



REDEFINING IMMUNO-ONCOLOGY

Genelux Corporation Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

April 1, 2024

- Continued active enrollment of Olvi-Vec in our pivotal Phase 3 OnPrime/GOG-3076 trial in platinum resistant/refractory ovarian cancer with topline results anticipated in 2H 2025 –
- Initiation of Phase 2 trial in non-small cell lung cancer (recurrent/platinum-ICI failure) with systemic administration of Olvi-Vec expected in 1H 2024 –
 - Ongoing Phase 1b/2 trial with systemic administration of Olvi-Vec in small cell lung cancer expected interim readout in 2H 2024 –
 - \$23.2 million in cash, cash equivalents and short-term investments –

WESTLAKE VILLAGE, Calif., April 01, 2024 (GLOBE NEWSWIRE) -- [Genelux Corporation](#) (NASDAQ: GNLX), a late clinical-stage immuno-oncology company, reported fourth quarter and full year 2023 financial results and business updates.

"Last year was highlighted by the ongoing advancement of our clinical pipeline focused on platinum re-sensitization, including our pivotal Phase 3 trial in platinum resistant/refractory ovarian cancer and development of our two systemic administration trials in lung cancer," said [Thomas Zindrick](#), President, Chairman and CEO of Genelux. "Looking ahead, we anticipate the culmination of these trials not only holds promise for enhancing the therapeutic landscape but also underscores our dedication to advancing scientific understanding and offering new hope to patients grappling with the complexities of various cancers."

Pipeline Updates

- Actively enrolling patients in ongoing Phase 3 OnPrime/GOG-3076 registrational trial in platinum resistant/refractory ovarian cancer (PRROC) in the United States. Currently, 21 sites have been activated to enroll patients with additional sites identified and in various stages of activation ([NCT05281471](#)). On track for topline results in 2H 2025. FDA Fast Track designation previously granted by the FDA.
- Patient enrollment has been increasing in the ongoing Phase 1b part of the Phase 1b/2 trial in patients with recurrent small cell lung cancer. Building on data from early clinical trials, Olvi-Vec is being systemically administered, a physician-preferred route of delivery. Genelux and our partner Newsoara co-sponsor the trial, which is being conducted by Newsoara in greater China. The lead investigator is renowned clinician Professor Shun Lu, M.D., Ph.D. of the prestigious Shanghai Chest Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai China. Interim readout anticipated in 2H 2024.
- Initiation of the Phase 2 non-small cell lung cancer trial is anticipated to begin in the 1H 2024. Patients will receive Olvi-Vec through systemic administration.

Business Updates

- The Company filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC). Under the shelf registration statement, Genelux 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, 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 agent.
- In 2023, the Company grew the core management team to further bolster the development of Olvi-Vec.
- As Genelux's clinical trial program progresses and diversifies, the company intends to expand its preliminary commercial strategy initiatives and support corporate development efforts.

Fourth Quarter 2023 and Yearly Financial Results

Cash, cash equivalents and short-term investments were \$23.2 million as of December 31, 2023 compared to \$0.4 million on December 31, 2022. During the 12 months ended December 31, 2023, the Company closed its initial public offering (IPO) and two private placements and received \$37.8 million of net proceeds from the offerings. The Company expects its cash, cash equivalents and short-term investments as of December 31, 2023 will provide runway into 2Q 2025.

Research and development (R&D) expenses were approximately \$4.2 million and \$2.5 million for the three months ended December 31, 2023 and 2022, respectively. R&D expenses were \$12.8 million compared to \$9.1 million for the years ended December 31, 2023 and 2022, respectively. The

year-over-year increase in R&D expenses in 2023 was primarily due to new employee hires, stock compensation, clinical manufacturing, and regulatory increases related to our On-Prime Phase 3 clinical trial in PRROC patients.

General and administrative (G&A) expenses were approximately \$2.8 million and \$0.7 million for the three months ended December 31, 2023 and 2022, respectively. G&A expenses were \$11.6 million and \$5.0 million for the years ended December 31, 2023 and 2022, respectively. The year-over-year increases were primarily due to additional employee-related costs, including new employee hires, stock compensation expenses and an increase in professional service expenses related to being a newly publicly traded company.

