Anderson and Yale demonstrating the predictive potential for DetermaIO. Study data

showed that DetermaIO demonstrates superior accuracy compared to standard of care PD-L1 immunohistochemistry (IHC) for prediction of a patient's response to immunotherapy in TNBC. Previous data has been presented in lung, bladder, renal, and kidney cancers suggesting a broad pan-cancer utility of the test.

- Strengthened transplant IP portfolio with issuance of a U.S. patent covering digital PCR technology for early detection of organ transplant rejection, building upon prior issued U.S. and EU patent for quantification of donor derived cfDNA, supporting the launch of TheraSure Transplant Monitor as an LDT in the U.S.

- Launched and completed site enrollment of the first Real-World Evidence (RWE) registry intended to evaluate biomarker adoption and precision medicine in creating personalized treatment options for early-stage lung cancer patients, with enrollment targeting more than 1,000 patients at 25 sites across the U.S. beginning in Q4 2021.

Fourth Quarter and Full Year 2021 Financial Results

On December 31, 2021, Oncocyte had cash, cash equivalents and marketable securities of $36.5 million, as compared to $7.8 million on December 31, 2020.

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, Inc., which was acquired on January 31, 2020. During the first quarter of 2021, after accumulating additional history of cash receipts and other factors considered by management for Medicare and Medicare Advantage-covered DetermaRx tests, including the recently published Medicare rate, the Company transitioned to the accrual basis for tests covered by Medicare Advantage insurance plans. Oncocyte will continue to recognize revenues for commercial and other payors on a cash basis until we have reimbursement contracts with those payors. At that point, those contracts will also progress to the accrual basis for DetermaRx tests. Until that time, for all payors other than Medicare and Medicare Advantage, Oncocyte expects to recognize revenue for DetermaRx tests performed on a cash basis.

Revenues for the three and twelve months ended December 31, 2021, were approximately $3.6 million and $7.7 million, respectively, generated from three sources: DetermaRx tests, pharma services, and licensing revenues. Revenues for the three months and twelve months ended December 31, 2020, were approximately $503,000 and $1.2 million, respectively.

Research and development expenses for the fourth quarter of 2021 were $4.6 million as compared to $1.8 million for the same period in 2020, an increase of $2.8 million. Research and development expenses for the year ended December 31, 2021, were $13.6 million as compared to $9.8 million in 2020, an increase of $3.8 million primarily attributable to the increased investment in clinical studies to support the commercialization of the portfolio of tests in the pipeline.

General and administrative expenses for the three months ended December 31, 2021 were $4.1 million, as compared to $3.4 million for the same period in 2020, an increase of approximately $0.7 million. General and administrative expenses for the year ended December 31, 2021, were $22.3 million, as compared to $16.8 million for the same period in 2020, an increase of $5.5 million, primarily attributable to personnel growth and related expenses.

Sales and Marketing expenses for the three months ended December 31, 2021 were $3.3 million, as compared to $1.9 million for the same period in 2020. For the full year 2021, sales and marketing

expenses were approximately $11.2 million, as compared to $6.5 million for the full year 2020, primarily attributable to an increase in headcount and continued ramp in sales and marketing activities to support our continued commercialization efforts of our diagnostic tests.

GAAP loss from operations, as reported, for the three months ended December 31, 2021 was $35.7 million, as compared to a GAAP loss of $6.3 million the fourth quarter of 2020. Operating loss, on an adjusted basis, was $5.3 million for the fourth quarter of 2021, as compared to operating losses of $6.2 million for the fourth quarter of 2020. GAAP loss from operations, as reported, for the year ended December 31, 2021, was $74.2 million, as compared to $29.7 for the full year 2020. Operating loss, on an adjusted basis, was $33.2 million, as compared to an operating loss of $26.5 million for the full year 2020. The principal difference between GAAP and non-GAAP operating losses is the "Change in fair value of contingent consideration" related to the acquisition of Chronix Biomedical in 2021. This increase in Fair Value reflects a favorable risk-adjustment for the CNI product line and the likelihood of larger milestone payments to Chronix shareholders based on an increase in Oncocyte's predicted revenues. This benefits Oncocyte's shareholders because of the potential increase in expected revenues.

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, 2021, Oncocyte reported a net loss of $35.9 million, or ($0.39) per share, as compared to $6.3 million, or ($0.09) per share, for the fourth quarter ended December 31, 2020.

For the year ended December 31, 2021, Oncocyte reported a net loss of $64.1 million, or ($0.72) per share, compared to $29.9 million, or ($0.46) per share for 2020.

Net cash used in operations was approximately $7.1 million for the fourth quarter of 2021.

