



Oncocyte Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 17, 2021

-Oncocyte Q1 revenues beat consensus estimate, driven by strong DetermaRx and Pharma Services growth -

-Data in four indications (TNBC, NSCLC, bladder, and renal cell cancer) suggest pan-cancer utility of DetermaIO for immunotherapy response prediction -

-DetermaIO pilot projects secured from three biopharma companies developing novel 2nd generation immunotherapies-

-Acquisition of Chronix Biomedical provides a gateway to the rapidly growing markets for blood based immune therapy response monitoring and transplant rejection testing -

Conference Call to be Held Today at 4:30pm ET/ 1:30 pm PDT

IRVINE, Calif., May 17, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NASDAQ: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, reports financial results for the first quarter 2021 ended March 31, 2021, along with a corporate update.

“Oncocyte’s rapid execution across our four growth engines has continued into 2021 and solidified our potential opportunity in over \$10 billion in combined market TAMs. First quarter was marked by revenue above the consensus of analyst estimates, driven by DetermaRx™ and Pharma Services, as well as by the delivery of a compelling data set that supports the pan-cancer utility of DetermaIO™, and by the completion of acquisitions that solidify our leadership in providing a single, comprehensive solution for molecular diagnostics in solid tumors,” said Ron Andrews, Chief Executive Officer and President of Oncocyte. “DetermaIO has had a terrific start to 2021. With the podium presentation of our data in bladder cancer at AACR, and upcoming presentation of our renal cell carcinoma data at ASCO, we now have validated the test in four solid tumor types. Together with our prior results in TNBC and NSCLC, the evidence is clear that DetermaIO has the potential to be a disruptive pan-cancer immunotherapy treatment selection test, and we look forward to the anticipated clinical launch of DetermaIO in the second half of the year and expect this test to be a major revenue growth opportunity for Oncocyte over the next 18 - 24 months.”

Mr. Andrews continued, “Our recent acquisition of Chronix Biomedical will play an important role in our long-term growth, providing an entry into the emerging \$5 billion global therapy monitoring markets with a patented, novel, blood-only/tumor naïve approach that will deliver faster information on disease progression compared to the competing tumor-informed approaches that require tissue samples. We

also gain access to broader intellectual property that may enable Oncocyte to offer additional innovative blood-based tests. From an execution standpoint, we will replicate our proven DetermaIO playbook as we rapidly launch DetermaCNI™ for blood-based immunotherapy response monitoring for research use in pharmaceutical clinical trials in late 2021. In terms of immediate growth, our Pharma Services offerings are gaining significant traction as we have recently signed agreements with two of the largest molecular diagnostics platform companies to deliver test development and contract research services, as well as act as a priority launch site for one of their new companion diagnostic products. As I look out into the coming quarters of 2021, I envision a great year with rising revenue and at least three product launches:

DetermaIO, DetermaTx for clinical use and DetermaCNI for pharma clinical research use. The efforts of our incredibly dedicated team have enabled steady progress toward our goal of developing a comprehensive array of molecular diagnostic tests for cancer. We will continue to advance our suite of technology to develop novel commercial products across the continuum of care.”

First Quarter and Recent Highlights Include:

- DetermaRx had continued momentum with 50% sequential quarterly growth in onboarded physicians (to 208 total), a 50% increase in onboarded accounts (to 123 hospitals total), and a total of 236 billable samples in Q1 2021, with steady sample growth month over month despite the pandemic surge in January and February
- Announced agreement with MultiPlan Network, expanding access to DetermaRx to an additional 60 million covered lives at a negotiated price in line with CMS pricing
- Technology transfer to Burning Rock Biotech according to our license of DetermaRx in China, the world’s largest early-stage lung cancer market, remains on-track for full onboarding and validation in Q3 with market launch in China to follow in late Q4
- Closed second investment in Razor Genomics to complete acquisition with Oncocyte becoming sole shareholder of Razor, the initial developer of DetermaRx
- New DetermaIO data presented at two major medical meetings, American Association for Cancer Research Annual Meeting (AACR) 2021 and American Society of Clinical Oncology (ASCO) 2021 demonstrate the potential for pan-cancer utility for DetermaIO
 - AACR 2021: Oral symposium presentation of a bladder cancer study which achieved its primary endpoint, demonstrating significant correlation between DetermaIO positivity and two-year overall survival rate for patients receiving atezolizumab in metastatic bladder cancer. DetermaIO identified additional immunotherapy responsive patients missed by currently used standard of care biomarkers, PD-L1 and TMB.
 - ASCO 2021: Upcoming presentation at the 2021 ASCO Annual Meeting demonstrating utility as predictor of immunotherapy response in renal cell carcinoma, a fourth indication, further supporting the pan-cancer utility of the test
- DetermaIO pilot projects secured from three biopharma companies developing novel 2nd generation immunotherapies. Projects will evaluate DetermaIO as a predictive biomarker.
- Entered the rapidly growing blood-based cancer monitoring market with the acquisition of Chronix Biomedical Inc. The acquisition gives Oncocyte proprietary capabilities for blood-based immune therapy monitoring with the CNI monitor test and transplant rejection testing.
- Chronix Biomedical’s ongoing and completed studies of the CNI Monitor test in lung, head and neck, ovarian and pancreatic cancer have now recruited over 700 patients to date. Completed studies demonstrate broad potential utility of this blood only test, including predicting the presence of disease post-surgery (MRD) and recurrence in ovarian cancer, and predicting response to cancer treatment, including but not limited to immunotherapy treatment.
- Medicare Coverage Determination for molecular testing in solid organ allograft rejection, which exclusively cites multiple publications from Chronix Biomedical, Inc. This coverage policy for

transplant rejection monitoring establishes a simplified and accelerated pathway for Medicare coverage of Chronix's solid organ transplant rejection monitoring test that Oncocyte now owns.

- Initiated project with top 20 pharma company utilizing Oncocyte's proprietary blood-based cell-cycle test for monitoring resistance in an ongoing Phase 3 trial

Corporate

- Strengthened balance sheet with \$69 million raised in offerings of common stock
- Transitioned listing to Nasdaq Global Market
- Oncocyte Revenues for Q1 were \$1.12 million, above the consensus estimate, driven by DetermaRx growth and Pharma Services projects
- Completed relocation to new Irvine clinical facility

First Quarter 2021 Financial Results

At March 31, 2021, Oncocyte had cash, cash equivalents and marketable securities of \$59.8 million. In January and February 2021, Oncocyte raised an aggregate of \$69 million in net proceeds from a direct placement and a public offering, as well as shares sold from its at-the-market (ATM) program. In February 2021, Oncocyte completed the acquisition of the remaining equity interests in Razor Genomics and paid the \$10 million cash portion to the selling shareholders, so Oncocyte now owns all of the outstanding common stock of Razor and will consolidate Razor as of that date.

Consolidated revenues for the first quarter of 2021 were approximately \$1.12 million, a 123% increase from the fourth quarter of 2020, as revenues from both sources increased over the fourth quarter of 2020. Since inception, Oncocyte generated revenues for the first time in the first quarter of 2020, therefore comparison of current quarter consolidated revenues to the first quarter of 2020 is not meaningful. During the three months ended March 31, 2021, Oncocyte commenced recognizing Medicare Advantage covered tests on an accrual basis, rather than on a cash basis, after accumulating additional history of cash receipts and other factors considered by management that it believes entitles Oncocyte to get reimbursed for Medicare Advantage covered DetermaRx tests at the Medicare rate. Accordingly, DetermaRx tests performed for both Medicare covered patients and Medicare Advantage covered patients are being recognized when the tests are performed, on an accrual basis, at the Medicare rate, rather than on a cash basis. Oncocyte will continue to recognize revenues from commercial and other payors on a cash basis until it has reimbursement contracts with those payors, at which point Oncocyte will recognize all DetermaRx revenues on an accrual basis.

