enGene Reports Full Year 2024 Financial Results and Provides a Business Update

BLA filing for detalimogene in BCG-unresponsive NMIBC with CIS on track for mid-2026

All cohorts of the Phase 2 LEGEND study now recruiting under updated protocol

Additional preliminary data from pivotal cohort anticipated in 2H 2025

Cash, cash equivalents and marketable securities of $297.9 million provide runway into 2027

BOSTON & MONTREAL - enGene Holdings Inc. (Nasdaq: ENGN, or "enGene" or the "Company"), a clinical-stage genetic medicines company whose non-viral lead investigational product detalimogene voraplasmid, (also known as detalimogene, and previously EG-70), is in an ongoing pivotal study in patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), announced its financial results for the full year ended October 31, 2024 and provided a business update.

"Having demonstrated a 71% anytime complete response rate in the preliminary data from the LEGEND study's pivotal cohort of BCG-unresponsive NMIBC patients, initiated three additional NMIBC patient cohorts, and raised an additional $60 million in funding, enGene is in a strong clinical and financial position as we close the year," said Ron Cooper, Chief Executive Officer of enGene. "With trial recruitment open across all cohorts, the profile of detalimogene continues to become clearer and stronger and, with the protocol enhancements now in place, we look forward to sharing LEGEND study updates across all cohorts expected in the second half of 2025."

Recent Strategic Corporate Updates

Release of preliminary data from LEGEND's pivotal cohort: In September 2024, the Company announced preliminary data from 21 patients assessed at three months, including 17 patients who were also assessed at six months, in the ongoing pivotal cohort of the LEGEND study. The Complete Response (CR) rate at any time was 71%, the CR rate at three months was 67% and the CR rate at six months was 47%. Detalimogene was generally well-tolerated by patients and no patients discontinued due to treatment-related adverse events.

LEGEND study protocol amendment: In addition to reporting preliminary clinical data from LEGEND's pivotal cohort, the Company has implemented protocol changes that affect how disease is managed throughout the trial as well as the criteria for study discontinuation. The Company believes the revised LEGEND protocol better aligns with current treatment standards and real-world practice.

LEGEND study now enrolling across all four cohorts: enGene initiated recruitment across three additional cohorts of NMIBC patients, including Cohort 2a and 2b (i.e., NMIBC patients with CIS who are naïve to treatment with BCG and NMIBC patients with CIS who have been exposed to BCG, but have not received adequate BCG treatment), and Cohort 3 (BCG-unresponsive high-risk NMIBC patients with papillary-only disease).

LEGEND study now includes maintenance dosing: The above-mentioned amendment to the LEGEND protocol also allows patients from any cohort who are in complete response at 12 months to continue receiving detalimogene on a dose-reduced maintenance schedule throughout their second year of treatment. At the end of year two, patients may optionally elect to remain on maintenance therapy for another year, for a total of three years of therapy. Maintenance treatment will consist of two instillations of detalimogene per three-month cycle, administered at week 1 and at week 2 of each cycle. The Company believes this could provide further evidence of the long-term benefit of detalimogene, with the dose-reduced maintenance regimen lessening the burden of frequent urology visits for instillations.

Inclusion in the Society of Urologic Oncology's Clinical Trial Consortium (SUO CTC): The LEGEND study was

selected for inclusion in the SUO-CTC, a U.S. and Canadian-based organization with over 250 trial sites dedicated to the successful enrollment and conduct of clinical trials for their patients with urologic cancers.

Key executive hires and management appointments: In October 2024, the Company announced the appointment of Joan Connolly, a seasoned technical operations leader with more than 30 years' experience, as Chief Technology Officer (CTO) and member of the corporate leadership team. enGene Co-Founder and former CTO, Anthony Cheung, Ph.D., transitioned to the role of Chief Scientific Officer, while Alex Nichols, Ph.D., previously the Chief Operating Officer, was appointed Chief Strategy and Operations Officer.

Fourth Quarter 2024 Financial Results

As of October 31, 2024, cash, cash equivalents and marketable securities were $297.9 million. The Company expects that its existing cash and cash equivalents will fund operating expenses, debt obligations and capital expenditures into 2027.

Full Year Financial Results ended October 31, 2024

Total operating expenses were $62.3 million for the full year ended October 31, 2024, compared to $26.1 million for 2023. Research and development expenses increased by $21.9 million, mainly due to increasing manufacturing and clinical costs related to our LEGEND study and headcount costs. General and administrative expenses increased by $14.4 million, primarily driven by headcount costs and professional fees and other expenses as the Company scales its general and administrative function to support the operation of a public company.