Conference Call Information

The Company will host a conference call today, March 10th 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 1-877-407-9716; for international participants, the number is 1-201-493-6779. For all callers, please refer to Conference ID: 13726740. To access the live webcast, go to the investor relations section on the Company's website, or by clicking here https://viavid.webcasts.com/starthere.jsp?ei=1526783&tp_key=769c96014b. A webcast replay will be available on the Oncocyte website for 90 days following the completion of the call.

About Oncocyte

Oncocyte is a precision diagnostics and monitoring company with the mission to improve patient outcomes by providing clear insights that inform critical decisions in the diagnosis, treatment, and monitoring of cancer. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company's tests are designed to help provide clarity and confidence to physicians and their patients at every stage. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™, a gene expression test currently used as a research-use only tool, assesses the tumor microenvironment to predict response to immunotherapies. The Company's pipeline of tests in development also includes DetermaTx™, which will assess mutational status of a tumor, blood-based monitoring test DetermaCNI™, and long-term recurrence monitoring test DetermaMx™. In addition, Oncocyte's pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development

process.

DetermaRx™, DetermaIO™, DetermaTx™, DetermaCNI™, DetermaMx™ and TheraSure™ 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 those pertaining to, among other things, the transactions contemplated by the development and co-marketing agreement for two distributed in vitro diagnostic (IVD) assays on Thermo Fisher Scientific's Ion Torrent™ Genexus™ System, the expansion of IVD assays beyond the U.S. market, the expected growth of Oncocyte's sample volume and revenue once early-stage lung cancer surgeries return to pre-pandemic levels, the belief that DetermaCNI may ultimately become a valuable treatment monitoring tool that will complete Oncocyte's treatment decision test menu, the expectation that TheraSure Transplant Monitor will be launched by the end of March as a lab-developed test, the belief that Oncocyte's patented digital PCR method can deliver unique capabilities, including absolute quantification and better turn-around time more cost effectively than current methods, the ability to ally with a world-class company as a development and channel partner, the expectation that Oncocyte will decentralize the TheraSure Transplant Monitor to transplant centers in the US and Europe, the anticipated launch of DetermaTx in mid-Q2, the belief that the combination of DetermaIO and DetermaTx will offer the most complete precision diagnostic solution to inform transplant decisions for 1.8 million patients diagnosed with cancer in the US each year, the expectation that the launch of DetermaCNI will enable Oncocyte to become the only company to provide upfront testing to inform immunotherapy treatment via TIME assessment as well as monitor patients on treatment for early detection of progression, the expectation that Oncocyte will launch three major products across oncology and transplant and expand indications and secure reimbursement over the course of the year, the belief that Oncocyte is well positioned to achieve the promise of the Determa platform and help physicians address unanswered questions in treating patients across all stages of cancer, and 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 Oncocyte or its subsidiaries' financial and operational results, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte's third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential 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 (SEC) 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
CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31,	
	2021	**2020**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 35,605	$ 7,143
Accounts receivable	1,437	203
Marketable equity securities	904	675
Prepaid expenses and other current assets	1,197	1,205
Total current assets	39,143	9,226
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,779	3,262
Machinery and equipment, net, and construction in progress	5,748	3,262
Equity method investment in Razor	-	13,417
Goodwill	18,684	9,187
Intangible assets, net	91,245	15,009

Restricted cash	1,700	1,700
Other noncurrent assets	264	356
TOTAL ASSETS	$ 159,563	$ 55,419
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,447	$ 432
Accrued compensation	3,376	3,468
Accrued expenses and other current liabilities	2,425	2,284
Accrued severance from acquisition, current	2,352	-
Accrued liabilities from acquisition, current	1,388	-
Loans payable, net of deferred financing costs, current	1,313	2,390
Right-of-use and financing lease liabilities, current	819	422
Total current liabilities	14,120	8,996
NONCURRENT LIABILITIES		
Loans payable, net of deferred financing costs, noncurrent	-	1,508
Right-of-use and financing lease liabilities, noncurrent	3,545	4,312
Contingent consideration liabilities, noncurrent	76,681	7,120
TOTAL LIABILITIES	94,346	21,936
Commitments and contingencies		
SHAREHOLDERS' EQUITY		

Preferred stock, no par value, 5,000 shares authorized; no shares issued and outstanding	-	-
Common stock, no par value, 230,000 shares authorized; 92,232 and 69,117 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	252,954	157,160
Accumulated other comprehensive loss	37	-
Accumulated deficit	(187,774)	(123,677)
Total shareholders' equity	65,217	33,483
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 159,563	$ 55,419

