Oncocyte Reports Third Quarter 2022 Financial Results

Nov 10, 2022

IRVINE, Calif., Nov. 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 third quarter 2022, ended September 30, 2022.

Third Quarter and Recent Highlights:

- SWOG Cancer Research Network selected the DetermaIO™ test to be used in its S1418 clinical trial, a prospectively designed biomarker study of breast cancer tissues.
- DetermaIO sample volume from Early Adopters grew at 117% quarter over quarter.
- DetermaRx™ test sample volume increased by 51%, compared to third quarter of 2021 and onboarded physician base increased by 62%, as compared to the same period in 2021.
- Received recommendation from the Advisory Panel for the DetermaRx test to be cross walked to CPT code 81522, increasing reimbursement rate by 23% beginning January 2023.
- Announced that Palmetto GBA, a Medicare administrative contractor for the Molecular Diagnostics Services program (MolDX), has conveyed the validity of a Local Coverage Determination (LCD) reconsideration request for broader coverage for DetermaRx to include risk-stratification to assess the risk of recurrence for the early-stage non-small cell lung cancer patient to determine the best course of action for patient management.
- Completed initial phase of our cost reduction initiatives to streamline the company.

”We have maintained our momentum against our major milestones across our portfolio, leveraging our newly streamlined organization, as we announced in August. Our reimbursement efforts for our VitaGraft™ products are in a productive dialogue with MolDx as we get close to a final determination,” said Ron Andrews, Chief Executive Officer of Oncocyte. “We have learned a lot about the potential utility for our VitaGraft Liver test during our Early Access Program launch and have identified a compelling opportunity from the experts we have engaged to date. We also continued to make solid progress with DetermaRx in the third quarter, delivering 51% year over year growth in sample volumes and successfully onboarding new physicians and accounts.”

“Looking ahead, we remain on track to submit our dossier for DetermaIO reimbursement in coming weeks. Additionally, our corporate development activities are yielding several interesting opportunities, and we have engaged Perella Weinburg Partners as our advisor to assist us in identifying and evaluating a range of potential strategic alternatives.On a parallel path, we continue to explore avenues to bolster our cash runway and to reduce our spend. We believe that Oncocyte has a bright future in front of us as the

product development efforts from the past few years transition to market launches of several new high-value, reimbursed tests over coming quarters."

Third Quarter 2022 Financial Results

Total revenue was $1.0 million for the third quarter of 2022, compared to $2.1 million for the prior quarter. Third quarter revenues associated with DetermaRx were $1.0 million, an increase of $0.1 million sequentially, and $0.5 million year over year. Operating expenses for the third quarter 2022 were $8.0 million, compared to $12.7 million, a decrease of $4.7 million from the same period in the prior year. Research and Development expense for the third quarter 2022 was $4.4 million, an increase of $1.3 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 enrollment of our clinical trials, and added headcount related to the buildout of our IVD product development capabilities in the first quarter. General and Administrative expense for the third quarter of 2022 was $5.8 million, an increase of $0.3 million for the same period in 2021. Sales and Marketing expense in the quarter was $4.0 million, an increase of $1.1 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 $9.3 million for the third quarter of 2022 and net loss per share was $0.08 on a weighted-average basic and diluted share count of 118.6 million, compared to a net loss of $13.8 million and a net loss per share of $0.15 on a weighted-average basic and diluted share count of 91.5 million in the same period of the prior year.

Cash, cash equivalents, restricted cash and marketable securities were $34.2 million as of September 30, 2022.

Webcast and Conference Call Information

Oncocyte will host a conference call to discuss the third quarter 2022 financial results after market close on Thursday, November 10, 2022 at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. The conference call can be accessed by dialing (877) 407-9716 for U.S. callers or (201) 493-6779 for international callers, using conference ID: 13732984. 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, reimbursement efforts for VitaGraft products, the anticipated submission of the Company’s dossier for DetermaIO reimbursement in coming weeks, potential strategic alternatives, plans to bolster the Company’s cash runway and reduce its spend, anticipated market launches of new high value, reimbursed tests over coming quarters , 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)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 32,053	$ 35,605
Accounts receivable	1,990	1,437
Marketable equity securities	419	904
Prepaid expenses and other current assets	2,174	1,197
Total current assets	36,636	39,143
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	2,337	2,779
Machinery and equipment, net, and construction in progress	9,256	5,748
Goodwill	18,684	18,684
Intangible assets, net	88,365	91,245
Restricted cash	1,700	1,700
Other noncurrent assets	366	264
TOTAL ASSETS	$ 157,344	$ 159,563
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,826	$ 2,447
Accrued compensation	4,067	3,376
Accrued expenses and other current liabilities	3,809	2,425