Net loss was approximately \$6.8 million, or \$0.25 per basic and diluted share for the three months ended December 31, 2023, compared to a net loss of \$3.5 million or \$0.38 per basic and diluted share for the same period in 2022. Net loss was approximately \$28.3 million, or \$1.16 per basic and diluted share for the year ended December 31, 2023, compared to \$5.2 million or \$0.57 per basic and diluted share for the same period in 2022.

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 (olimvulogene 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 platinum-doublet + bevacizumab in patients with platinum-resistant/refractory ovarian cancer. The core of Genelux' discovery and development efforts revolves around the company's 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 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

Ankit Bhargava, MD
Allele Communications, LLC
genelux@allelecomms.com

Source: Genelux Corporation

Genelux Corporation

Balance Sheets

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

	December 31,	
	2023	2022
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 9,418	\$ 397
Short-term investments	13,773	-
Prepaid expenses and other current assets	1,012	1,495
Total Current Assets	24,203	1,892
Property and equipment, net	1,170	644
Right of use assets	2,428	1,335
Deferred offering costs	-	1,568
Other assets	92	92
Total Other Assets	3,690	3,639
TOTAL ASSETS	\$ 27,893	\$ 5,531

LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)

Current Liabilities

Accounts payable and accrued expenses	\$ 3,784	\$ 6,775
Accrued payroll and payroll taxes	2,117	2,852
Accrued interest payable	-	1,178
Accrued interest payable - director and shareholders	-	3,817
Deferred revenue	-	170
Warrant liabilities	-	169
Lease liability, current portion	653	266
Notes payable - shareholders, net of debt discount of \$108 in 2022	-	992
Convertible notes payable - shareholders, current portion	-	15,407
Total Current Liabilities	6,554	31,626
Long-term Liabilities		
Lease liability, long-term portion	1,866	1,164
Convertible notes payable, net of debt discount of \$541 in 2022	-	8,524
Total Long-term Liabilities	1,866	9,688
Total Liabilities	8,420	41,314
Shareholders' Equity (Deficit)		
Preferred stock, Series A through K, par value \$0.001, 10,000,000 shares authorized as of 12/31/2023 and 29,927,994 authorized as of 12/31/2022; no shares and 22,094,889 shares issued and outstanding, respectively;	-	22
Common stock, par value \$0.001, 200,000,000 shares authorized; 26,788,986 and 9,126,726 shares issued and outstanding, respectively	27	9
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	241,389	154,401
Accumulated other comprehensive income	14	2
Accumulated deficit	(221,524)	(189,784)
Total Shareholders' Equity (Deficit)	19,473	(35,783)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)	\$ 27,893	\$ 5,531

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

Genelux Corporation
Statements of Operations
(in thousands, except for share amounts and per share data)

	Years Ended December 31,	
	2023	2022
Revenues	\$ 170	\$ 11,068
Operating expenses:		
Research and development	12,767	9,078
General and administrative	11,568	5,003
Total operating expenses	24,335	14,081
Loss from operations	(24,165)	(3,013)
Other income (expenses):		
Interest income	244	-
Interest expense	(173)	(1,150)
Debt discount amortization	(649)	(258)
Financing costs	(3,152)	-
Debt extinguishment costs	(402)	-

Gain on forgiveness of PPP loan payable	-	314
Total other income (expenses), net	(4,132)	(1,094)
Loss before provision for foreign income taxes	(28,297)	(4,107)
Provision for foreign income taxes	-	(1,100)
NET LOSS	\$ (28,297)	\$ (5,207)
LOSS PER COMMON SHARE - BASIC AND DILUTED	\$ (1.16)	\$ (0.57)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING - BASIC AND DILUTED	24,429,278	9,116,489

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

Genelux Corporation
Statements of Comprehensive Loss
(in thousands)

	Years Ended December 31,	
	2023	2022
Net loss	\$ (28,297)	\$ (5,207)
Other comprehensive loss:		
Net unrealized gain on short-term investments	12	-
Comprehensive loss	\$ (28,285)	\$ (5,207)

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



Source: Genelux Corporation