Oncocyte Reports Second Quarter 2021 Financial Results and Provides Corporate Update

Aug 10, 2021

DetermaRx Q2 Sample Volume Grows 23% over Q1 2021

Potential pan-cancer utility of DetermaIO strengthened by data in breast, lung, bladder and renal cell cancer, validating the test in all four tumor types evaluated; upcoming oral presentation of randomized clinical trial in TNBC at ESMO

Chronix acquisition positions Oncocyte to enter growing field of blood-based monitoring for immune therapy response and transplant rejection testing

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

IRVINE, Calif., Aug. 10, 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 second quarter 2021 ended June 30, 2021, along with a corporate update.

“Oncocyte continues its solid growth trajectory, driven by strategic acquisitions and is on a path to deliver three product launches: DetermaIO™, DetermaTx™ and DetermaCNI™, in Q4 as we committed,” said Ron Andrews, Chief Executive Officer and President of Oncocyte. “We are encouraged by our steady quarter over quarter sample volume growth with DetermaRx™ despite the ongoing headwinds of the pandemic, and we expect to gain traction in Pharma Services with a number of near-term opportunities on the horizon with global leaders in pharma and molecular diagnostic platforms. DetermaIO, which is on track for clinical launch before year end, continues to prove to be a better predictor of immunotherapy response than the current prognostic assays and has the potential to be transformative for immunotherapy response prediction for both patients and pharma partners. We have now built a foundation of data, across tumor types, that support the pan-cancer utility of the test, so when combined with DetermaTx, which is also on track for launch in late fall for comprehensive molecular profiling, Oncocyte will offer a complete menu of treatment selection tests.”

Mr. Andrews continued, “Our entry into blood-based monitoring through the acquisition of Chronix positions Oncocyte to enter two large and rapidly growing markets, therapy response and recurrence monitoring in oncology, and transplant rejection monitoring in the EU. And while outside of our original focus in oncology, the recent LCD recognizing molecular testing for solid organ allograft rejection as a category test eligible for Medicare reimbursement, based solely on extensive scientific validation from Chronix studies, is a critical de-risking event for our transplant monitoring test. With this in place, we have a clear path forward to commercialize the TheraSure transplant monitor test in Europe to improve

testing sensitivity, reduce costs, and ultimately kit and democratize the monitoring test to improve turnaround times and patient outcomes."

Second Quarter and Recent Highlights Include:

- Announced upcoming oral presentation at the European Society for Medical Oncology (ESMO) Congress 2021 detailing results from the NeoTRIP randomized clinical trial which evaluated DetermaIO as a predictive biomarker for immunotherapy response prediction when administered before surgery in triple negative breast cancer (TNBC).
- Presented new data at the 2021 American Association for Cancer Research (AACR) Annual Meeting demonstrating a significant correlation between DetermaIO and two-year overall survival rate of patients treated with atezolizumab for metastatic bladder cancer, bolstering the potential for pan-cancer utility of DetermaIO.
- Presented new data at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating DetermaIO response prediction in renal cell carcinoma, extending the utility of DetermaIO across four tumor types tested.
- Collaboration with Gruppo Oncologico del Nord Ovest, a leading European clinical trials group which conducts independent investigator-sponsored clinical trials for targeted immunotherapy, to evaluate DetermaIO in colorectal cancer.
- Completed the acquisition of Chronix Biomedical, Inc., positioning Oncocyte to enter the rapidly growing immune therapy monitoring and transplant monitoring markets with DetermaCNI and TheraSure™ transplant monitor.
- Announced the Medicare Local Coverage Determination (LCD) for molecular testing for solid tumor allograft rejection, exclusively citing data from Oncocyte subsidiary Chronix Biomedical, Inc. The coverage policy for transplant rejection monitoring establishes a simplified and accelerated pathway for Medicare coverage of Chronix's solid organ transplant rejection monitoring test, TheraSure™ transplant monitor.
- With collaborators from subsidiary Chronic Biomedical, Inc., announced the publication of a review article in *Nature Reviews Nephrology*, highlighting the use of donor-derived cell-free DNA (dd-cfDNA) to provide actionable information for early detection of rejection in kidney transplants.
- Collaboration for a new "Day One" launch site in the Company's Nashville CLIA lab for Qiagen's companion diagnostics test to identify patients for Amgen's newly FDA-Approved drug Lumakras for advanced stage lung cancer. Offering the Therascreen RGQ KRAS test expands Oncocyte's offerings for lung cancer treatment decisions.
- Collaboration with Echelon Diagnostics, Inc. to develop analytical software that can scale to support the commercial expansion of Oncocyte's proprietary clinical test offerings and solutions.

