Oncocyte Reports Second Quarter 2022 Financial Results

Aug 10, 2022

IRVINE, Calif., Aug. 10, 2022 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company with the mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey, today reports financial results for the second quarter 2022, ended June 30, 2022.

Second Quarter and Recent Highlights:

- Recent rightsizing of organization to match new program priorities is expected to reduce headcount carrying costs by over $4.5 million annually and, in combination with reprioritization cost reduction and anticipated strategic activities, annualized operating costs are expected to be reduced by approximately $12 million in 2023 as compared to 2022.
- Reported total revenue of $2.1 million in the second quarter of 2022, compared with $2.0 million in the second quarter of 2021.
- Received $1.0 million milestone payment from the final delivery of DetermaRx™ to Burning Rock, our Chinese partner.
- Grew DetermaRx sample volume by 66% compared to second quarter of 2021 and increased onboarded physician base by 82% as compared to the same period in 2021.
- Launched our CLIA validated laboratory test for our newly branded VitaGraft™ Liver Transplant Monitoring, a donor-derived cell-free DNA (dd-cfDNA) test.
- Submitted VitaGraft Liver and VitaGraft Kidney for CMS reimbursement.
- Clinical Partners presented five abstracts at ASCO and AACR expanding the evidence supporting DetermaIO™ as clinically relevant to decision making in six different cancer types including:
  - Independent, prospective randomized clinical trial (RCT) evidence that DetermaIO can identify responders and expand the market for immune checkpoint inhibitor (ICI) therapy in colorectal cancer.
  - Phase II independent blinded clinical trial evidence that DetermaIO can inform the use of pembrolizumab therapy (Keytruda) in the neoadjuvant treatment of triple negative breast cancer, expanding upon prior reported RCT data with atezolizumab.
- Closed an underwritten offering of $32.8 million in net proceeds of common stock and warrants, and a preferred stock offering of $4.9 million in net proceeds, to strengthen the balance sheet and further support our product portfolio.

“Our recent reprioritization efforts have led to a rightsizing of our employee base to better match the resourcing required to deliver DetermaIO, DetermaCNI™ and VitaGraft to the market. The expected program cost reductions combined with the reduction in headcount and planned monetization of assets through strategic activities are anticipated to result in a decrease of approximately $12 million in annualized operating expenses year over year, extending our cash runway into 2024,” said Ron Andrews, Chief Executive Officer of Oncocyte. “We continued to make solid progress in the second quarter, delivering 66% year over year growth in DetermaRx sample volumes and successfully onboarding new physicians and accounts. We also successfully completed our CLIA lab test validation of our VitaGraft product line and submitted both Liver and Kidney for CMS reimbursement.”

Continuing, Mr Andrews commented, “Looking ahead, we are excited by the response to the anticipated launch of our VitaGraft Liver test and expect our first samples from a high-profile liver transplant center by the end of August. We also remain on track to submit our dossier for DetermaIO reimbursement this fall. Despite the continued market headwinds, we believe that Oncocyte has an incredibly bright future in front of us as the product development efforts from the past few years are expected to result in new product launches of high value, reimbursed products over the next four to six quarters. I would also like to recognize the promotion of Anish John to CFO and Gisela Paulsen to President and COO. These are well-deserved promotions for two executives that have been instrumental in reshaping our priorities and helping find ways to reduce our burn while still accomplishing our mission. We are now aligned around key areas where our skill sets can best serve Oncocyte’s future. I appreciate the continued support of our shareholders and look forward to updating you as we work to deliver on the key product milestones throughout the second half of 2022.”

Second Quarter 2022 Financial Results

Total revenue was $2.1 million for the second quarter of 2022, compared to $1.4 million for the prior quarter. Second quarter revenues associated with DetermaRx were $0.8 million, down $0.2 million sequentially, and up $0.2 million year over year. Operating expenses for the second quarter 2022 were $8.2 million, compared to $13.2 million, a decrease of $5.0 million from the same period in the prior year. Research and Development expense for the second quarter 2022 was $5.6 million, an increase of $3.0 million from the same period a year ago. The increase in R&D expense was due to full integration of the Chronix R&D team, the growth and enrolment of our clinical trials, and added headcount related to the buildout of our IVD product development capabilities. General and Administrative expense for the second quarter of 2022 was $5.5 million, a decrease of $2.4 million for the same period in 2021, primarily due to one-time acquisition related costs related Chronix Biomedical acquisition in the same period in the prior year. Sales and Marketing expense in the quarter was $3.5 million, an increase of $0.8 million year over year, primarily attributable to an increase in headcount and continued ramp in sales and marketing activities related to the transplant business, as well as support the commercialization efforts within oncology.

