Oncocyte Reports Third Quarter 2020 Financial Results and Provides Corporate Update

Nov 12, 2020

DetermaRx™ receives final CMS pricing and records first full quarter with Medicare revenues; more than doubles second quarter volumes with adoption at NCCN and NCI designated cancer centers

DetermaIO™ selected for use in checkpoint inhibitor clinical trial; will generate near term pharmaceutical services revenue and solidifies use in triple negative breast cancer research

TheraSure™-CNI MONITOR licensing and collaboration agreement with Chronix will add a fourth engine of potential revenue growth in blood-based therapy monitoring and provide access to EUlab network for DetermaRx

Conference Call Today, November 12, at 4:30PM EDT

IRVINE, Calif., Nov. 12, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today reported financial results for the third quarter and nine months ended September 30, 2020, and provided a corporate update.

“I am very proud of our progress over the past year as we have established four growth engines to drive revenue that will help us reduce our cash burn as we progress in our vision to become a leader in molecular diagnostics for oncology and immunotherapy,” said Ron Andrews, Chief Executive Officer of Oncocyte. “This has been a quarter of growth and milestone achievements, solidifying our position as an innovator in the advancement of molecular diagnostics for early stage lung cancer. We have successfully repositioned the company over the past year by refining and expanding our suite of offerings and establishing multiple independent revenue growth engines: DetermaRx™, DetermaIO™, immunotherapy response monitoring, and Pharma Services, all with the potential to support our long-term growth and value creation. DetermaRx and pharma services are already generating revenue, and with our first agreement to utilize DetermaIO as a predictive biomarker in a clinical trial, DetermaIO is poised to become revenue generating before year end. The third quarter was a terrific period for DetermaRx as we received our final pricing from CMS, allowing us to bill and collect our first Medicare revenues. We continue to build upon our strong scientific foundation with collaborators publishing prospective data that further demonstrate that treatment decisions informed by DetermaRx significantly improve lung cancer patient survival. DetermaRx’s adoption at leading cancer centers and its rapid growth, with test volume more than doubling from the second quarter, reflects stakeholders’ recognition of the test’s significant clinical utility.”

Mr. Andrews added, “We also continue to expand our reach in the large and rapidly growing immunotherapy space with our second growth engine, DetermaIO™, our gene expression test currently

available for research use only, which identifies patients most likely to respond to therapy. Our recent presentation at the Society for Immunotherapy of Cancer Annual Meeting demonstrates the power of DetermaIO to identify patients who are not likely to respond to checkpoint inhibitors and may require alternative or combinatorial therapy, which significantly expands the utility of the DetermaIO test. We believe that DetermaIO's inclusion as a predictive biomarker in an international investigator-sponsored triple negative breast cancer clinical trial has increased our visibility among academic and pharma trial groups over the last few months, and we remain on pace to achieve our goal of a U.S. clinical launch in the second half of 2021. In addition, studies such as this generate immediate revenue through our Pharma Services business which will continue to grow as we secure additional contracts with pharmaceutical and molecular diagnostic platform companies. Our newly announced immunotherapy response monitoring opportunity, anticipated to be available in our Pharma Services arsenal in the first half of 2021, launches Oncocyte's differentiated and comprehensive offering for immune therapy diagnostics. Finally, we have solid momentum in our Pharma Services business and expect to exit 2020 ahead of our $2 million of committed projects goal for the year and expect the business to generate positive operating margin in 2021. Overall, we are on track across all our major milestones despite the continued headwind of the ongoing pandemic which is a testimony to the dedication of the Oncocyte team."

