Oncocyte Reports Third Quarter 2021 Financial Results and Provides Corporate Update

Nov 09, 2021

Clinical launch of DetermaIO as first and only immunotherapy response prediction clinical test that comprehensively assesses the tumor microenvironment and consistently outperforms PD-L1 IHC and other biomarkers

DetermaIO data in Triple Negative Breast Cancer published in a peer reviewed journal and confirmed in a randomized clinical trial study presented at ESMO; Evidence in fourth tumor type suggests pan-cancer utility

DetermaRx test volume grows 65% year over year

US transplant IP issued supporting the planned launch of TheraSure Transplant Monitor LDT testing in the U.S. and Europe

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

IRVINE, Calif., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), 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, reports financial results for the third quarter 2021 ended September 30, 2021, along with a corporate update.

“The recently announced clinical launch of our DetermaIO™ test, via an early access program (EAP), is an important milestone to inform immunotherapy decisions which strengthens Oncocyte’s differentiated position in precision diagnostics,” said Ron Andrews, Chief Executive Officer and President of Oncocyte. “We believe that the combination of DetermaIO with our comprehensive genomic profiling test DetermaTx™, expected to be launched late in the first quarter of 2022 upon completion of the DetermaIO EAP program, 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 and allows us to enter a total available market of $5 billion. This combined offering is further differentiated by its ability to deliver comprehensive treatment decision information while conserving the limited tumor tissue sample available for testing, with industry leading turnaround time. We are very encouraged with the response to our recently announced early access program for DetermaIO, we have begun onboarding the accounts, and are excited to receive our first clinical patient samples in the coming weeks. Our clinical studies have now reported results for over 1,000 patients, validated DetermaIO in four different tumor types, and shown consistent outperformance of the current tests being used to select patients for treatment.”

Mr. Andrews continued, “We’ve continued our progress with DetermaRx™ and, despite significant disruptions in early-stage lung cancer surgeries over the summer due to the surge of the COVID-19 Delta variant, we generated 65% year over year growth in test volume. We also continue to deliver on our two metrics used to measure test adoption during the current market environment: new hospital onboards increased by 42 facilities, growing 24% quarter over quarter, and our ordering physicians grew by 66 doctors or 22% quarter over quarter. We have now established a solid install base that is poised to grow our sample volume and revenue once early-stage lung cancer surgeries return to pre-pandemic levels.”

“With the issuance of our IP in blood-based monitoring for transplant rejection, we now have a clear path to launching our own LDT test into the large transplant rejection market in the U.S. and Europe. Oncocyte expects to complete 2021 with solid momentum toward our goal of building a compelling and powerful portfolio of molecular diagnostic tests. As a complement to this progress, our recent appointment of Gisela Paulsen as Chief Operating Officer brings additional world-class talent to the experienced leadership team at Oncocyte and comes on board at an important time as we expand our operations to support the anticipated growth ahead.”

Third Quarter and Recent Highlights Include:

- Announced the clinical launch of the DetermaIO immunotherapy response prediction test via an early access program.

- 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.

Corporate

- Appointed industry veteran Gisela A. Paulsen as Chief Operating Officer in October 2021.

Third Quarter 2021 Financial Results

On September 30, 2021, Oncocyte had cash, cash equivalents and marketable securities of $44.3 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, 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 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 months ended September 30, 2021, were approximately $1.0 million, generated from three sources: DetermaRx tests, pharma services, and licensing revenues. This compares to revenues of $555,000 for the three months ended September 30, 2020, a year over year growth rate of 77%. DetermaRx samples received this quarter grew 3% compared to last quarter, primarily due to the impact of the Delta Variant on surgical volumes in key sales regions of the United States and 65% versus Q3 2020 .

Cost of revenues for the third quarter 2021 were approximately $1.9 million, which includes approximately $1.0 million in non-cash amortization expenses from the Razor Genomics and Insight Genetics acquisitions. The cost of our Razor asset amortization, which is a non-cash amortization expense over the remaining life of the Razor patent, will be included in cost of revenues each quarter. Cost of revenues also include testing services we perform for our pharma customers.