Cost of revenues for the first quarter 2021 was approximately \$1.0 million, which included \$307,000 in non-cash amortization expenses from the Razor Genomics asset acquired in February. 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 first quarter of 2021 were \$3.4 million as compared to \$2.2 million for the same period in 2020, an increase of \$1.2 million, primarily due to increased investment in DetermaIO, personnel and related expenses.

General and administrative expenses for the first quarter of 2021 were \$4.8 million, as compared to \$4.6 million for the same period in 2020, an increase of \$0.2 million.

Sales and marketing expenses for the three months ended March 31, 2021, were \$2.3 million, as compared to \$1.5 million for the same period in 2020. The increase during the respective period was

primarily due to personnel and related expenses for ramp up in sales and marketing activities for the commercialization efforts of DetermaRx as well as market development investments in preparation for the launch of new products later this year.

Operating losses, as reported, for the first quarter of 2021 were \$11.4 million, an increase of \$3.0 million from \$8.4 million as compared to the first quarter of 2020. Operating losses, on an adjusted basis, were \$8.6 million, an increase of \$1.2 million from \$7.4 million as compared to the first 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 first quarter ended March 31, 2021, Oncocyte reported a net loss of \$3.9 million, or (\$0.05) per share, as compared to \$7.7 million, or (\$0.13) per share, for the first quarter ended March 31, 2020.

Cash used in operations was approximately \$9.8 million for the first quarter of 2021. The first quarter of each year is generally our largest cash burn quarter due to annual merit and bonus payments.

Conference Call Information

The Company will host a conference call today, May 17, 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 13719464. 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=144784>. 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. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives and improve outcomes by accelerating and optimizing the diagnosis and treatment of cancer. The Company's tests and services present multiple opportunities to advance cancer care while also driving revenue growth for the Company. Oncocyte launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection, and predicts benefit from adjuvant chemotherapy. Oncocyte has also launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the Company anticipates launching DetermaTx™ in the second half of 2021 as a test to assess mutational status of a tumor to help identify the appropriate targeted therapy. The Company recently completed the acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor (to be rebranded as DetermaCNI) and TheraSure™ Transplant Monitor test, which are both available for clinical research use in EU, and also plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide a full suite of molecular testing services to support the drug development process for pharmaceutical companies that are developing new cancer treatments.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation, and TheraSure™ is a trademark of Chronix Medical, 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 Chronix TheraSure™ CNI Monitor test, including its potential use and efficacy, the potential for Medicare reimbursement and pricing, potential addressable market sizes, 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 our or our 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 our 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, and the need to obtain third party reimbursement for patients’ use of any diagnostic tests we or our subsidiaries commercialize, 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 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@westwicke.com

ONCOCYTE CORPORATION

CONSOLIDATED BALANCE SHEETS

(\$ in thousands)

March 31,

**December
31,**

	2021	2020
ASSETS	unaudited	
CURRENT ASSETS		
Cash and cash equivalents	\$ 58,907	\$ 7,143
Accounts receivable	703	203
Marketable equity securities	887	675
Prepaid expenses and other current assets	2,327	1,205
Total current assets	62,824	9,226
NONCURRENT ASSETS		
Right-of use-assets, machinery and equipment, net and construction in progress	7,266	6,524
Equity method investment in Razor	-	13,417
Goodwill	9,194	9,187
Intangibles, net	47,986	15,009
Deposits and other non current assets	2,035	2,056
TOTAL ASSETS	\$ 129,305	\$ 55,419
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	1,092	432
Accrued expenses and other current liabilities	5,264	5,752
Loans payable, current	2,590	2,390
Right-of-use and financing lease liabilities, current	740	422
Total current liabilities	9,686	8,996

NONCURRENT LIABILITIES

Loans payable, net of deferred financing costs, noncurrent	951	1,508
Right-of-use and financing lease liabilities, noncurrent	3,860	4,312
Contingent consideration liabilities	8,180	7,120
TOTAL LIABILITIES	22,677	21,936