RecentCorporate Highlights

DetermaRx

- Medicare coverage policy established for DetermaRx, a new class of predictive tests, based on compelling clinical evidence that positions DetermaRx as the first and only test of its kind for early-stage non-small cell lung cancer (NSCLC)
- Received final pricing decision from Centers for Medicare and Medicaid Services (CMS) with pricing in line with comparable high-value molecular tests for oncology indications
- Continued rapid commercial growth and adoption through Q3:
  -- Testing volume more than doubled, from 64 billable samples in Q2, to 175 in Q3
  -- Maintained physician re-order rate of approximately 60 percent
  -- Increased onboarded hospitals from 36 in Q2 to 67 in Q3, including prestigious National Comprehensive Cancer Network (NCCN) and National Cancer Institute (NCI) designated cancer centers
  -- Increased adoption at major healthcare systems including HCA Healthcare, Cancer Treatment Centers of America (CTCA), Florida Cancer Specialists (FCS), Scripps Health, and Providence Cancer Institute
  -- Test added to "standard of care menu" at an NCI cancer center and at FCS
- International expansion continued with Mexico, Columbia, Brazil, and Germany being added to our current network of distribution and commercial partners in Israel, India, the Middle East and Africa
- Presented new prospective survival data at the IASLC 2020 North America Conference on Lung Cancer demonstrating DetermaRx informed treatment significantly improves lung cancer patient survival
- Presented data demonstrating that combining DetermaRx with EGFR mutation status may help inform optimal treatment strategies for NSCLC patients who are EGFR-mutation-positive. Oncocyte is now offering EGFR mutation testing and DetermaRx from a single patient sample to provide an integrated solution for patients and physicians
- Continued successful physician engagement with our webinar series with over 250 healthcare professional participants in online physician education programs in Q3 featuring renowned lung

cancer experts Dr. David Gandara, Dr. Johannes Kratz, and Dr. Gavitt Woodard

DetermaIO

- DetermaIO selected as a predictive biomarker in the NeoTRIPaPDL1 international investigator-sponsored trial for an immune-checkpoint inhibitor (ICI)
  -- Trial will evaluate DetermaIO as biomarker for a neoadjuvant (pre-surgical) ICI indication in patients with triple negative breast cancer (TNBC)
  -- Collaboration expected to generate near-term pharma services revenue, with a path to U.S. clinical launch in 2021

TheraSure™-CNI MONITOR Blood-based Immune Therapy monitoring test

- Announced agreement to license TheraSure™-CNI MONITOR clinical assay from Chronix Biomedical. The blood-based assay uses copy number instability (CNI) to monitor patients' response to immunotherapy treatments, potentially across a range of cancers
- License agreement will expand Oncocyte's suite of immunotherapy products to include response monitoring. Coordinating response monitoring with DetermaIO's response prediction capability could create the first integrated solution for immunotherapy treatment selection and monitoring. Tech transfer to begin in Q1 2021

Pharma Services

- Announced strategic alliance with the Guardian Research Network® (GRN) to establish an integrated platform for precision medicine clinical trials, combining Oncocyte's proprietary molecular tests and fully certified pharma services lab with GRN's nationwide consortium of 150 hospitals, clinical trial networks and real-world evidence data technology
  -- Initial immune-oncology focus will leverage Oncocyte's DetermaIO test for patient selection in immunotherapy clinical trials across the network
- Continued growth of pharma services offering with a full suite of molecular analyses including tissue and blood-based technologies, proprietary platforms such as DetermaIO and TNBCType Assay, as well as custom next-generation sequencing and PCR services including whole exome sequencing, RNA-seq and targeted mutation panels

Corporate

- Appointed Jennifer Carter, M.D., MPH, MBA, to Board of Directors, bringing deep expertise and experience in precision oncology to the Board

Third Quarter 2020 Financial Highlights

At September 30, 2020, Oncocyte had cash, cash equivalents and marketable securities of $10.7 million.

Prior to January 1, 2020, Oncocyte had no revenues. Oncocyte currently derives its revenues from pharma services generated by its wholly owned subsidiary, Insight Genetics, which was acquired on January 31, 2020, and from the sale of its lung cancer test, DetermaRx, which was commercially launched in early 2020. In light of the recent CMS and Noridian final pricing decision for the DetermaRx test, which became effective in September, 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 its pharma services and diagnostic tests, including DetermaRx.

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

For the third quarter ended September 30, 2020, Oncocyte reported a net loss of $6.8 million, or ($0.10) per share, as compared to $5.2 million, or ($0.10) per share, for the third quarter ended September 30, 2019.

Operating losses, as reported, for the third quarter of 2020 were $6.2 million, an increase of $0.9 million from $5.3 million as compared to the third quarter of 2019; and operating losses, on an adjusted basis, were $6.1 million, an increase of $2.0 million from $4.1 million as compared to the third quarter of 2019.