Corporate

- Oncocyte Revenues for Q2 were $2.03 million, above the consensus estimate, driven by DetermaRx growth and delivery of key milestones in the tech transfer of DetermaRx to Burning Rock Biotech for launch in China.

Second Quarter 2021 Financial Results

At June 30, 2021, Oncocyte had cash, cash equivalents and marketable securities of $47.5 million.

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 payers other than Medicare, Oncocyte expects to recognize revenue for DetermaRx tests performed on a cash basis.

Revenues for the three months ended June 30, 2021, were $2.0 million, generated from three sources: DetermaRx tests, pharma services, and licensing revenues. This compares to revenues of $143,000 in the three months ended June 30, 2020. DetermaRx revenues grew solidly in Q2 2021 versus Q2 2020, primarily due to marketing efforts and revenue recognized for Medicare and Medicare Advantage tests performed following the receipt of final CMS pricing decision in September 2020.

Revenue for the second quarter of 2021 was driven primarily by licensing revenues earned upon the attainment of a technology transfer milestone in a licensing agreement. DetermaRx revenue also increased but the increase in patient samples tested grew at a faster pace than revenue due to accounting rules discussed above requiring the Company to continue to utilize the cash method rather than the accrual method of revenue recognition for DetermaRx tests performed for patients not covered by Medicare or a Medicare Advantage plan. Pharma Services revenues were slow during the second quarter as those revenues are generated under discrete agreements for particular customer projects that generally expire with the completion or termination of the customer's project. Accordingly, different customers may account for greater or lesser portions of Pharma Services during different accounting periods, and Pharma Services revenues may exhibit a larger variance from accounting period to accounting period than other revenues such as DetermaRx testing revenues due to reliance on client's ability to collect patient samples for their therapeutic clinical trials.

Cost of revenues for the second quarter 2021 was approximately $2.4 million, which included $1.1 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 second quarter of 2021 were $2.5 million as compared to $3.2 million for the same period in 2020, a decrease of $0.7 million, primarily reflecting decreases in outside services and clinical consulting for our development programs, and a $0.3 million decrease in depreciation expense.

General and administrative expenses for the second quarter of 2021 were $7.9 million, as compared to $3.8 million for the same period in 2020, an increase of $4.1 million, with $2.7 million in personnel and related expenses, including non-cash stock-based compensation expense, comprising the largest portion of the increase. Personnel and related expenses for the three months ended June 30, 2021 include a $2.5 million severance expense incurred from the Chronix Merger.

Sales and marketing expenses for the three months ended June 30, 2021, were $2.7 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.

Operating losses, as reported, for the second quarter of 2021 were $13.6 million, an increase of $4.8 million as compared to $8.8 million for the second quarter of 2020. Operating losses, on an adjusted

basis, were $10.3 million, an increase of $3.4 million from $6.9 million as compared to the second quarter of 2020.

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 second quarter ended June 30, 2021, Oncocyte reported a net loss of $10.5 million, or ($0.12) per share, as compared to $9.1 million, or ($0.14) per share, for the second quarter ended June 30, 2020.

Cash used in operations was approximately $8.1 million for the second quarter of 2021.

Conference Call Information

The Company will host a conference call today, August 10, 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 13721938. 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=145975. 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 of care. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and predicts benefit from adjuvant chemotherapy. DetermaIO™, a gene expression test currently used as a research tool in drug development, assesses the tumor microenvironment to predict response to immunotherapies. The Company's robust pipeline of future tests 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 and DetermaMx 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. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our or any distributor's financial and operational results, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to our or any distributor's supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, 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 we commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, greater than estimated allocations of resources to develop and commercialize technologies, or failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	June 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 46,469	$ 7,143
Accounts receivable	1,025	203

Marketable equity securities	1,062	675
Prepaid expenses and other current assets	1,439	1,205
Total current assets	49,995	9,226
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,949	3,262
Machinery and equipment, net, and construction in progress	4,396	3,262
Equity method investment in Razor	-	13,417
Goodwill	24,237	9,187
Intangible assets, net	93,712	15,009
Restricted cash	1,700	1,700
Other noncurrent assets	393	356
TOTAL ASSETS	$ 177,382	$ 55,419
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,088	$ 432
Accrued compensation	2,783	3,468
Accrued expenses and other current liabilities	1,933	2,284
Accrued liabilities from acquisition, current	11,734	-
Loans payable, current	1,500	2,390
Right-of-use and financing lease liabilities, current	737	422
Total current liabilities	19,775	8,996
NONCURRENT LIABILITIES		

