

REDEFINING IMMUNO-ONCOLOGY

Genelux Corporation Reports Third Quarter 2024 Financial Results and Provides General Business Updates

November 14, 2024

WESTLAKE VILLAGE, Calif., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Genelux Corporation (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, today announced financial results for the third quarter of 2024 and provided general business updates.

The Company initiated its second lung cancer trial, a US-based, Phase 2 trial (VIRO-25) treating patients with recurrent advanced or metastatic non-small cell lung cancer (NSCLC) with Olvi-Vec, followed by platinum-doublet chemotherapy + immune checkpoint inhibitor. Additionally, a Phase 1b/2 lung cancer trial is ongoing in recurrent small cell lung cancer (SCLC) in China which is co-sponsored with Newsoara BioPharma Co., Ltd.

Both trials utilize Olvi-Vec delivered intravenously to treat patients who have previously failed platinum-based chemotherapy. The trials are designed based on earlier clinical results, including Olvi-Vec demonstrating (i) positive outcomes in patients with primary or metastatic lung cancer when delivered intravenously and (ii) clinical reversal of platinum resistance and refractoriness in a Phase 2 trial in platinum-resistant/refractory ovarian cancer (PRROC).

"Over the past quarter, we marked another important step forward in our efforts to advance the systemic delivery of Olvi-Vec and to demonstrate the re-sensitization to platinum-based chemotherapy in multiple tumor types," said Thomas Zindrick, President, CEO and Chairman of Genelux. "With interim data from our SCLC trial anticipated by the end of 2024 and data releases from our Phase 3 registration trial in PRROC and Phase 2 trial in NSCLC anticipated in 2025, we are confident that Genelux is positioned to make a meaningful impact in the lives of cancer patients."

Pipeline Highlights

The Company's clinical program is designed to position Olvi-Vec as an ideal backbone of combination cancer therapy due to its unique mechanism of action to modify the tumor immune microenvironment. Building on the promising results from our previous clinical trials, we see the potential of Olvi-Vec to induce platinum re-sensitization as a strategy to enhance patient response and extend survival in platinum-resistant populations. In addition, the VIRO-25 trial expands the program to include combination therapies with immune checkpoint inhibitors as we aim to unlock synergistic activity that amplify the immune response against tumors.

- Patient enrollment continues to progress in the Phase 3 OnPrime/GOG-3076 trial for PRROC, now active at over 25 sites (NCT05281471). Topline results are anticipated in the latter half of 2025.
- Phase 2 VIRO-25 is actively enrolling recurrent NSCLC patients (NCT06463665), with interim data expected by mid-2025.
- Interim results from the Phase 1b portion of a Phase 1b/2 SCLC trial projected by end of 2024.

Third Quarter 2024 Financial Results

Cash and cash equivalents, and short and long-term investments were \$35.1 million as of September 30, 2024. The Company expects its existing cash and cash equivalents, and short and long-term investments will provide runway into the first quarter of 2026.

Research and development (R&D) expenses \$4.1 million and \$2.8 million for the three months ended September 30, 2024 and 2023, respectively, an increase of \$1.2 million. Significant variations between periods are primarily a result of a \$0.4 million increase in stock-related compensation in 2024, relating to the increased cost of stock options and restricted stock units in 2024; and a \$0.9 million increase in clinical and regulatory expenses relating to increased clinical trial costs associated with our Phase 3 OnPrime Registration trial in 2024.

General and administrative (G&A) expenses were \$2.9 million and \$2.5 million for the three months ended September 30, 2024 and 2023, respectively, an increase of \$0.4 million. Significant variations between periods are primarily a result of a \$0.7 million increase in stock compensation expense in 2024, due to the increase in the cost of stock options and restricted stock units in 2024; offset by a \$0.3 million decrease in professional service expenses in 2024, primarily resulting from decreased corporate legal costs.

Net loss was \$6.5 million for the third quarter of 2024 or a net loss per share of \$0.19, as compared to net loss of \$5.3 million for the third quarter of 2023, or a net loss per share of \$0.20.

