enGene Reports Second Quarter 2024 Financial Results and Provides a Business Update

Company announces plans for initial indication expansion for EG-70 into high-risk papillary-only NMIBC

BOSTON & MONTREAL - enGene Holdings Inc. (Nasdaq: ENGN, "enGene" or the "Company"), a clinical-stage genetic medicines company whose non-viral, intravesical lead product candidate, EG-70, is in a pivotal study for BCG-unresponsive high-risk non-muscle invasive bladder cancer (NMIBC), today announced its financial results for the second quarter ended April 30, 2024, and provided a business update.

"Our $200 million private placement in February positioned us well to execute our primary strategy of broadly developing EG-70 to be a patient- and practice-friendly option across a multitude of potential bladder cancer indications. Correspondingly, our planned initial expansion of the LEGEND study will include a cohort focused on enrollment of patients with high-risk, BCG-unresponsive papillary-only NMIBC, a disease with persistent unmet need for which EG-70 may be well-suited," said Jason Hanson, Chief Executive Officer of enGene. "Furthermore, we plan to provide the interim data for the LEGEND BCG-unresponsive cohort by the end of September 2024. We believe the design of EG-70, with its ease-of-use and non-viral profile, positions it well to seamlessly slot into the standard of care, with the goal of becoming a practice-changing product that does not require a change in practice for urologists."

Anticipated Milestones and Strategic Corporate Updates

Release of interim data from LEGEND Cohort 1: The Company expects to release interim data from the LEGEND study's BCG-unresponsive cohort by the end of September, comprised of responses from approximately 20 patients focused on the three- and six-month time points. Study enrollment remains ongoing, and based on current projections, enGene expects to file a Biologics License Application (BLA) for EG-70 in mid-2026.

Commitment to expanding the clinical development of EG-70 within the bladder: Building on the design of EG-70 to have category-leading ease of use, scalable manufacturing process, and low cost-of-goods, the Company plans to explore additional applications of EG-70 within the bladder by expanding the LEGEND study to include a third cohort targeting high-risk BCG-unresponsive papillary-only NMIBC patients and modifying the second cohort (previously, the BCG-naïve cohort) to include BCG-exposed patients. Collectively, these potential indications represent an expansion into several areas of persistent unmet medical need with substantial patient populations. These clinical development plans include:

- **Papillary-only LEGEND expansion:** The Company plans to expand LEGEND to enroll a third cohort of patients with BCG-unresponsive, papillary-only Ta/T1 disease. This cohort, whose target enrollment is 70-100 patients, is estimated to begin enrollment in the fourth quarter of 2024.
- **Modification of the second cohort of LEGEND study to separately analyze responses between BCG-naïve patients and BCG-exposed patients:** In anticipation of this planned cohort modification and expected corresponding engagement with FDA, enrollment has been temporarily paused in this second cohort, with enrollment in both groups expected to resume in the fourth quarter of 2024.

As a result of the prioritization of these potential new indications in bladder cancer, the Company has deprioritized pre-clinical development of EG-i08 for cystic fibrosis and has paused further activities on that program.

Key leadership hires and board additions: In May 2024, enGene announced the election of Paul Hastings and Wouter Joustra as new members of its Board of Directors at the Company's 2024 annual meeting of shareholders. Lota Zoth was also re-elected to the Board. Each will serve a three-year term expiring at the 2027 annual meeting of shareholders. enGene's Board is comprised of seven members including Richard Glickman (Chairman), Gerald Brunk,

Jasper Bos, and enGene CEO, Jason Hanson.

In April 2024, the Company announced that Raj Pruthi MD MHA FACS joined the Company as SVP, Urologic Oncology and Clinical Development. Dr. Pruthi joined enGene from Johnson & Johnson Innovative Medicine, where he was most recently the Global Medical Affairs Leader, Bladder Cancer and Senior Medical Director, Oncology (Global - Prostate and Bladder Cancer).

Second Quarter 2024 Financial Results

Cash and cash equivalents, as of April 30, 2024, were $264.8 million. The Company expects that its existing cash and cash equivalents will fund operating expenses, debt obligations and capital expenditures into 2027.

Three Months ended April 30, 2024

Total operating expenses were $17.3 million for the three months ended April 30, 2024, compared to $4.7 million for the three months ended April 30, 2023. Research and development expenses increased by $6.6 million, mainly due to increasing manufacturing and clinical costs related to our pivotal EG-70 study. General and administrative expenses increased by $5.9 million, primarily driven by headcount costs and professional fees such as legal, accounting and audit as the Company scales its general and administrative function to support the operation of a public company.

For the three months ended April 30, 2024, net loss attributable to common shareholders was approximately $15.0 million, or $0.38 per share, compared to approximately $6.5 million, or $9.30 per share, for the same period for the three months ended April 30, 2023. The increase in net loss is mainly attributed to the increase in operating expenses partially offset by net interest income earned during the period.

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 EG-70 for patients with non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (Cis) who are unresponsive or naïve to treatment with Bacillus Calmette-Guérin (BCG) - a disease with a high clinical burden. EG-70 is being evaluated in an ongoing Phase 2 pivotal study. EG-70 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. enGene became a publicly traded company effective November 1, 2023, upon the completion of a business combination with Forbion European Acquisition Corporation, a special purpose acquisition company. 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", "intend", "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 interim results, plans regarding the composition of any interim clinical trial data presentations, beliefs as to the potential benefits of EG-70, expectations regarding the potential submission of a BLA for EG-70, plans regarding expansion and modification of LEGEND for potential additional bladder cancer indications for EG-70 and expectations regarding enrollment of patients, and the expected period over which enGene estimates its cash and cash equivalents

will be sufficient to fund its 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" sections of the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2023, our Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2024 and our Quarterly Report on Form 10-Q for the fiscal quarter ended April 30, 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)

	Three months ended April 30,		Six months ended April 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$9,855	$3,215	$15,493	$6,886
General and administrative	7,455	1,522	12,590	2,484
Total operating expenses	17,310	4,737	28,083	9,370
Loss from operations	17,310	4,737	28,083	9,370
Total other (income) expense, net	(2,347)	545	(2,379)	3,330
Net loss before provision for income tax	14,963	5,282	25,704	12,700
Provision for (benefit from) income taxes	21	-	(9)	-
Net loss	$14,984	$5,282	$25,695	$12,700
Deemed dividend attributable to redeemable convertible preferred shareholders	-	1,175	-	2,389
Net loss attributable to common shareholders, basic and diluted	14,984	6,457	25,695	15,089
Weighted-average common shares outstanding, basic and diluted	39,443,768	694,497	31,186,238	680,003
Net loss per share of common shares, basic and diluted	$0.38	$9.30	$0.82	$22.19

enGene Holdings Inc.

Condensed Consolidated Balance Sheet Information

(unaudited)

(Amounts in thousands of USD)

	April 30, 2024	October 31, 2023
Cash and cash equivalents	$264,810	$81,521
Total assets	273,528	86,959
Total liabilities	30,562	14,473
Total shareholders' equity (deficit)	242,966	72,486

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