



enGene Reports Full Year 2023 Financial Results and Recent Operational Progress

Achieved primary and secondary endpoints in Phase 1 portion of LEGEND study in non-muscle invasive bladder cancer (NMIBC); pivotal portion underway with interim data expected mid this year

Completed a reverse merger transaction with Forbion European Acquisition Corp (FEAC), launched as a public company on November 1, 2023, and completed an upsized PIPE financing

Combined transactions resulted in net proceeds of approximately \$109 million

Closed an expanded \$50M debt facility with Hercules Capital in December 2023; extends cash runway into Q2 2025

BOSTON and MONTREAL, Jan. 29, 2024 /CNW/ - enGene Holdings Inc. (Nasdaq: ENGN) (or "enGene" or the "Company"), a clinical-stage genetic medicines company whose non-viral lead program is in a pivotal study for BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), today announced its financial results for the fiscal year ended October 31, 2023 and provided a corporate update.

"During 2023, enGene made substantial progress advancing our lead program, EG-70 (detalimogene voraplasmid), in our ongoing pivotal-stage LEGEND study in BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ. In addition, we were pleased to build out an accomplished leadership team and transition into a public company," said Jason Hanson, Chief Executive Officer of enGene. "Based on the highly differentiated attributes of our non-viral DDX genetic medicine platform, we believe that EG-70 may become a powerful and heavily utilized therapy in the practicing urologists's armamentarium, providing both therapeutic benefits for patients as well as ease-of-use advantages as compared to existing NMIBC therapeutics and those in late-stage development. We continue to enroll patients in our pivotal study and look forward to reporting interim clinical results in mid-2024."

Ryan Daws, Chief Financial Officer of enGene commented: "Together with our \$50M expanded debt facility with Hercules Capital, the financing transactions completed concurrent with the reverse merger provide support for the ongoing LEGEND study of EG-70 in BCG-unresponsive and BCG-naïve NMIBC patients with Cis, BLA-enabling activities, and additional clinical applications. The Company is in a strong financial position, with cash on hand expected to support operations into Q2 2025, beyond the anticipated completion of the interim EG-70 clinical data and additional expected corporate milestones."

Recent Business Highlights:

- **Public Company Launch and EG-70 Clinical Program Progress:** On November 1, 2023, enGene Holdings Inc launched as a publicly traded company focused on developing non-viral gene therapies based on its novel and proprietary dually derived chitosan, or "DDX", gene delivery platform, which allows localized delivery of multiple gene cargos directly to mucosal tissues and other organs. The Company's lead product candidate, EG-70, is an intravesically administered, non-viral, polymeric nanoparticle comprising a DNA plasmid encoding three genes designed to generate a local immune reaction in proximity to tumors. enGene is enrolling patients in a combined Phase 1/2 open label registrational study of EG-70, referred to as "LEGEND" (ClinicalTrials.gov identifier [NCT04752722](https://clinicaltrials.gov/ct2/show/study/NCT04752722)) with interim data expected mid-year.
- **Achieved Primary and Secondary Endpoints in Phase 1 Portion of LEGEND Study in NMIBC:** The Phase 1 portion enrolled 22 BCG-unresponsive patients, exhibited an encouraging safety profile, a 3-month complete response rate of 68% and supported dose selection for the Phase 2 portion of the study.

- **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:** enGene continued to invest in its senior leadership and add experienced members to its Board of Directors. On February 2, 2023, Alex Nichols, Ph.D., joined as President and Chief Operating Officer, on September 7, 2023, Richard Bryce, M.D. was hired as Chief Medical Officer and on November 29, 2023, Ryan Daws joined as Chief Financial Officer. Additionally, on December 19, 2023, Lota Zoth, CPA, was appointed to the Company's Board of Directors and serves as the Company's Audit Committee Chair.

Past and Upcoming Anticipated Milestones

- Presented clinical data from LEGEND Phase 1 trial at 24th Annual Meeting of the Society of Urologic Oncology in November 2023.
- Announce interim readout from the pivotal Phase 2 LEGEND study mid-2024.

Full Year 2023 Financial Results

Cash and cash equivalents, as of October 31, 2023, were \$81.5 million, compared to \$20.4 million as of October 31, 2022. The Company expects that its existing cash and cash equivalents will fund operating expenses and capital expenditures into the second quarter of 2025.

Full Year 2023

- Total operating expenses were \$26.0 million for 2023, compared to \$19.4 million for 2022. Research and development expenses increased by \$1.0 million, mainly due to increasing CMC and clinical costs relating to our pivotal EG-70 study. General and administrative expenses increased by \$5.6 million, primarily driven by share-based compensation and professional fees associated with accounting and audit related fees.
- For the full year 2023, net loss attributable to common shareholders was \$104.7 million, or \$151.22 per share, compared to \$29.0 million, or \$44.30 per share, for the same period in 2022. The increase in net loss is mainly attributed to the increase in other expense. In 2023, within other expense are non-cash charges of \$80.7 million arising from fair value adjustments on our convertible debentures and related derivative liabilities and a loss on extinguishment upon conversion of our convertible debentures; partially offset by non-cash fair value gain of \$10.8 million from the cancellation of Series C preferred share warrants liabilities upon the Reverse Recapitalization on October 31, 2023.

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, 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" section of the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2023 (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,**2023****2022**

Operating expenses:

Research and development

\$ 16,458

\$ 15,467

General and administrative

9,602

3,960

Total operating expenses

26,060

19,427

Loss from operations

26,060

19,427

Total other (income) expense, net

73,840

5,013

Net loss before provision for income tax

99,900

24,440

Provision for income tax

17

22

Net loss

\$ 99,917

\$ 24,462

Deemed dividend attributable to redeemable convertible preferred shareholders

4,822

4,562

Net loss attributable to common shareholders, basic and diluted

104,739

29,024

Weighted-average common shares outstanding, basic and diluted

692,609

655,153

Net loss per share of common shares, basic and diluted

\$ 151.22

\$ 44.30

enGene Holdings Inc.**Condensed Consolidated Balance Sheet Information****(unaudited)****(Amounts in thousands of USD)****October 31, 2023****October 31, 2022**

Cash and cash equivalents

\$ 81,521

\$ 20,434

Total assets

86,959

23,909

Total liabilities

14,473

47,405

Total liabilities, redeemable convertible preferred shares and shareholders' equity

86,959

23,909

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