About Genelux Corporation

Genelux is a late-stage clinical biopharmaceutical company focused on developing a pipeline of next-generation oncolytic immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types. The Company's most advanced product candidate, Olvi-Vec (olvimulogene nanivacirepvec), is a proprietary, modified strain of the vaccinia virus. Olvi-Vec currently is being evaluated in OnPrime/GOG-3076, a multi-center, randomized, open-label Phase 3 registrational trial evaluating the efficacy and safety of Olvi-Vec in combination platinum-doublet + bevacizumab compared with physician's choice of chemotherapy and bevacizumab in patients with platinum-resistant/refractory ovarian cancer. The core of

Genelux's discovery and development efforts revolves around its' proprietary CHOICE™ platform from which the Company has developed an extensive library of isolated and engineered oncolytic vaccinia virus immunotherapeutic product candidates, including Olvi-Vec. For more information, please visit www.genelux.com and follow us on Twitter @Genelux Corp and on LinkedIn.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "believes," "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to Genelux's future plans and prospects, Genelux's anticipated cash runway and the sufficiency of its resources to support its planned operations, the planned timing of Genelux's data results in its ongoing clinical trials and continued development of Olvi-Vec, and the potential capabilities and advantages of Olvi-Vec. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements. These and other risks are identified under the caption "Risk Factors" in Genelux's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Genelux does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

Investor and Media Contacts

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Source: Genelux Corporation

Genelux Corporation Condensed Balance Sheets

(in thousands, except for share amounts and par value data)

	September 30,			December 31,		
		2024		2023		
ASSETS		(Unaud		dited)		
Current Assets						
Cash and cash equivalents	\$	6,102	\$	9,418		
Short-term investments		27,955		13,773		
Prepaid expenses and other current assets		1,910		1,012		
Total Current Assets		35,967		24,203		
Property and equipment, net		1,278		1,170		
Right of use assets		1,930		2,428		
Long-term investments		1,003		-		
Other assets		92		92		
Total Other Assets		4,303		3,690		
TOTAL ASSETS	\$	40,270	\$	27,893		
LIABILITIES AND SHAREHOLDERS' EQUITY						
Current Liabilities						
Accounts payable and accrued expenses	\$	4,454	\$	3,784		
Accrued payroll and payroll taxes		686		2,117		
Lease liabilities, current portion		415		653		
Total Current Liabilities		5,555		6,554		
Lease liabilities, long-term portion		1,624		1,866		
Total Liabilities		7,179		8,420		
Shareholders' Equity						
Preferred stock, par value \$0.001, 10,000,000 shares authorized;						
no shares issued and outstanding, respectively;		-		-		
Common stock, par value \$0.001, 200,000,000 shares authorized;						
34,538,185 and 26,788,986 shares issued and outstanding		35		27		
Treasury stock, 433,333 shares, at cost		(433)		(433)		

Additional paid-in capital Accumulated other comprehensive income	275,782 124	241,389 14
Accumulated deficit	(242,417)	(221,524)
Total Shareholders' Equity	33,091	19,473
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 40,270 \$	27,893

The accompanying notes are an integral part of these condensed financial statements.

Genelux Corporation Condensed Statements of Operations

(in thousands, except for share amounts and per share data)

	Three Months Ended			Nine Months Ended				
	September 30,		September 30,			30,		
		2024		2023		2024		2023
	(Unaudited)		(Unaudited)			d)		
Revenues	\$	-	\$		\$	8	\$	170
Operating expenses:								
Research and development		4,051		2,819		12,478		8,607
General and administrative		2,890		2,488		9,478		8,727
Total operating expenses		6,941		5,307		21,956		17,334
Loss from operations		(6,941)		(5,307)		(21,948)		(17,164)
Other income (expenses):								
Interest income		474		4		1,055		4
Interest expense		-		-		-		(167)
Debt discount amortization		-		-		-		(649)
Financing costs		-		(42)		-		(3,152)
Debt extinguishment costs				-				(402)
Total other income (expenses), net		474		(38)		1,055		(4,366)
NET LOSS	\$	(6,467)	\$	(5,345)	\$	(20,893)	\$	(21,530)
LOSS PER COMMON SHARE - BASIC AND DILUTED	\$	(0.19)	\$	(0.20)	\$	(0.69)	\$	(0.91)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING -								
BASIC AND DILUTED		34,532,355		26,210,068		30,405,615		23,640,995

The accompanying notes are an integral part of these condensed financial statements.

Genelux Corporation Condensed Statements of Comprehensive Loss

(in thousands)

Three Mor	ths Ended	Nine Months Ended	
Septen	September 30,		nber 30,
2024	2023	2024	2023
(Unau	(Unaudited) (Unaudited)		dited)

Net loss	\$ (6,467) \$	(5,345) \$	(20,893) \$	(21,530)
Other comprehensive loss:				
Net unrealized gain on short and long-term investments	 135	<u> </u>	110	-
Comprehensive loss	\$ (6,332) \$	(5,345) \$	(20,783) \$	(21,530)

The accompanying notes are an integral part of these condensed financial statements.



Source: Genelux Corporation