Loans payable, net of deferred financing costs, noncurrent	541	1,508
Right-of-use and financing lease liabilities, noncurrent	3,895	4,312
Contingent consideration liabilities, noncurrent	50,505	7,120
TOTAL LIABILITIES	74,716	21,936
Commitments and contingencies (Note 10)		
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; 90,316 and 69,117 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	240,755	157,160
Accumulated deficit	(138,089)	(123,677)
Total shareholders' equity	102,666	33,483
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 177,382	$ 55,419

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended	**Six Months Ended**
	June 30,	**June 30,**

	2021	2020	2021	2020
Net revenue	$ 2,030	$ 143	$ 3,154	$ 158
Cost of revenues	1,350	365	2,088	538
Cost of revenues – amortization of acquired intangibles	1,074	-	1,381	-
Gross profit	(394)	(222)	(315)	(380)
Operating expenses:				
Research and development	2,537	3,225	5,898	5,385
Sales and marketing	2,673	1,562	4,927	3,052
General and administrative	7,934	3,759	12,698	8,383
Change in fair value of contingent consideration	30	-	1,090	-
Total operating expenses	13,174	8,546	24,613	16,820
Loss from operations	(13,568)	(8,768)	(24,928)	(17,200)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(49)	(75)	(117)	(97)
Unrealized gain (loss) on marketable equity securities	173	16	386	(38)
Pro rata loss from equity method investment in Razor	-	(301)	(270)	(630)
Gain on extinguishment of debt (PPP loan)	1,141	-	1,141	-

Other income, net	16	20	18	30
Total other expenses, net	1,281	(340)	1,158	(735)
LOSS BEFORE INCOME TAXES	(12,287)	(9,108)	(23,770)	(17,935)
Income tax benefit	1,794	-	9,358	1,095
NET LOSS	$ (10,493)	$ (9,108)	$ (14,412)	$ (16,840)
Net loss per share: basic and diluted	$ (0.12)	$ (0.14)	$ (0.17)	$ (0.26)
Weighted average shares outstanding: basic and diluted	89,758	65,833	85,961	63,628

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		

Net loss	$ (14,412)	$ (16,840)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	327	127
Amortization of intangible assets	1,381	37
Amortization of right-of-use assets and liabilities	218	301
Impairment charge for long-lived assets	-	422
Pro rata loss from equity method investment in Razor	270	630
Stock-based compensation	3,286	2,298
Unrealized (gain) loss on marketable equity securities	(387)	38
Amortization of debt issuance costs	34	57
Change in fair value of contingent consideration	1,090	-
Deferred income tax benefit	(9,358)	(1,095)
Gain on extinguishment of debt (PPP loan)	(1,141)	-
Accrued severance from Chronix Biomedical acquisition	2,452	-
Changes in operating assets and liabilities:		
Accounts receivable	(817)	(85)
Amount due to Lineage and affiliates	-	(6)
Prepaid expenses and other assets	(103)	(779)
Accounts payable and accrued liabilities	(766)	1,064
Net cash used in operating activities	(17,926)	(13,831)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	(607)	(6,189)
Acquisition of Razor Genomics asset, net of cash	(6,648)	-

acquired		
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	(1,452)	(535)
Net cash used in investing activities	(13,166)	(10,724)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	1,600	-
Proceeds from sale of common shares	65,262	18,342
Financing costs to issue common shares	(2,676)	(31)
Proceeds from sale of common shares under at-the-market transactions	6,483	-
Financing costs for at-the-market sales	(203)	-
Proceeds from exercise of warrants	823	-
Common shares received and retired for employee taxes paid	(37)	(14)
Repayment of loan payable	(750)	(125)
Repayment of financing lease obligations	(84)	(35)
Proceeds from PPP loan	-	1,141
Net cash provided by financing activities	70,418	19,278
Net INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	39,326	(5,277)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	8,843	23,772
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$ 48,169	$ 18,495

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
Adjusted Loss from Operation
(Amounts in Thousands)

	For the Three Months Ended June 30,		For the Si J
	2021	**2020**	**2021**
	(unaudited)	**(unaudited)**	**(unaudited)**
GAAP loss from operations - as reported	**$ (13,568)**	**$ (8,768)**	**$ (24,928**
Stock-based compensation expense	1,996	1,361	3,286
Impairment charge for long-lived assets	-	422	-
Change in fair value of contingent consideration	30	-	1,090
Depreciation and amortization expense	1,280	120	1,708
Non-GAAP loss from operations, as adjusted	$ (10,262)	$ (6,865)	$ (18,844

Source: Oncocyte Corporation

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