

REDEFINING IMMUNO-ONCOLOGY

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

August 14, 2024

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

"The past quarter has continued to be transformative for the company as we completed a key financing expected to provide runway through three trial readouts, including our ongoing Phase 3 trial in platinum resistant/refractory ovarian cancer," said Thomas Zindrick, President, Chairman and CEO of Genelux. "Beyond our pivotal Phase 3 trial, we look to provide interim data for systemic delivery of Olvi-Vec in both small and non-small cell lung cancer in the next 12 months."

The Company anticipates announcing interim results from the Phase 2 trial in recurrent non-small cell lung cancer by mid-2025, with interim data from our Phase 1b trial in recurrent small cell lung cancer expected later this year. Both trials involve the intravenous administration of Olvi-Vec and the re-challenging of patients who have previously failed platinum-based chemotherapy. These designs are based on a prior clinical trial that demonstrated the benefits of intravenously administered Olvi-Vec in patients with lung disease (either primary or metastatic), as well as on our Phase 2 data in platinum-resistant/refractory ovarian cancer (PRROC).

Pipeline Highlights

The ongoing Phase 3 OnPrime/GOG-3076 registrational trial in PRROC continues to enroll patients with over 23 sites activated (NCT05281471). The Company anticipates topline results in the second half of 2025.

The United States based Phase 2 trial in recurrent non-small cell lung cancer (NSCLC) is expected to report interim results in mid-2025. The Company anticipates an interim readout in the second half of 2024 for the Phase 1b part of the Phase 1b/2 trial in patients with recurrent small cell lung cancer in China. Both trials leverage Olvi-Vec via systemic administration, unlocking Olvi-Vec's potential to be the first Phase 3 systemic oncolytic vaccinia virus.

Business Updates

In May 2024, the Company completed an underwritten public offering of its common stock and accompanying warrants. The total gross proceeds of the offering were \$30.0 million USD and the Company raised \$27.7 million USD in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company. The net proceeds from the offering are expected to provide working capital into the first quarter of 2026 for general corporate purposes, including the continued clinical development of Olvi-Vec.

Second Quarter 2024 Financial Results

Cash, cash equivalents, short and long-term investments were \$40.4 million as of June 30, 2024. The Company expects its existing cash, cash equivalents, short and long-term investments will provide runway into the first quarter of 2026.

Research and development (R&D) expenses were \$4.4 million for the second quarter of 2024, as compared to \$2.9 million for the second quarter 2023, respectively. The \$1.5 million year-over-year increase in R&D expenses in 2024 was primarily due to a \$0.7 million increase in clinical and regulatory expenses associated with the Company's Phase 3 On Prime registration trial, a \$0.4 million increase in outsourced manufacturing services, a \$0.3 million increase in employee compensation and related expenses in 2024 and a \$0.3 million increase in stock-related compensation in 2024 offset by decreases in other R&D expenses of \$0.2 million.

General and administrative (G&A) expenses were flat year-over year at \$2.5 million in the second quarter of 2024 and 2023. A year-over-year increase of \$0.4 million in stock compensation in 2024 was offset by a decrease of \$0.5 million in professional service expenses, primarily from a decrease in corporate legal costs in 2024.

Net loss was \$6.6 million for the second quarter of 2024 or a net loss per share of \$0.22, as compared to net loss of \$5.8 million for the second quarter of 2023, or a net loss per share of \$0.23.

About Genelux Corporation

Genelux is a late clinical-stage 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 CHOICETM 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)

	June 30,		December 31,		
		2023			
ASSETS	(U				
Current Assets					
Cash and cash equivalents	\$	7,858 \$	9,418		
Short-term investments		25,778	13,773		
Prepaid expenses and other current assets		1,234	1,012		
Total Current Assets		34,870	24,203		
Property and equipment, net		1,306	1,170		
Right of use assets		2,098	2,428		
Long-term investments		6,813			
Other assets		92	92		
Total Other Assets		10,309	3,690		
TOTAL ASSETS	\$	45,179 \$	27,893		
LIABILITIES AND SHAREHOLDERS' EQUITY					
Current Liabilities					
Accounts payable and accrued expenses	\$	4,786 \$	3,784		
Accrued payroll and payroll taxes		517	2,117		
Lease liabilities, current portion		500	653		
Total Current Liabilities		5,803	6,554		
Lease liabilities, long-term portion		1,707	1,866		
Total Liabilities		7,510	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;					
34,512,642 and 26,788,986 shares issued and outstanding, respectively		35	27		
Treasury stock, 433,333 shares, at cost		(433)	(433		
Additional paid-in capital		274,028	241,389		
Accumulated other comprehensive income (loss)		(11)	14		
Accumulated deficit		(235,950)	(221,524		

Total Shareholders' Equity	 37,669	19,473
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 45,179 \$	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 June 30,			Six Months Ended June 30,		
		2024	2023		2024	2023
		(Unaudited			(Unaudited	
Revenues	\$	- \$		\$	8 \$	170
Operating expenses:						
Research and development		4,417	2,943		8,427	5,788
General and administrative		2,475	2,452		6,588	6,239
Total operating expenses		6,892	5,395		15,015	12,027
Loss from operations		(6,892)	(5,395)		(15,007)	(11,857)
Other income (expenses):						
Interest income		316	-		581	-
Interest expense		-	(24)		-	(167)
Debt discount amortization		-	-		-	(649)
Financing costs		-	-		-	(3,110)
Debt extinguishment costs			(402)			(402)
Total other income (expenses), net		316	(426)		581	(4,328)
NET LOSS	\$	(6,576) \$	(5,821)	\$	(14,426) \$	(16,185)
LOSS PER COMMON SHARE - BASIC AND DILUTED	\$	(0.22) \$	(0.23)	\$	(0.51) \$	(0.72)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED	∂ -	29,689,344	25,068,334		28,308,046	22,334,311

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

Genelux Corporation Condensed Statements of Comprehensive Loss

(in thousands)

	Three Months Ended June 30,			Six Months Ended June 30,			
		2024	2023		2024	2023	
	(Unaudited)				(Unaudited)		
Net loss	\$	(6,576) \$	(5,821)	\$	(14,426) \$	(16,185)	
Other comprehensive loss: Net unrealized loss on short and long-term investments		(6)	<u>-</u>		(25)	_	
Comprehensive loss	\$	(6,582) \$	(5,821)	\$	(14,451) \$	(16,185)	

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



Source: Genelux Corporation