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

Revenues for the three and nine months ended September 30, 2020 were $0.6 million and $0.7 million respectively, generated from pharma services and DetermaRx tests that are covered by Medicare on an accrual basis since Oncocyte received a final pricing from CMS in September.

Cost of revenues for the three and nine months ended September 30, 2020 were $0.6 million and $1.1 million, respectively, incurred from performing the DetermaRx tests and pharma services.

Research and development expenses for third quarter of 2020 were $2.6 million as compared to $1.6 million for the same period in 2019, an increase of $1.0 million primarily attributable to personnel and related expenses, including a noncash stock-based compensation expense increase of $0.3 million. Personnel and related expenses for the current quarter also include a $0.4 million severance charge and $0.2 million in accelerated stock-based compensation expense recorded as part of the partial reduction in force plan and salary reduction agreements instituted in September 2020.

General and administrative expenses for the third quarter of 2020 were $5.0 million, as compared to $3.0 million for the same period in 2019, an increase of $2.0 million primarily attributable to personnel and related expenses, including a noncash stock-based compensation expense. Personnel and related expenses for the current quarter also include a $0.9 million severance charge and $0.5 million in accelerated stock-based compensation expense recorded as part of the partial reduction in force plan and salary reduction agreements instituted in September 2020.

Sales and marketing expenses for the three months ended September 30, 2020, were $1.6 million, as compared to $0.6 million for the same period in 2019, an increase of approximately $1.0 million. The increase was primarily due to personnel and related expenses for ramp up in sales and marketing activities for the commercialization effort of DetermaRx.

Change in fair value of contingent consideration liability - The change in fair value of contingent consideration is based on Oncocyte's reassessment of the key assumptions underlying the determination of this liability as changes in circumstances and conditions occur from the Insight acquisition date to the reporting period being presented, with the subsequent change in fair value recorded as part of

Oncocyte's consolidated loss from operations for that period. Accordingly, for the three and nine months ended September 30, 2020, Oncocyte recorded an unrealized gain of approximately $3.0 million related to the decrease in the fair value of contingent consideration liability primarily attributable to a revised estimate of the timing of the possible future payouts.

Cash used in operations was $6.0 million for the third quarter of 2020, which included about $0.9 million in transactional and other business development related expenses.

Conference Call

The Company will host a conference call today, November 12, 2020, at 4:30 pm EDT / 1:30 pm PDT to discuss the results along with recent corporate developments.

The dial-in number in the U.S./Canada is 877-407-9716; for international participants, the number is 201-493-6779. For all callers, please refer to Conference ID 13709425, 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=141419. 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, 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. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint immunotherapies.

DetermaRx and DetermaIO 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 the commercial launch of DetermaRx, development of DetermaIO, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from acquisitions, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our financial and operational results, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to our supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients' use of any diagnostic tests we commercialize, and risks inherent in acquisitions such as failure to realize anticipated benefits, unexpected expenditures or assumed liabilities, unanticipated difficulties in conforming business practices including accounting policies, procedures and internal controls, greater

than estimated allocations of resources to develop and commercialize technologies, or failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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ONCOCYTE COPORATION

CONSOLIDATED BALANCE SHEETS

($ in thousands)

	September 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
CURRENT ASSETS		

Cash and cash equivalents	10,292	22,072
Accounts receivable	366	-
Marketable equity securities	361	379
Prepaid expenses and other current assets	953	505
Total current assets	11,972	22,956
CURRENT ASSETS		
Right-of use-assets, machinery and equipment, net and construction in progress	5,657	3,728
Equity method investment in Razor	13,852	10,964
Goodwill	9,187	-
Intangibles, net	15,031	-
Deposits and other non current assets	2,077	2,211
TOTAL ASSETS	57,776	39,859
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to Lineage and affiliates	-	6
Accounts payable	1,264	469
Accrued expenses and other current liabilities	5,115	2,610
Loan payable, current	2,061	1,125
Right-of-use and financing lease liabilities, current	456	230
Total current liabilities	8,896	4,440
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	3,868	2,676

