Oncocyte Provides Corporate Update and Reports Second Quarter 2020 Financial Results

Jul 29, 2020

Secured National Medicare Reimbursement for DetermaRx™ Starting August 2020 with Final Medicare LCD from Palmetto GBA and Noridian Healthcare Solutions

International Distribution with ProGenetics Expands Global Availability of DetermaRx to Israel in Addition to India, the Middle East and Africa

Rapid Growth of DetermaRx™ Physician Adoption and Testing Volume Translating into Revenue

DetermaDx™ Development Program Discontinuation Expected to Deliver Approximately $3 million in Annualized Savings

Conference Call Today, July 29, at 4:30 PM EDT

IRVINE, Calif., July 29, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today reported financial and operating results for the second quarter ended June 30, 2020, and provided a corporate update.

“Oncocyte is a much stronger company today than when I stepped into the CEO role a year ago with two acquisitions that de-risked our product portfolio by adding two proprietary, well validated and published tests to our menu,” said Ron Andrews, Chief Executive Officer of Oncocyte. “The second quarter proved to be an important chapter in the evolution of Oncocyte as we continue to gain momentum with our two commercial products with multiple important milestones for DetermaRx™, which include securing national Medicare payment, revenue generation with reimbursements from multiple payers, a solid increase in physician adoption, increased testing volume with now well over 100 patients tested, and global distribution in Israel, India, the Middle East and Africa. In addition, with our compelling clinical data, the final LCD from Noridian established a new class of predictive tests for Medicare coverage in NSCLC, with DetermaRx now positioned as the first and only test in this class. This is a momentous accomplishment that establishes Oncocyte as a true pioneer in the advancement of molecular diagnostics for lung cancer.”

Mr. Andrews continued, “We also continue our progress with DetermaIO™ with data presented at ASCO that demonstrated the potential utility of DetermaIO for immunotherapy response prediction in triple negative breast cancer, the deadliest form of breast cancer. These data, combined with the lung cancer data presented at SITC in 2019, suggest that DetermaIO may have broad applicability in solid tumors regardless of tissue type, which could enable our access to the estimated $5 billion and rapidly growing molecular diagnostic market for both comprehensive profiling to identify patients likely to respond to

immune therapy and identifying patients who may require combination therapy to attain full sustained responses. We are actively pursuing near-term opportunities in both pharma services and academia for immunotherapy trials as we advance toward our ultimate goal of clinical launch and use of DetermaIO. Our continued track record of consistent execution with DetermaRx and DetermaIO, combined with our growing pharma services lab opportunity which has secured over $1 million in pharma services contracts already this year, positions Oncocyte for rapid revenue growth as an innovative leader in molecular diagnostics for lung cancer, TNBC and potentially other solid tumors."

Recent Corporate Highlights

- **DetermaRx**
  - ° Announced final Medicare local coverage determination (LCD) from both Noridian Healthcare Solutions and Palmetto GBA securing national Medicare payment for DetermaRx starting in August 2020
  - ° Noridian Healthcare Solutions LCD established a new class of predictive tests for Medicare coverage, based on compelling DetermaRx clinical evidence
    - • Noridian Healthcare Solutions LCD positions DetermaRx as the first and only test in this class for early-stage non-small cell lung cancer
  - ° Announced commercial availability in January and now have 47 sites onboarded, including a number of community healthcare systems where most early stage cancer is treated
  - ° Rapid growth of DetermaRx physician adoption has resulted in over 100 patients tested, and a physician reorder rate of 60%
  - ° Expanded international availability through a distribution agreement with ProGenetics Ltd, adding commercial availability of DetermaRx to Israel, which is complementary to the prior agreement with CORE Diagnostics for India, the Middle East and Africa
  - ° Announced publication of new long-term follow up data for DetermaRx in the *American Journal of Respiratory and Clinical Care Medicine* demonstrating potential clinical utility and benefit to patients and payers through reduced post-surgery follow-up of lung cancer patients
  - ° Continued successful physician engagement with both virtual and in-person activities with over 1,800 participants in online physician education programs
  - ° Announced KOL webinar showcasing new data and real-world usage of DetermaRx featuring renowned lung cancer experts Dr. David Gandara and Dr. Johannes Kratz on July 30, 2020

