Oncocyte Reports Third Quarter 2023 Financial Results

Nov 09, 2023

-Launching First Products in 1H 2024-

-Conference Call on Thursday, November 9, 2023 at 5:00 a.m. PT / 8:00 a.m. ET-

IRVINE, Calif., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Oncocyte Corporation (Nasdaq: OCX), a precision diagnostics company, today reported financial results for the third quarter of 2023, ended September 30, 2023.

Third Quarter and Recent Highlights

- VitaGraft™ Kidney, the Company's kidney transplant diagnostic test, received a positive coverage decision from CMS coverage; commercial revenue is expected beginning in 1H 2024.
- Significant new clinical data was presented at the European Society of Organ Transplant Conference demonstrating the VitaGraft assay detects antibody-mediated transplant rejection 10 months sooner than commonly used monitoring protocols ($p<0.001$).
- Cash burn declined to $3.6 million and is projected to remain below a $5 million quarterly average.
- $14.2 million in cash, cash equivalents, and marketable securities as of September 30, 2023.
- VitaGraft Liver, Oncocyte's second transplant test, continues under review for CMS coverage at MolDX.

Josh Riggs, CEO of Oncocyte, commented, "Oncocyte received a positive coverage decision from CMS during the third quarter for the Company's innovative VitaGraft Kidney. This is the test that was recently demonstrated to detect signs of transplant organ rejection a full 10 months earlier than standard of care methods. Going into next year we expect the startup of revenues from the VitaGraft Kidney test and our RUO product, GraftAssure."

"Financially, we reduced our cash burn to $3.6 million in the third quarter, the lowest level in several years and a reflection of the sharp reductions in non-revenue related activities that we instituted earlier in the year. Going forward, we expect to maintain this lower level of cash burn and remain below $5 million on a quarterly basis. With $14.2 million in cash, cash equivalents, and marketable securities, a declining cash burn, and multiple products nearing commercialization, we believe that Oncocyte is well positioned for growth in 2024 and the years beyond," concluded Mr. Riggs.

Third Quarter 2023 Financial Results

Consolidated revenue for the third quarter of 2023 was approximately $0.4 million primarily due to

increased revenue from Pharma Services. Cost of revenue was approximately $0.2 million.

Net consolidated operating loss for the three months ended September 30, 2023, was $6.5 million compared to a net consolidated operating loss of $1.7 million for the third quarter of 2022, which included a positive non-cash benefit of $6.1 million for change in fair value of contingent consideration.

Research and Development expense for the third quarter was $2.2 million compared to $1.5 million in the third quarter of 2022, an increase of 48%, driven by continued focused investment in developing manufacturable versions of assays including DetermaIO™, VitaGraft, and DetermaCNI™.

General and Administrative expense for the third quarter was $2.5 million compared to $5.7 million in the year ago period, a decrease of 56%, primarily due to decreased stock-based compensation and personnel expenses.

Sales and Marketing expense for the third quarter was $0.7 million compared to $0.4 million in the comparable period of 2022, an increase of 76%. The increase was driven by a continued ramp in sales, marketing and commercialization activities related to the recent coverage decision and expected upcoming launch of VitaGraft Kidney.

For Oncocyte's complete financial results for the third quarter ended September 30, 2023, see the Company's Quarterly Form 10-Q to be filed with the Securities and Exchange Commission on November 9, 2023.

Webcast and Conference Call Information

Oncocyte will host a conference call to discuss the third quarter 2023 financial results prior to market open on Thursday, November 9, 2023 at 5:00 a.m. Pacific Time / 8:00 a.m. Eastern Time. The live call may be accessed via telephone by dialing toll free (888) 550-5422 for both domestic and international callers. Once dialed in, ask to be joined to the Oncocyte Corporation call.

The live webinar of the call may be accessed by visiting the "Events & Presentation" section of the Company's website at https://investors.oncocyte.com.

About Oncocyte

Oncocyte is a precision diagnostics company. The Company's tests are designed to help provide clarity and confidence to physicians and their patients. DetermaIO™ is a gene expression test that assesses the tumor microenvironment in order to predict response to immunotherapies. VitaGraft™ is a blood-based solid organ transplantation monitoring test, and pipeline test DetermaCNI™ is a blood-based monitoring tool for monitoring therapeutic efficacy. For more information, visit www.oncocyte.com.