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021 (unaudited)	**2020 (unaudited)**	**2021**	**2020**
Net revenue	$ 3,589	$ 503	$ 7,727	$ 1,216
Cost of revenues	1,237	716	4,185	1,855
Cost of revenues – amortization of	983	-	3,354	-

acquired intangibles				
Gross profit	1,369	(213)	188	(639)
Operating expenses:				
Research and development	4,591	1,800	13,631	9,800
Sales and marketing	3,309	1,874	11,167	6,494
General and administrative	4,143	3,410	22,336	16,788
Change in fair value of contingent consideration	25,006	(1,030)	27,266	(4,010)
Total operating expenses	37,049	6,054	74,400	29,072
Loss from operations	(35,680)	(6,267)	(74,212)	(29,711)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(42)	(77)	(209)	(252)
Unrealized gain (loss) on marketable equity securities	(19)	315	229	297
Pro rata loss from equity method	-	(435)	(270)	(1,547)

investment in Razor				
Gain on extinguishment of debt (PPP loan)	-	-	1,141	-
Other income, net	(47)	(4)	(37)	27
Total other income (expenses), net	(108)	(201)	854	(1,475)
LOSS BEFORE INCOME TAXES	(35,788)	(6,468)	(73,358)	(31,186)
Income tax benefit	(97)	159	9,261	1,254
NET LOSS	$ (35,885)	$ (6,309)	$ (64,097)	$ (29,932)
Net loss per share: basic and diluted	$ (0.39)	$ (0.09)	$ (0.72)	$ (0.46)
Weighted average shares outstanding: basic and diluted	92,210	67,368	88,920	65,478

ONCOCYTE CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (64,097)	$ (29,932)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	844	313
Amortization of intangible assets	3,361	81
Impairment charge for long-lived assets	-	422
Pro rata loss from equity method investment in Razor	270	1,547
Stock-based compensation	6,841	5,066
Unrealized (gain) loss on marketable equity securities	(229)	(297)
Amortization of debt issuance costs	56	102
Change in fair value of contingent consideration	27,266	(4,010)
Deferred income tax benefit	(9,260)	(1,254)
Gain on extinguishment of debt (PPP loan)	(1,141)	-
Changes in operating assets and liabilities:		
Accounts receivable	(1,229)	(182)
Lease liabilities	147	1,504
Prepaid expenses and other assets	226	(188)
Accounts payable and accrued liabilities	(1,348)	848
Accrued severance from Chronix Biomedical acquisition	2,352	-
Net cash used in operating activities	(35,941)	(25,980)

CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	(607)	(6,189)
Acquisition of Razor Genomics asset, net of cash acquired	(6,648)	-
Acquisition of Chronix Biomedical, net of cash acquired	(4,459)	(325)
Equity method investment in Razor	-	(4,000)
Construction in progress and purchases of furniture and equipment	(2,247)	(1,227)
Security deposit and other	-	(7)
Net cash used in investing activities	(13,961)	(11,748)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	2,584	1,445
Proceeds from sale of common shares	65,263	18,343
Financing costs to issue common shares	(2,675)	(58)
Proceeds from sale of common shares under at-the-market transactions	12,724	2,462
Financing costs for at-the-market sales	(390)	(74)
Proceeds from exercise of warrants	2,631	-
Common shares received and retired for employee taxes paid	(239)	(14)
Repayment of loan payable	(1,500)	(375)
Repayment of financing lease obligations	(34)	(71)
Proceeds from PPP loan	-	1,141
Net cash provided by financing activities	78,364	22,799

NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	28,462	(14,929)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	8,843	23,772
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$ 37,305	$ 8,843
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ 114	$ 209
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES		
Common stock issued for acquisition of Razor Genomics asset	$ 5,756	$ -
Deferred tax liability generated from the acquisition of Razor Genomics asset	7,077	-
Common stock issued for acquisition of Insight Genetics	-	5,000
Common stock issued for acquisition of Chronix Biomedical	3,299	-
Deferred tax liability generated from the acquisition of Chronix	2,183	-
Initial fair value of contingent consideration at acquisition date	42,295	11,130
Assumed liability from Chronix Acquisition	3,352	-
Holdback liability	-	600
Construction in progress, machinery and equipment purchases included in accounts payable, accrued liabilities and landlord liability	1,083	2,049
Accounts receivable from agent for at-the-market sales of common stock, net of financing costs	-	262

Issuance of common stock in lieu of cash for payment of board fees and deferred salaries	-	169

Oncocyte Corporation

Reconciliation of Non-GAAP Financial Measure
Adjusted Loss from Operations
(Amounts in Thousands)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
GAAP loss from operations - as reported	**$ (35,680)**	**$ (6,267)**	**$ (74,212)**	**$ (29,711**
Stock-based compensation expense	1,704	984	6,841	5,066
Impairment charge for long-lived assets	-	-	-	422
Change in fair value of contingent consideration	25,006	(1,030)	27,266	(4,010
Severance charge	32	-	2,707	1,260
Depreciation and amortization expense	3,624	140	4,205	461

Non-GAAP loss from operations, as adjusted	**$ (5,314)**	**$ (6,173)**	**$ (33,193)**	**$ (26,512**

Source: Oncocyte Corporation

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