- **DetermaIO**
  - ° Presented data at 2020 ASCO Virtual Meeting highlighting the potential utility of DetermaIO for immunotherapy response prediction in triple-negative breast cancer. In this study, DetermaIO outperformed standard of care PD-L1 testing in identifying responders to the FDA-approved checkpoint inhibitor atezulimab
  - ° Announced KOL webinar featuring MD Anderson breast cancer medical oncologist, and triple negative study Principal Investigator, Dr. Naeto Ueno on August 19, 2020
  - ° Initiated an Investigator Sponsored Trial utilizing DetermaIO as the predictive biomarker for an FDA-approved checkpoint inhibitor in the early stage neoadjuvant setting
  - ° Continued advancement of pharma services opportunities, including immunotherapy trials and the potential for development of companion diagnostics for lung cancer and other solid tumors

- **Pharma Services**
  - ° 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
  - ° Closed over $1M in secured pharma services contracts

- With collaborators from MD Anderson Cancer Center, announced the peer-reviewed publication in *PLOS One* with data demonstrating the utility of the TNBCType Assay to inform triple-negative breast cancer drug development by identifying the most suitable cell lines to help biopharma and academic researchers develop new treatments

- **Financial and Corporate**
  - In April, Oncocyte successfully completed a $10.7 million registered offering of common shares, priced at the market, directly with fundamentally driven, healthcare focused institutional investors.

Second Quarter 2020 Financial Highlights

At June 30, 2020, Oncocyte had cash, cash equivalents and marketable securities of $17.1 million as compared to $22.5 million at December 31, 2019.

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 cash basis receipts from the sale of its lung cancer test, DetermaRx™, which was commercially launched in early 2020.

Under U.S. accounting principles, 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, 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 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 second quarter ended June 30, 2020, Oncocyte reported a net loss of $9.1 million, or $(0.14) per share, as compared to $5.4 million, or $(0.10) per share, for the second quarter ended June 30, 2019.

Operating losses, as reported, for the second quarter of 2020 were $8.8 million, an increase of $3.3 million from $5.5 million as compared to the second quarter of 2019; and operating losses, on an adjusted basis, were $6.9 million, an increase of $2.2 million from $4.7 million as compared to the second 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 six months ended June 30, 2020 were $143,000 and $158,000, respectively, primarily generated from pharma services, as revenues from DetermaRx tests were recognized only when Oncocyte received cash payment for the test rather than on an accrual basis when the tests were performed.

Cost of revenues for the three and six months ended June 30, 2020 were $0.4 million and $0.5 million, respectively, primarily incurred from performing the DetermaRx tests and pharma services.

Research and development expenses for second quarter of 2020 were $3.2 million as compared to $1.5 million for the same period in 2019, an increase of $1.7 million primarily attributable to personnel,

outside services and laboratory related expenses for Clinical Validation activities of DetermaDx.

General and administrative expenses for the second quarter of 2020 were $3.8 million, as compared to $3.6 million for the same period in 2019, which remained relatively unchanged from the prior year comparative period.

Sales and marketing expenses for the three months ended June 30, 2020, were $1.6 million, as compared to $0.3 million for the same period in 2019, an increase of $1.3 million. The increase was primarily due personnel and related expenses for ramp up in sales and marketing activities for commercialization of DetermaRx.

Cash used in operations was $7.0 million for the second quarter of 2020, which included some transactional, acquisition-related legal and business development costs paid this quarter of approximately $1 million.

Conference Call

The Company will host a conference call today, July 29, 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 13706018. 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=140441.

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.