SHAREHOLDERS' EQUITY

Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 150,000 shares authorized; 88,914 and 69,117 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	234,224	157,160
Accumulated deficit	(127,596)	(123,677)
Total shareholders' equity	106,628	33,483
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 129,305	\$ 55,419

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

Three Months Ended

March 31,

2021**2020**

	unaudited	unaudited
REVENUE		
Total revenue	\$ 1,124	\$ 16
TOTAL COSTS AND OPERATING EXPENSES		
Cost of revenues	738	158
Cost of revenues - amortization of acquired intangibles	307	15
Research and development	3,361	2,159
General and administrative	4,764	4,625
Sales and marketing	2,254	1,490
Change in fair value of contingent consideration	1,060	-
Total operating expenses	12,484	8,447
Loss from operations	(11,360)	(8,431)
OTHER INCOME (EXPENSES), NET		
Interest expense, net	(68)	(22)
Unrealized gain (loss) on marketable equity securities	213	(53)
Pro rata loss from equity method investment in Razor	(270)	(329)
Other income, net	2	8
Total other expenses, net	(123)	(396)
LOSS BEFORE INCOME TAXES	(11,483)	(8,827)
Income tax benefit	7,564	1,095

NET LOSS	\$	(3,919)	\$	(7,732)
Net loss per share; basic and diluted	\$	(0.05)	\$	(0.13)
Weighted average shares outstanding; basic and diluted		82,123		61,459

ONCOCYTE CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended			
	March 31,			
	2021		2020	
	unaudited		unaudited	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$	(3,919)	\$	(7,732)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation expense		121		60
Amortization of intangible assets		307		15
Amortization of right-of-use assets and liabilities		25		152
Pro rata loss from equity method investment in Razor		270		329
Amortization of prepaid maintenance		21		36

Stock-based compensation	1,290	937
Unrealized (gain) loss on marketable equity securities	(213)	53
Amortization of debt issuance costs	19	35
Change in fair value of contingent consideration	1,060	-
Deferred income tax benefit	(7,564)	(1,095)
Changes in operating assets and liabilities:		
Accounts receivable	(499)	8
Amount due to Lineage and affiliates	-	(6)
Prepaid expenses and other assets	(1,168)	(909)
Accounts payable and accrued liabilities	405	1,247
Net cash used in operating activities	(9,845)	(6,870)

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)	-
Deposit paid for Chronix merger agreement	(175)	-
Construction in progress and purchases of furniture and equipment	(842)	(44)
Security deposit and other	10	42
Net cash used in investing activities	(8,262)	(6,191)

CASH FLOWS FROM FINANCING ACTIVITIES:

Proceeds from exercise of stock options	348	-
Proceeds from sale of common shares	65,262	7,597
Financing costs to issue common shares	(2,676)	(1)
Proceeds from sale of common shares under at-the-market	6,754	-

transactions		
Financing costs for at-the-market sales	(203)	-
Proceeds from exercise of warrants	802	-
Common share received and retired for employee taxes paid	-	(14)
Repayment of loan payable	(375)	-
Repayment of financing lease obligations	(41)	(17)
Net cash provided by financing activities	69,871	7,565
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	51,764	(5,496)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	8,843	23,773
At end of the period	\$ 60,607	\$ 18,277

ONCOCYTE CORPORATION

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.

Reconciliation of Non-GAAP Financial Measure

Adjusted Loss from Operations

	Three Months Ended	
	March 31,	
	(In thousands)	
	2021	2020
	(unaudited)	
GAAP loss from operations - as reported	\$ (11,360)	\$ (8,431)
Stock-based compensation expense	1,290	937
Depreciation and amortization expense	428	111
Change in fair value of contingent consideration	1,060	-
Non-GAAP loss from operations, as adjusted	\$ (8,582)	\$ (7,383)



Source: Oncocyte Corporation