Research and development expenses for the third quarter of 2021 were $3.1 million as compared to $2.6 million for the same period in 2020, an increase of $0.5 million, representing the increased investment in clinical studies to support the commercialization of the portfolio of tests in the pipeline.

General and administrative expenses for the third quarter of 2021 were $5.5 million, as compared to $5.0 million for the same period in 2020, an increase of approximately $0.5 million.

Sales and marketing expenses for the three months ended September 30, 2021 were $2.9 million, as compared to $1.6 million for the same period in 2020. The increase was primarily due to personnel and related expenses resulting from the ramp up in sales and marketing activities for DetermaRx, as well as market development investments in preparation for the launch of new products later this year.

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 third quarter ended September 30, 2021, Oncocyte reported a net loss of $13.8 million, or ($0.15) per share, as compared to $6.8 million, or ($0.10) per share, for the third quarter ended September 30, 2020.

Cash used in operations was approximately $11.0 million for the third quarter of 2021.

Conference Call Information

The Company will host a conference call today, November 9th 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: 13722620. 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=146378. The 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 expected launch of DetermaTX late in the first quarter Q1 of 2022; the expectation that the combination of DetermaIO and DetermaTX 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, allow Oncocyte to enter a total available market of $5 billion and deliver comprehensive treatment decision information while conserving the limited samples available for testing, and with industry leading turnaround time; the expected receipt of Oncocyte's first clinical patient samples for the DetermaIO early access program in the coming weeks; the expectation that the DetermaRx install base is poised to grow Oncocyte's sample volume and revenue once early-stage lung cancer surgeries return to pre-pandemic levels; the expected launch of Oncocyte's own LDT test (TheraSure Transplant Monitor) into the large transplant rejection market in the U.S. and Europe; the expectation that Oncocyte will complete 2021 with solid momentum toward its goal of building a compelling and powerful portfolio of molecular diagnostic tests; the anticipation of growth ahead; the planned enrollment of more than 1,000 patients at 25 sites across the U.S. beginning in Q4 2021, for the first Real-World Evidence registry intended to evaluate biomarker adoption and precision medicine in creating personalized treatment options for early-stage lung cancer patients; 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.

Investor Contact
Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

Media Contact
Terri Clevenger
Westwicke/ICR
203-856-4326
Terri.clevenger@icrinc.com

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 43,340	$ 7,143
Accounts receivable	1,032	203

Marketable equity securities	923	675
Prepaid expenses and other current assets	2,296	1,205
Total current assets	47,591	9,226
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,918	3,262
Machinery and equipment, net, and construction in progress	4,719	3,262
Equity method investment in Razor	-	13,417
Goodwill	18,432	9,187
Intangible assets, net	92,722	15,009
Restricted cash	1,700	1,700
Other noncurrent assets	259	356
TOTAL ASSETS	$ 168,341	$ 55,419
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,198	$ 432
Accrued compensation	3,336	3,468
Accrued expenses and other current liabilities	1,869	2,284
Accrued severance from acquisition, current	2,452	-
Accrued liabilities from acquisition, current	2,236	-
Loans payable, current	1,500	2,390
Right-of-use and financing lease liabilities, current	786	422
Total current liabilities	13,377	8,996

NONCURRENT LIABILITIES		
Loans payable, net of deferred financing costs, noncurrent	178	1,508
Right-of-use and financing lease liabilities, noncurrent	3,762	4,312
Contingent consideration liabilities, noncurrent	51,675	7,120
TOTAL LIABILITIES	68,992	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; 92,158 and 69,117 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	251,238	157,160
Accumulated deficit	(151,889)	(123,677)
Total shareholders' equity	99,349	33,483
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 168,341	$ 55,419