Accrued severance from acquisition	2,314	2,352
Accrued liabilities from acquisition	109	1,388
Loans payable, net of deferred financing costs	-	1,313
Right-of-use and financing lease liabilities, current	827	819
Total current liabilities	12,952	14,120
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	2,935	3,545
Contingent consideration liabilities	59,524	76,681
TOTAL LIABILITIES	75,411	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 September 30, 2022; aggregate liquidation preference of $6,001 as of September 30, 2022	5,076	-
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; 118,619 and 92,232 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	292,536	252,954
Accumulated other comprehensive income	19	37
Accumulated deficit	(215,698)	(187,774)

Total shareholders' equity	76,857	65,217
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 157,344	$ 159,563

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net revenue	$ 1,017	$ 984	$ 4,508	$ 4,138
Cost of revenues	1,215	860	3,641	2,948
Cost of revenues – amortization of acquired intangibles	976	990	2,888	2,371
Gross profit	(1,174)	(866)	(2,021)	(1,181)
Operating expenses:				
Research and development	4,421	3,142	15,123	9,040
Sales and marketing	4,005	2,931	10,764	7,858
General and administrative	5,763	5,495	16,927	18,193

Change in fair value of contingent consideration	(6,142)	1,170	(17,157)	2,260
Total operating expenses	8,047	12,738	25,657	37,351
Loss from operations	(9,221)	(13,604)	(27,678)	(38,532)
OTHER INCOME (EXPENSES), NET				
Interest expense, net	(14)	(50)	(65)	(167)
Unrealized gain (loss) on marketable equity securities	(160)	(138)	(485)	248
Pro rata loss from equity method investment in Razor	-	-	-	(270)
Gain on extinguishment of debt (PPP loan)	-	-	-	1,141
Other income (expenses), net	62	(8)	304	10
Total other income (expenses), net	(112)	(196)	(246)	962
LOSS BEFORE INCOME TAXES	(9,333)	(13,800)	(27,924)	(37,570)
Income tax benefit	-	-	-	9,358
NET LOSS	$ (9,333)	$ (13,800)	$ (27,924)	$ (28,212)
Accretion of Series A redeemable convertible preferred stock	(222)	-	(294)	-

NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS: BASIC AND DILUTED	$ (9,555)	$ (13,800)	$ (28,218)	$ (28,212)
Net loss per share: basic and diluted	$ (0.08)	$ (0.15)	$ (0.26)	$ (0.32)
Weighted average shares outstanding: basic and diluted	118,610	91,453	108,158	87,812

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (27,924)	$ (28,212)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,062	582
Amortization of intangible assets	2,880	2,371

Pro rata loss from equity method investment in Razor	-	270
Stock-based compensation	7,423	5,136
Unrealized (gain) loss on marketable equity securities	485	(248)
Amortization of debt issuance costs	12	46
Change in fair value of contingent consideration	(17,157)	2,260
Change in fair value of Series A redeemable convertible preferred stock second tranche obligation	(352)	-
Deferred income tax benefit	-	(9,358)
Gain on extinguishment of debt (PPP loan)	-	(1,141)
Changes in operating assets and liabilities:		
Accounts receivable	(553)	(824)
Lease liabilities	(156)	169
Prepaid expenses and other assets	(745)	(787)
Accounts payable and accrued liabilities	422	(1,592)
Accrued severance and liabilities from Chronix Biomedical acquisition	(1,317)	2,452
Net cash used in operating activities	(35,920)	(28,876)
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 equipment	(3,538)	(1,846)
Net cash used in investing activities	(3,538)	(13,560)

CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	-	2,573
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	12,724
Financing costs for at-the-market sales	(1)	(390)
Proceeds from exercise of warrants	-	2,631
Common shares received and retired for employee taxes paid	-	(239)
Repayment of loan payable	(1,325)	(1,125)
Repayment of financing lease obligations	(4)	(127)
Net cash provided by financing activities	35,906	78,633
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(3,552)	36,197
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	37,305	8,843
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$ 33,753	$ 45,040
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ 24	$ 96

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	-	3,489
Construction in progress, machinery and equipment purchases included in accounts payable, accrued liabilities and landlord liability	1,032	193

Oncocyte Corporation

Reconciliation of Non-GAAP Financial Measure

Adjusted Loss from Operations

(Amounts in Thousands)

	For the Three Months Ended		
	September 30,	**December 31,**	**Septeml 30,**
	2022	**2021**	**2021**

		(unaudited)		(unaudited)		(unaudit
GAAP loss from operations - as reported	**$**	**(9,221)**	**$**	**(35,680)**	**$**	**(13,6**
Stock-based compensation expense		3,181		1,706		1,8
Change in fair value of contingent consideration		(6,142)		25,006		1,1
Severance charge		1,046		255		
Depreciation and amortization expense		1,367		1,251		1,2
Non-GAAP loss from operations, as adjusted	**$**	**(9,769)**	**$**	**(7,462)**	**$**	**(9,3**

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Source: Oncocyte Corporation

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