For the full year ended October 31, 2024, net loss attributable to common shareholders was approximately $55.1 million, or $1.46 per share, compared to approximately $104.7 million, or $151.22 per share, for the full year 2023. The decrease in net loss is mainly attributed to other expenses incurred in 2023 related to convertible debentures and warrants, partially offset by the increase in operating expenses during 2024.

About enGene

enGene is a clinical-stage biotechnology company mainstreaming genetic medicines through the delivery of therapeutics to mucosal tissues and other organs, with the goal of creating new ways to address diseases with high clinical needs. enGene's lead program is detalimogene voraplasmid (also known as detalimogene, and previously EG-70) for patients with Non-Muscle Invasive Bladder Cancer (NMIBC) - a disease with a high clinical burden. Detalimogene is being evaluated in the ongoing multi-cohort LEGEND Phase 2 study, which includes a registrational cohort studying detalimogene in Bacillus Calmette-Guérin (BCG)-unresponsive patients with carcinoma in situ (CIS). Detalimogene was developed using enGene's proprietary Dually Derivatized Oligochitosan (DDX) platform, which enables penetration of mucosal tissues and delivery of a wide range of sizes and types of cargo, including DNA and various forms of RNA. For more information, visit enGene.com.

Forward-Looking Statements

Certain statements contained in this press release may constitute "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, and "forward-looking information" within the meaning of Canadian securities laws (collectively, "forward-looking statements"). enGene's forward-looking statements include, but are not limited to, statements regarding enGene's management teams' expectations, hopes, beliefs, intentions, goals or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate", "appear", "approximate", "believe", "continue", "could", "estimate", "expect", "foresee", "intends", "may", "might", "plan", "possible", "potential", "predict", "project", "seek", "should", "would", and similar expressions (or the negative version of such words or expressions) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements may include, for example, statements about: the timing and anticipated results of our current and future clinical trials, including preliminary results, beliefs as to the timing and anticipated results of the LEGEND study,

including the timing of preliminary data or other updates, the timing of our planned BLA submission to the Food and Drug Administration, the anticipated uses of our cash and cash equivalents, the potential benefits of detalimogene, and the expected period over which we estimate our cash and cash equivalents will be sufficient to fund our current operating plan .

Many factors, risks, uncertainties and assumptions could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, the Company's ability to recruit and retain qualified scientific and management personnel, establish clinical trial sites and enroll patients in its clinical trials, execute on the Company's clinical development plans and ability to secure regulatory approval on anticipated timelines, and other risks and uncertainties detailed in filings with Canadian securities regulators on SEDAR+ and with the U.S. Securities and Exchange Commission ("SEC") on EDGAR, including those described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2024 (copies of which may be obtained at www.sedarplus.ca or www.sec.gov).

You should not place undue reliance on any forward-looking statements, which speak only as of the date on which they are made. enGene anticipates that subsequent events and developments will cause enGene's assessments to change. While enGene may elect to update these forward-looking statements at some point in the future, enGene specifically disclaims any obligation to do so, unless required by applicable law. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved.

enGene Holdings Inc.
Condensed Consolidated Statements of Operations Information
(unaudited)
(Amounts in thousands of USD, except share and per share data)

	Year Ended October 31,	
	2024	2023
Operating expenses:		
Research and development	$ 38,315	$ 16,458
General and administrative	23,982	9,602
Total operating expenses	62,297	26,060
Loss from operations	62,297	26,060
Total other (income) expense, net	(7,136)	73,840
Net loss before provision for income tax	55,161	99,900
Provision for (benefit from) income taxes	(19)	17
Net loss	$ 55,142	$ 99,917
Deemed dividend attributable to redeemable convertible preferred shareholders	-	4,822
Net loss attributable to common shareholders, basic and diluted	55,142	104,739
Weighted-average common shares outstanding, basic and diluted	37,782,346	692,609
Net loss per share of common shares, basic and diluted	$ 1.46	$ 151.22

enGene Holdings Inc.
Condensed Consolidated Balance Sheet Information
(unaudited)
(Amounts in thousands of USD)

	October 31, 2024	**October 31, 2023**
Cash and cash equivalents	$ 173,004	$ 81,521
Total assets	311,173	86,959
Total liabilities	38,561	14,473
Total shareholders' equity	272,612	72,486

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