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended	**Nine Months Ended**

	September 30,		September 30,	
	2021	**2020**	**2021**	**2020**
Net revenue	$ 984	$ 555	$ 4,138	$ 713
Cost of revenues	860	601	2,948	1,139
Cost of revenues – amortization of acquired intangibles	990	-	2,371	-
Gross profit	(866)	(46)	(1,181)	(426)
Operating expenses:				
Research and development	3,142	2,615	9,040	8,000
Sales and marketing	2,931	1,568	7,858	4,620
General and administrative	5,495	4,995	18,193	13,378
Change in fair value of contingent consideration	1,170	(2,980)	2,260	(2,980)
Total operating expenses	12,738	6,198	37,351	23,018
Loss from operations	(13,604)	(6,244)	(38,532)	(23,444)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(50)	(78)	(167)	(175)
Unrealized gain (loss) on marketable equity securities	(138)	20	248	(18)
Pro rata loss from equity method investment in Razor	-	(482)	(270)	(1,112)

Gain on extinguishment of debt (PPP loan)	-	-	1,141	-
Other income, net	(8)	1	10	31
Total other income (expenses), net	(196)	(539)	962	(1,274)
LOSS BEFORE INCOME TAXES	(13,800)	(6,783)	(37,570)	(24,718)
Income tax benefit	-	-	9,358	1,095
NET LOSS	$ (13,800)	$ (6,783)	$ (28,212)	$ (23,623)
Net loss per share: basic and diluted	$ (0.15)	$ (0.10)	$ (0.32)	$ (0.36)
Weighted average shares outstanding: basic and diluted	91,453	67,247	87,812	64,843

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2021	**2020**

CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (28,212)	$ (23,623)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	582	529
Amortization of intangible assets	2,371	59
Amortization of right-of-use assets and liabilities	169	959
Impairment charge for long-lived assets	-	88
Pro rata loss from equity method investment in Razor	270	1,112
Stock-based compensation	5,136	4,081
Unrealized (gain) loss on marketable equity securities	(248)	18
Amortization of debt issuance costs	46	80
Change in fair value of contingent consideration	2,260	(2,980)
Deferred income tax benefit	(9,358)	(1,095)
Gain on extinguishment of debt (PPP loan)	(1,141)	-
Changes in operating assets and liabilities:		
Accounts receivable	$ (824)	$ (372)
Amount due to Lineage and affiliates	-	(6)
Prepaid expenses and other assets	(787)	(529)
Accounts payable and accrued liabilities	(1,592)	1,843
Accrued severance from Chronix Biomedical acquisition	2,452	-
Net cash used in operating activities	(28,876)	(19,836)
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)	-
Equity method investment in Razor	-	(4,000)
Construction in progress and purchases of furniture and equipment	(1,846)	(1,061)
Net cash used in investing activities	(13,560)	(11,250)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	2,573	72
Proceeds from sale of common shares	65,262	18,343
Financing costs to issue common shares	(2,676)	(58)
Proceeds from sale of common shares under at-the-market transactions	12,724	-
Financing costs for at-the-market sales	(390)	-
Proceeds from exercise of warrants	2,631	-
Common shares received and retired for employee taxes paid	(239)	(14)
Repayment of loan payable	(1,125)	(125)
Repayment of financing lease obligations	(127)	(53)
Proceeds from PPP loan	-	1,141
Net cash provided by financing activities	78,633	19,306
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	36,197	(11,780)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	8,843	23,772

CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$ 45,040	$ 11,992
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ 96	$ 131
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	7,564	-
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	1,794	-
Initial fair value of contingent consideration at acquisition date	42,295	11,130
Assumed liability from Chronix Acquisition	3,489	
Holdback liability	-	600
Construction in progress, machinery and equipment purchases included in accounts payable, accruedliabilities and landlord liability	193	1,109

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, change in fair value of contingent consideration and depreciation and amortization expenses. 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)

	For the Three Months Ended		For the Nine Mont
	September 30,		September
	2021	2020	2021
	(unaudited)	(unaudited)	(unaudited) (u
GAAP loss from operations - as reported	**$ (13,604)**	**$ (6,244)**	**$ (38,532)** **$**
Stock-based compensation expense	1,849	1,784	5,136
Impairment charge for long-lived assets	-	-	-
Change in fair value of contingent consideration	1,170	(2,980)	2,260
Severance charge	-	1,260	-
Depreciation and amortization expense	1,246	91	2,954
Non-GAAP loss from operations, as adjusted	**$ (9,339)**	**$ (6,089)**	**$ (28,182)** **$**

Source: Oncocyte Corporation

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