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 CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	June 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 16,795	$ 22,072
Accounts Receivable	79	-
Marketable equity securities	341	379

Prepaid expenses and other current assets	1,230	505
Total current assets	18,445	22,956
NONCURRENT ASSETS		
Right-of-use assets, machinery and equipment, net	4,387	3,728
Equity method investment in Razor	14,334	10,964
Goodwill	9,187	-
Intangibles, net	15,053	-
Deposits and other noncurrent assets	2,049	2,211
TOTAL ASSETS	$ 63,455	$ 39,859
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to Lineage and affiliates	$ -	$ 6
Accounts payable	1,164	469
Accrued expenses and other current liabilities	3,820	2,610
Loan payable, current	1,482	1,125
Right-of-use and financing lease liabilities, current	376	230
Total current liabilities	6,842	4,440
NONCURRENT LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	2,622	1,905
Financing lease and right of use liabilities, noncurrent	3,110	2,676
Contingent consideration liabilities	11,130	-
Deferred tax liability	158	-

TOTAL LIABILITIES	23,862	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; 67,218 and 57,032 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	150,178	124,583
Accumulated other comprehensive loss	-	-
Accumulated deficit	(110,585)	(93,745)
Total shareholders' equity	39,593	30,838
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 63,455	$ 39,859

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
REVENUE				
Total revenue	$ 143	$ -	$ 158	$ -
TOTAL COSTS AND OPERATING EXPENSES				
Cost of revenue	365	-	538	-
Research and development	3,225	1,508	5,385	2,851

General and administrative	3,759	3,636	8,383	6,085
Sales and marketing	1,562	318	3,052	523
Total costs and operating expenses	8,911	5,462	17,358	9,459
Loss from operations	(8,768)	(5,462)	(17,200)	(9,459)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(75)	167	(97)	147
Unrealized gain (loss) on marketable equity securities	16	(88)	(38)	90
Pro rata loss from equity method investment in Razor	(301)	-	(630)	-
Other income (expenses), net	20	-	30	(25)
Total other income (expenses), net	(340)	79	(735)	212
LOSS BEFORE INCOME TAXES	(9,108)	(5,383)	(17,935)	(9,247)
Income tax benefit	-	-	1,095	-
NET LOSS	$ (9,108)	$ (5,383)	$ (16,840)	$ (9,247)
Net loss per share; basic and diluted	$ (0.14)	$ (0.10)	$ (0.26)	$ (0.19)

Weighted average shares outstanding; basic and diluted	65,833	51,973	63,628	49,324

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(UNAUDITED)

	Six Months Ended June 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,840)	$ (9,247)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	127	194
Amortization of intangible assets	37	-
Amortization of right-of-use assets and liabilities	301	-
Impairment charge for long-lived assets	422	-
Pro rata loss from equity method investment in Razor	630	-
Amortization of prepaid maintenance	67	18
Stock-based compensation	2,298	1,388
Unrealized (gain) loss on marketable equity securities	38	(90)
Amortization of debt issuance costs	57	22
Deferred income tax benefit	(1,095)	-

Other	-	26
Changes in operating assets and liabilities:		
Accounts receivable	(85)	-
Amount due to Lineage and affiliates	(6)	(2,096)
Prepaid expenses and other assets	(889)	(540)
Accounts payable and accrued liabilities	1,064	767
Net cash used in operating activities	(13,874)	(9,558)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	(6,189)	-
Equity method investment in Razor	(4,000)	-
Purchase of equipment	(535)	(18)
Security deposit and other	43	54
Net cash provided by (used in) investing activities	(10,681)	36
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	-	943
Proceeds from sale of common shares	18,342	40,250
Financing costs to issue common shares	(31)	(3,252)
Common shares received and retired for employee taxes paid	(14)	-
Repayment of loan payable	(125)	(400)
Repayment of financing lease obligations	(35)	(227)
Proceeds from PPP Loan	1,141	-
Net cash provided by financing activities	19,278	37,314

NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,277)	27,792
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	23,772	8,034
At end of the period	$ 18,495	$ 35,826

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 and an impairment charge for certain long-lived assets. 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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
GAAP loss from operations - as reported	**$ (8,768)**	**$ (5,462)**	**$ (17,200)**	**$ (9,459)**
Stock-based compensation expense	1,361	702	2,298	1,388
Impairment charge for long-lived assets	422	-	422	-
Depreciation and amortization expense	120	94	230	212
Non-GAAP loss from operations, as adjusted	$ (6,865)	$ (4,666)	$ (14,250)	$ (7,859)



Source: OncoCyte Corporation

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