enGene Reports First Quarter 2024 Financial Results and Recent Corporate Progress

Pivotal phase 2 LEGEND study of EG-70 in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) remains on track with interim data anticipated in mid-2024

Closed a $200 million oversubscribed private financing, expected to extend cash runway into 2027

BOSTON and MONTREAL, March 11, 2024 /CNW/ - enGene Holdings Inc. (Nasdaq: ENGN or "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 non-muscle invasive bladder cancer (NMIBC), today announced its financial results for the first quarter ended January 31, 2024.

"This is an exciting time for the Company as we move closer to realizing our vision of mainstreaming genetic medicines to address diseases with high unmet clinical needs. EG-70 was designed from the ground up to achieve this vision as a readily scalable, easy to use product candidate without the onerous storage and handling requirements typical of viral approaches. Our previously announced Phase 1 data for EG-70 in BCG-unresponsive NMIBC demonstrated an encouraging safety profile and a 73% complete response rate at any time, which has garnered significant enthusiasm from patients, the urology community, and investors," said Jason Hanson, Chief Executive Officer of enGene. "We are proud to enter our second quarter as a public company with significant momentum, having raised $200 million from top tier investors in a private financing in February. With existing cash and cash equivalents expected to fund the current operating plan into 2027, we believe enGene is well-positioned to complete the ongoing pivotal-stage LEGEND study of EG-70 in BCG-unresponsive NMIBC, execute on our plan to file our BLA in the first quarter of 2026, and pursue pipeline expansion via additional EG-70 development opportunities and potential new R&D programs."

Recent Business Highlights:

- **Completed $200 Million Oversubscribed Private Placement:** On February 20, 2024, enGene completed the private placement of 20 million common shares at a price per share of $10.00, representing a 31% premium over the closing price prior to pricing the transaction (the "February 2024 PIPE Financing"). The financing included participation from new and existing investors.
- **Expanded Hercules Capital Debt Facility:** On December 22, 2023, enGene announced the expansion of its existing debt facility with Hercules to up to $50 million, subject to certain milestones, with $22.5 million advanced at closing, of which approximately $8.6 million was applied to refinance in full the term loans outstanding under the prior loan agreement with Hercules.
- **Key Leadership Hires, Board Additions and Succession Planning:** enGene continued to build out its executive leadership with the appointment of Ryan Daws as Chief Financial Officer and Lee Giguere as Chief Legal Officer and Corporate Secretary. Additionally, Lota Zoth, CPA, was appointed to the Company's Board of Directors and serves as the Company's Audit Committee Chair.

On February 14, 2024, enGene announced that due to personal family and health reasons, Jason Hanson intends to resign from his role as Chief Executive Officer and a member of the Board of Directors upon the appointment of a successor CEO. The Board of Directors is conducting a search for his successor. Following the hiring of a new CEO, Mr. Hanson will support the Company and the new CEO as a strategic advisor.

Anticipated Milestones and Corporate Updates

- Announce a new indication and development plans for EG-70 in the first half of 2024.
- Interim data readout from the ongoing pivotal Phase 2 LEGEND study of EG-70 in BCG-unresponsive NMIBC

with *carcinoma-in-situ* (Cis) in mid-2024.
- Initial efficacy data from the ongoing Phase 2 LEGEND study in a BCG-naive NMIBC cohort in the second half of 2024.

First Quarter 2024 Financial Results

Cash and cash equivalents, as of January 31, 2024, were $85.6 million, compared to $81.5 million as of October 31, 2023. The Company expects that its existing cash and cash equivalents together with the recent net proceeds of $187.5 million from its February 2024 PIPE Financing will fund operating expenses and capital expenditures into 2027.

Three Months ended January 31, 2024

- Total operating expenses were $10.8 million for the three months ended January 31, 2024, compared to $4.6 million for the three months ended January 31, 2023. Research and development expenses increased by $2.0 million, mainly due to increasing CMC and clinical costs related to our pivotal EG-70 study. General and administrative expenses increased by $4.2 million, primarily driven by headcount costs and professional fees such as legal, accounting and audit as the Company scales its G&A function to support the operation of a public company.
- For the three months ended January 31, 2024, net loss attributable to common shareholders was $10.7 million, or $0.46 per share, compared to $8.6 million, or $13.29 per share, for the same period for the three months ended January 31, 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

Some of the 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 expectations, hopes, beliefs, intentions, goals, strategies, forecasts and projections. 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 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, beliefs as to the potential benefits of EG-70, the expected period over which enGene estimates its cash and cash equivalents will be sufficient to fund its current operating plan, anticipated uses of the enGene's cash and cash equivalents, anticipated results of the chief executive officer succession process and expectations as to the future financial position of enGene, including maximum proceeds that may be available under the Hercules facility.

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 and most recent Quarterly Report on Form 10-Q (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 January 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 5,638	$ 3,671
General and administrative	5,135	962
Total operating expenses	10,773	4,633
Loss from operations	10,773	4,633
Total other (income) expense, net	(32)	2,785
Net loss before provision for income taxes	10,741	7,418
Provision for income taxes	(30)	-
Net loss	$ 10,711	$ 7,418
Deemed dividend attributable to redeemable convertible preferred shareholders	-	1,234
Net loss attributable to common shareholders, basic and diluted	10,711	8,652
Weighted-average common shares outstanding, basic and diluted	23,197,976	651,074
Net loss per share of common shares, basic and diluted	$ 0.46	$ 13.29

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

	January 31, 2024	October 31, 2023
Cash and cash equivalents	$ 85,646	$ 81,521
Total assets	93,421	86,959
Total liabilities	31,066	14,473
Total shareholders' equity	62,355	72,486

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