



REDEFINING IMMUNO-ONCOLOGY

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

May 9, 2024

WESTLAKE VILLAGE, Calif., May 09, 2024 (GLOBE NEWSWIRE) -- [Genelux Corporation](#) (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, today announced financial results for the first quarter of 2024 and provided general business updates.

“Our pivotal Phase 3 registration trial of Olvi-Vec in platinum resistant/refractory ovarian cancer continues to enroll patients,” said [Thomas Zindrick](#), President, Chairman and CEO of Genelux. “Looking ahead, we are excited about advancing Olvi-Vec into additional cancer indications through intravenous administration, a physician-preferred route of delivery, and seeking to further validate our hypothesis that Olvi-Vec may reverse resistance to platinum in multiple tumor types.”

The Company expects to initiate our Phase 2 trial in recurrent non-small cell lung cancer in the second quarter of this year and to report interim data of our Phase 1b trial in recurrent small cell lung cancer later this year. Both trials are designed to intravenously administer Olvi-Vec and to re-challenge patients who previously failed platinum-based chemotherapy. The designs build on a previous clinical trial showing the benefit of intravenously administered Olvi-Vec in patients with lung disease (primary or metastatic) and on our Phase 2 data in platinum resistant/refractory ovarian cancer (PRROC).

Pipeline Highlights

We are actively enrolling patients in ongoing Phase 3 OnPrime/GOG-3076 registrational trial in PRROC in the United States. Currently, 22 sites have been activated to enroll patients with additional sites identified and in various stages of activation ([NCT05281471](#)). We are on track for topline results in the second half of 2025.

Patient enrollment has been increasing in the ongoing Phase 1b part of the Phase 1b/2 trial testing systemic administration of Olvi-Vec in patients with recurrent small cell lung cancer. The trial is co-sponsored with our partner Newsoara BioPharma Co., Ltd. and is being conducted at pre-eminent sites in China. We anticipate interim readout in the second half of 2024.

Initiation of the Phase 2 trial in the United States testing systemic administration of Olvi-Vec in recurrent non-small cell lung cancer trial is anticipated to begin in the first half of 2024.

Business Updates

In the first quarter of 2024, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission. Under the shelf registration statement, we may offer and sell, from time to time, up to \$300.0 million in common stock, preferred stock, debt securities and/or warrants in one or more offerings. Concurrent with the shelf registration statement, the Company entered into a sales agreement under which the Company may offer to sell shares of our common stock up to \$100.0 million through Guggenheim Securities, acting as our sales agent.

First Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments were \$19.6 million as of March 31, 2024. We expect our existing cash, cash equivalents, and short-term investments will provide runway into the second quarter of 2025.

Research and development (R&D) expenses were \$4.0 million for the first quarter of 2024, as compared to \$2.8 million for the first quarter 2023, respectively. The \$1.2 million year-over-year increase in R&D expenses in 2024 was primarily due to a \$0.4 million increase related to new employee hires after the first quarter of 2023, a \$0.3 million increase in stock compensation and a \$0.4 million increase related to clinical manufacturing, regulatory and other R&D expenses.

General and administrative (G&A) expenses were \$4.1 million in the first quarter of 2024, as compared to \$3.8 million for the first quarter of 2023. The \$0.3 million year-over-year increase in G&A expenses in 2024 was primarily the result of a \$0.4 million increase in professional service expenses in 2024, primarily due to costs associated with our shelf registration on Form S-3 and a \$0.5 million increase due to consulting expenses, employee related costs and other G&A expenses, offset by a \$0.6 million decrease in stock compensation expense in the first quarter of 2024 compared to the first quarter of 2023.

Net loss was \$7.9 million for the first quarter of 2024 or a net loss per share of \$0.29, as compared to net loss of \$10.4 million for the first quarter of 2023, or a net loss per share of \$0.53.

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 with platinum-doublet + bevacizumab compared to 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](https://twitter.com/Genelux_Corp) and on [LinkedIn](https://www.linkedin.com/company/genelux).

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 the Genelux's data results in its ongoing clinical trials and continued development of Olvi-Vec, the planned initiation of the Phase 2 non-small cell lung cancer trial and the timing thereof; 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)

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 4,061	\$ 9,418
Short-term investments	15,566	13,773
Prepaid expenses and other current assets	1,577	1,012
Total Current Assets	21,204	24,203
Property and equipment, net	1,116	1,170
Right of use assets	2,264	2,428
Other assets	92	92
Total Other Assets	3,472	3,690
TOTAL ASSETS	\$ 24,676	\$ 27,893
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued expenses	\$ 5,313	\$ 3,784
Accrued payroll and payroll taxes	1,908	2,117
Lease liabilities, current portion	584	653
Total Current Liabilities	7,805	6,554
Lease liabilities, long-term portion	1,787	1,866
Total Liabilities	9,592	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; 26,996,740 and 26,788,986 shares issued and outstanding, respectively	27	27
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	244,869	241,389

Accumulated other comprehensive income (loss)	(5)	14
Accumulated deficit	(229,374)	(221,524)
Total Shareholders' Equity	<u>15,084</u>	<u>19,473</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 24,676	\$ 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	
	March 31,	
	2024	2023
	(Unaudited)	
Revenues	\$ 8	\$ 170
Operating expenses:		
Research and development	4,010	2,845
General and administrative	4,113	3,787
Total operating expenses	<u>8,123</u>	<u>6,632</u>
Loss from operations	<u>(8,115)</u>	<u>(6,462)</u>
Other income (expenses):		
Interest income	265	-
Interest expense	-	(143)
Debt discount amortization	-	(649)
Financing costs	-	(3,110)
Total other income (expenses), net	<u>265</u>	<u>(3,902)</u>
NET LOSS	\$ (7,850)	\$ (10,364)
LOSS PER COMMON SHARE - BASIC AND DILUTED	\$ (0.29)	\$ (0.53)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING - BASIC AND DILUTED	26,849,737	19,575,631

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

Genelux Corporation
Condensed Statements of Comprehensive Loss
(in thousands)

	Three Months Ended	
	March 31,	
	2024	2023
	(Unaudited)	
Net loss	\$ (7,850)	\$ (10,364)
Other comprehensive loss:		
Net unrealized loss on short-term investments	(19)	-
Comprehensive loss	<u>\$ (7,869)</u>	<u>\$ (10,364)</u>

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



Source: Genelux Corporation