Net loss was $8.3 million for the second quarter of 2022 and net loss per share was $0.07 on a weighted-average basic and diluted share count of 113.0 million, compared to a net loss of $10.5 million and a net loss per share of $0.12 on a weighted-average basic and diluted share count of 89.8 million in the same period of the prior year.

Cash, cash equivalents, restricted cash and marketable securities were $47.1 million as of June 30, 2022.

Webcast and Conference Call Information

Oncocyte will host a conference call to discuss the second quarter 2022 financial results after market close on Wednesday, August 10, 2022 at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. The conference call can be accessed live over the phone (877) 407-9716 for U.S. callers or (201) 493-6779 for international

callers, using conference ID: 13731553. The live webinar can be accessed at https://investors.oncocyte.com.

About Oncocyte

Oncocyte is a precision diagnostics company with a mission to improve patient outcomes by providing personalized insights that inform critical decisions throughout the patient care journey.

Through its proprietary tests and pharmaceutical services business, the Company aims to help save lives by accelerating the diagnosis of cancer and advancing cancer care. The Company's tests are designed to help provide clarity and confidence to physicians and their patients at every stage. DetermaRx™ identifies early-stage lung cancer patients who are at high risk for cancer recurrence and who may benefit from adjuvant chemotherapy. DetermaIO™ is a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies. The Company's pipeline of tests in development also includes DetermaTx™, which will assess mutational status of a tumor, DetermaCNI™, a blood-based monitoring test, DetermaMx™, a long-term recurrence monitoring test, and VitaGraft™, a blood-based solid organ transplantation monitoring test. In addition, Oncocyte's pharmaceutical services provide companies that are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx™, DetermaIO™, DetermaTx™, DetermaCNI™, DetermaMx™ and VitaGraft™ are trademarks of Oncocyte Corporation.

Forward-Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, expected program cost reductions, planned monetization of assets through strategic activities, the anticipation of a $12 million improvement in annualized operating expenses related to such cost reductions and planned monetization of assets, the expectation that our cash runway will extend well into 2024, the anticipated launch of our VitaGraft Liver product and the expectation that we will receive our first samples from a high-profile liver transplant center by the end of August, the anticipated submission of our dossier for DetermaIO reimbursement this fall, the expectation of new product launches of high value, reimbursed products over the next four to six quarter, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on Oncocyte or its subsidiaries' financial and operational results, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Oncocyte's third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Oncocyte or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission (SEC) filings, which are

available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 44,836	$ 35,605
Accounts receivable	1,802	1,437
Marketable equity securities	579	904
Prepaid expenses and other current assets	2,151	1,197
Total current assets	49,368	39,143
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,489	2,779

Machinery and equipment, net, and construction in progress	9,087	5,748
Goodwill	18,684	18,684
Intangible assets, net	89,341	91,245
Restricted cash	1,700	1,700
Other noncurrent assets	382	264
TOTAL ASSETS	$ 171,051	$ 159,563
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,465	$ 2,447
Accrued compensation	2,789	3,376
Accrued expenses and other current liabilities	4,564	2,425
Accrued severance from acquisition	2,314	2,352
Accrued liabilities from acquisition	609	1,388
Loans payable, net of deferred financing costs	574	1,313
Right-of-use and financing lease liabilities, current	839	819
Total current liabilities	14,154	14,120
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	3,134	3,545
Contingent consideration liabilities	65,666	76,681
TOTAL LIABILITIES	82,954	94,346

Commitments and contingencies		
Series A Redeemable Convertible Preferred Stock, no par value; stated value $1,000 per share; 12 shares authorized, 6 shares issued and outstanding at June 30, 2022; aggregate liquidation preference of $5,911 as of June 30, 2022	4,854	-
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; 118,609 and 92,232 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	289,649	252,954
Accumulated other comprehensive loss	31	37
Accumulated deficit	(206,437)	(187,774)
Total shareholders' equity	83,243	65,217
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 171,051	$ 159,563

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended		**Six Months Ended**	
	June 30,		**June 30,**	
	2022	**2021**	**2022**	**2021**