DetermaIO™, DetermaCNI™, 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 revenues and commercial launch of VitaGraft Kidney and GraftAssure in 2024, plans to maintain a cash burn of below $5 million on a quarterly basis, the belief that Oncocyte is well positioned for growth in 2024 and the years beyond, 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, changes to regulatory oversight and/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

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 13,783	$ 19,993
Accounts receivable, net of allowance for credit losses of	1,882	2,012

$178 and $154, respectively		
Marketable equity securities	441	433
Prepaid expenses and other current assets	672	977
Assets held for sale	139	-
Current assets of discontinuing operations	-	2,121
Total current assets	16,917	25,536
NONCURRENT ASSETS		
Right-of-use and financing lease assets, net	1,757	2,088
Machinery and equipment, net, and construction in progress	4,076	8,763
Intangible assets, net	56,617	61,633
Restricted cash	1,700	1,700
Other noncurrent assets	520	371
TOTAL ASSETS	$ 81,587	$ 100,091
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,136	$ 1,253
Accrued compensation	1,722	1,771
Accrued royalties	1,116	2,022
Accrued expenses and other current liabilities	826	1,817
Accrued severance from acquisition	2,314	2,314
Accrued liabilities from acquisition	109	109
Right-of-use and financing lease liabilities, current	720	815
Current liabilities of discontinuing operations	90	2,005

Total current liabilities	8,033	12,106
NONCURRENT LIABILITIES		
Right-of-use and financing lease liabilities, noncurrent	2,354	2,729
Contingent consideration liabilities	28,715	45,662
TOTAL LIABILITIES	39,102	60,497
Commitments and contingencies		
Series A Redeemable Convertible Preferred Stock, no par value; stated value $1,000 per share; 5 and 6 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively; aggregate liquidation preference of $5,217 and $6,091 as of September 30, 2023 and December 31, 2022, respectively	4,923	5,302
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; 8,261 and 5,932 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	309,995	294,929
Accumulated other comprehensive income	32	39
Accumulated deficit	(272,465)	(260,676)
Total shareholders' equity	37,562	34,292
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 81,587	$ 100,091

ONCOCYTE CORPORATION

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net revenue	$ 429	$ 67	$ 1,189	$ 684
Cost of revenues	159	314	593	602
Cost of revenues – amortization of acquired intangibles	22	22	66	73
Gross profit	248	(269)	530	9
Operating expenses:				
Research and development	2,185	1,472	6,747	5,923
Sales and marketing	713	405	2,213	798
General and administrative	2,487	5,702	9,430	16,794
Change in fair value of contingent consideration	(435)	(6,142)	(16,947)	(17,157)
Impairment losses	1,811	-	6,761	-
Loss on disposal and held for sale assets	-	-	1,283	-
Total operating expenses	6,761	1,437	9,487	6,358

Loss from operations	(6,513)	(1,706)	(8,957)	(6,349)
Other income (expenses):				
Interest income (expense), net	117	(14)	108	(65)
Unrealized (loss) gain on marketable equity securities	(89)	(160)	8	(485)
Other (expenses) income, net	(4)	62	(22)	304
Total other income (expenses)	24	(112)	94	(246)
Loss from continuing operations	(6,489)	(1,818)	(8,863)	(6,595)
Loss from discontinuing operations	-	(7,515)	(2,926)	(21,329)
Net loss	$ (6,489)	$ (9,333)	$ (11,789)	$ (27,924)
Less: dividends and accretion of Series A redeemable convertible preferred stock	(198)	(294)	(739)	(294)
Net loss attributable to common stockholders	$ (6,687)	$ (9,627)	$ (12,528)	$ (28,218)
Net loss from continuing operations per share: basic and diluted	$ (0.79)	$ (0.31)	$ (1.19)	$ (1.22)
Net loss from discontinuing operations per share: basic and diluted	$ -	$ (1.27)	$ (0.39)	$ (3.94)

Net loss attributable to common stockholders per share: basic and diluted	$ (0.81)	$ (1.62)	$ (1.68)	$ (5.22)
Weighted average shares outstanding: basic and diluted	8,256	5,931	7,446	5,408

Oncocyte Corporation

Reconciliation of Non-GAAP Financial Measure

Consolidated Adjusted Loss from Operations

Note: In addition to financial results determined in accordance with U.S. generally accepted accounting princ
(GAAP), this press release also includes a non-GAAP financial measure (as defined under SEC Regulation G). W
the adjusted amounts are more representative of our ongoing performance. The following is a reconciliation
GAAP measure to the most directly comparable GAAP measure:

	For the Three Months Ended		
	September 30, 2023	**June 30, 2023**	**S**
	(unaudited)	**(unaudited)**	
	(In thousands)		
Consolidated GAAP loss from operations	**$ (6,513)**	**$ (8,294)**	**$**
Stock-based compensation expense	608	834	

Change in fair value of contingent consideration		(435)		1,795
Severance charge		(7)		604
Depreciation and amortization expense		426		457
Impairment losses		1,811		-
Consolidated Non-GAAP loss from operations, as adjusted	**$**	**(4,110)**	**$**	**(4,604)**	**$**

Source: OncoCyte Corporation

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