Loan payable, net of deferred financing costs, noncurrent	2,065	1,905
Contingent consideration liabilities	8,150	-
Other noncurrent liabilities	158	-
TOTAL LIABILITIES	23,137	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; 67,251 and 57,032 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	152,007	124,583
Accumulated other comprehensive loss	-	-
Accumulated deficit	(117,368)	(93,745)
Total shareholders' equity	34,639	30,838
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	57,776	39,859

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended	**Nine Months Ended**
	September 30,	**September 30,**

	2020	2019	2020	2019
	unaudited	unaudited	unaudited	unaudited
REVENUE				
Total revenue	$ 555	$ -	$ 713	$ -
TOTAL COSTS AND OPERATING EXPENSES				
Cost of revenue	$ 601	$ -	$ 1139	$ -
Research and development	2,615	1,625	8,000	4,476
General and administrative	4,995	3,002	13,378	9,087
Sales and marketing	1,568	630	4,620	1,153
Change in fair value of contingent consideration	(2,980)	-	(2,980)	-
Total operating expenses	6,799	5,257	24,157	14,716
Loss from operations	(6,244)	(5,257)	(23,444)	(14,716)
OTHER INCOME (EXPENSES), NET				
Interest income (expense), net	(78)	135	(175)	282
Unrealized gain (loss) on marketable equity securities	20	(103)	(18)	(13)
Pro rata loss from equity method investment in Razor	(482)	-	(1,112)	-
Other income (expense), net	1	-	31	(25)
Total other income (expenses), net	(539)	32	(1,274)	244

LOSS BEFORE INCOME TAXES	(6,783)	(5,225)	(24,718)	(14,472)
Income tax benefit	-	-	1,095	-
NET LOSS	$ (6,783)	$ (5,225)	$ (23,623)	$ (14,472)
Net loss per share; basic and diluted	$ (0.10)	$ (0.10)	$ (0.36)	$ (0.29)
Weighted average shares outstanding; basic and diluted	67,247	51,973	64,843	50,217

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (23,623)	$ (14,472)

Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	529	278
Amortization of intangible assets	59	-
Amortization of right-of-use assets and liabilities	959	-
Impairment charge for long-lived assets	88	-
Pro rata loss from equity method investment in Razor	1,112	-
Amortization of prepaid maintenance	52	28
Stock-based compensation	4,081	2,209
Unrealized loss on marketable equity securities	18	13
Amortization of debt issuance costs	80	30
Warrants issued for advisory services	-	234
Change in fair value of contingent consideration	(2,980)	-
Deferred income tax benefit	(1,095)	-
Other	-	25
Changes in operating assets and liabilities:		
Accounts receivable	(372)	-
Amount due to Lineage and affiliates	(6)	(2,100)
Prepaid expenses and other assets	(575)	(238)
Accounts payable and accrued liabilities	1,843	(416)
Net cash used in operating activities	(19,830)	(14,409)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	(6,189)	-
Equity method investment in Razor	(4,000)	(11,245)
Purchase of equipment	(1,061)	(18)

Security deposit and other	(6)	64
Net cash used in investing activities	(11,256)	(11,199)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	72	943
Proceeds from sale of common shares	18,343	40,250
Financing costs to issue common shares	(58)	(3,252)
Common shares received and retired for employee taxes paid	(14)	-
Repayment of loan payable	(125)	(600)
Repayment of financing lease obligations	(53)	(323)
Proceeds from PPP loan	1,141	-
Net cash provided by financing activities	19,306	37,018
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(11,780)	11,410
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	23,772	8,034
At end of the period	$ 11,992	$ 19,444

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 Nine Months Ended**	
	September 30,		**September 30,**	
	2020	**2019**	**2020**	**2019**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
GAAP loss from operations - as reported	**$ (6,244)**	**$ (5,257)**	**$ (23,444)**	**$ (14,716)**
Stock-based compensation expense	1,784	821	4,081	2,209
Impairment charge for long-lived assets	-	-	422	-
Noncash warrant expense	-	234	-	234
Depreciation and amortization expense	91	93	321	306
Change in fair value of contingent consideration	(2,980)	-	(2,980)	-
Severance charge	1,260	-	1,260	-

Non-GAAP loss from operations, as adjusted	$ (6,089)	$ (4,109)	$ (20,340)	$ (11,967)

Source: Oncocyte Corporation

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