Net revenue	$ 2,067	$ 2,030	$ 3,491	$ 3,154
Cost of revenues	1,405	1,350	2,426	2,088
Cost of revenues – amortization of acquired intangibles	976	1,074	1,912	1,381
Gross profit	(314)	(394)	(847)	(315)
Operating expenses:				
Research and development	5,574	2,537	10,702	5,898
Sales and marketing	3,522	2,673	6,759	4,927
General and administrative	5,511	7,934	11,164	12,698
Change in fair value of contingent consideration	(6,359)	30	(11,015)	1,090
Total operating expenses	8,248	13,174	17,610	24,613
Loss from operations	(8,562)	(13,568)	(18,457)	(24,928)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(21)	(49)	(51)	(117)
Unrealized gain (loss) on marketable equity securities	5	173	(325)	386
Pro rata loss from equity method investment in Razor	-	-	-	(270)
Gain on extinguishment of debt (PPP loan)	-	1,141	-	1,141
Other income, net	278	16	242	18

Total other expenses, net	262	1,281	(134)	1,158
LOSS BEFORE INCOME TAXES	(8,300)	(12,287)	(18,591)	(23,770)
Income tax benefit	-	1,794	-	9,358
NET LOSS	$ (8,300)	$ (10,493)	$ (18,591)	$ (14,412)
Net loss per share: basic and diluted	$ (0.07)	$ (0.12)	$ (0.18)	$ (0.17)
Weighted average shares outstanding: basic and diluted	113,042	89,758	102,700	85,961

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Six Months Ended June 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		

Net loss	$ (18,591)	$ (14,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	671	327
Amortization of intangible assets	1,904	1,381
Pro rata loss from equity method investment in Razor	-	270
Stock-based compensation	4,242	3,286
Unrealized (gain) loss on marketable equity securities	325	(386)
Amortization of debt issuance costs	11	33
Change in fair value of contingent consideration	(11,015)	1,090
Change in fair value of Series A redeemable convertible preferred stock second tranche obligation	(305)	33
Deferred income tax benefit	-	(9,358)
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	(365)	(817)
Lease liabilities	(94)	218
Prepaid expenses and other assets	(773)	(103)
Accounts payable and accrued liabilities	239	(766)
Accrued severance and liabilities from Chronix Biomedical acquisition	(817)	-
Net cash used in operating activities	(24,568)	(17,893)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of Insight Genetics, net of cash acquired	-	(607)

Acquisition of Razor Genomics asset, net of cash acquired	-	(6,648)
Acquisition of Chronix Biomedical, net of cash acquired	-	(4,459)
Construction in progress and purchases of furniture and equipment	(2,679)	(1,452)
Net cash used in investing activities	(2,679)	(13,166)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	-	1,600
Proceeds from sale of common shares	32,812	65,262
Financing costs to issue common shares	(389)	(2,676)
Proceeds from sale of redeemable convertible Series A preferred shares	4,875	-
Financing costs to issue redeemable convertible Series A preferred shares	(93)	-
Proceeds from sale of common shares under at-the-market transactions	31	6,483
Financing costs for at-the-market sales	(1)	(203)
Proceeds from exercise of warrants	-	823
Common shares received and retired for employee taxes paid	-	(37)
Repayment of loan payable	(750)	(750)
Repayment of financing lease obligations	(7)	(84)
Net cash provided by financing activities	36,478	70,418
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	9,231	39,359
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	37,305	8,843

CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$	46,536	$	48,202
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION				
Cash paid for interest	$	21	$	70
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES				
Common stock issued for acquisition of Razor Genomics asset	$	-	$	5,756
Deferred tax liability generated from the acquisition of Razor Genomics asset		-		7,564
Common stock issued for acquisition of Chronix Biomedical		-		3,299
Deferred tax liability generated from the acquisition of Chronix		-		1,794
Initial fair value of contingent consideration at acquisition date		-		42,295
Assumed liability from Chronix Acquisition		-		9,294
Construction in progress, machinery and equipment purchases included in accounts payable, accrued liabilities and landlord liability		1,331		9

Oncocyte Corporation

Reconciliation of Non-GAAP Financial Measure

Adjusted Loss from Operations

(Amounts in Thousands)

	For the Three Months Ended

	June 30, 2022	December 31, 2021	June 30, 2021
	(unaudited)	(unaudited)	(unaudited)
GAAP loss from operations - as reported	**$ (8,562)**	**$ (35,680)**	**$ (13,568)**
Stock-based compensation expense	2,232	1,706	1,996
Change in fair value of contingent consideration	(6,359)	25,006	30
Severance charge	143	255	2,452
Depreciation and amortization expense	1,360	1,251	1,280
Non-GAAP loss from operations, as adjusted	**$ (11,186)**	**$ (7,462)**	**$ (7,810)**

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Source: Oncocyte Corporation

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