enGene Reports Second Quarter 2026 Financial Results and Provides Business Update

12-month complete response data from LEGEND pivotal cohort and subsequent FDA engagement planned for 2H 2026

Initiation of Biologics License Application (BLA) filing for detalimogene planned for 2H 2026

First patients enrolled in surfactant plus detalimogene cohort

Approximately 50% reduction in force to streamline operations and preserve cash to focus on BLA and precommercial activities

Well capitalized with cash, cash equivalents and marketable securities of $285 million

BOSTON & MONTREAL - enGene Therapeutics Inc. (Nasdaq: ENGN, "enGene" or the "Company"), a clinical-stage, non-viral genetic medicines company today announced its financial results for the second quarter ended April 30, 2026, and provided clinical and corporate updates.

"Feedback from the urology community on the emerging detalimogene without surfactant profile, presented at the AUA meeting in May, supports our plan to await mature durability data in the second half of 2026 and meet with the FDA about initiating a BLA submission for detalimogene before year end," said Ron Cooper, President and Chief Executive Officer, enGene.

Mr. Cooper continued, "We are also encouraged by the interest in the detalimogene surfactant bladder rinse study from the medical community. With patients already enrolled, we are optimistic about the potential to further enhance efficacy while maintaining the ease of use and tolerability profile that has resonated with urologists."

"To preserve shareholder capital as we await additional durability data and meetings with the FDA, we made the very difficult decision to downsize the organization to streamline operations. We are sincerely grateful to the enGeneers who have created a high-performance culture and helped advance detalimogene and our mission to provide people living with NMIBC a new treatment option," added Mr. Cooper.

Recent Clinical Updates

LEGEND Pivotal Cohort 1: During a plenary presentation at the recent American Urological Association (AUA) meeting, interim data were shared from LEGEND's pivotal Cohort 1 studying detalimogene without surfactant in high-risk (HR), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS).

Efficacy overview:

- 54% (95% CI: 45%, 63%) complete response (CR) at any time (67/124)
- Low rate of progression to muscle invasive or more advanced disease (3.2%)

Safety overview:

- Low percentage of patients experienced treatment-related adverse events (TRAEs) leading to treatment interruption (2.4%) and treatment discontinuation (2.4%)

Twenty-one patients were pending disease assessments at either six-, nine-, or 12-months as of the data cutoff date of April 21, 2026. enGene is awaiting 12-month CR data from Cohort 1, as well as the majority of 12-month durability data, and expects to engage with the FDA in 2H 2026 to discuss a BLA filing.

Detalimogene plus Surfactant Cohort: In tandem with its pivotal update in May, the Company announced the initiation of an additional LEGEND cohort, which incorporates a short surfactant bladder rinse using diluted polidocanol

solution. Polidocanol is an FDA-approved product used for the treatment of spider and reticular veins. Surfactants have been shown to boost efficacy with other gene therapies in preclinical models and were subsequently incorporated into clinical development of those gene therapies. In murine models tested by the Company, pretreatment with polidocanol demonstrated a 10-fold increase in mean IL-12 expression and was able to boost efficacy of a subtherapeutic dose of detalimogene. Findings were validated in a large mammal model tested by the Company where a surfactant rinse increased the distribution of detalimogene nanoparticles throughout the bladder by approximately 50% and IL-12 expression by nine-fold. The first patients have been enrolled in the surfactant cohort, and the Company may enroll up to 80 patients in this global cohort. The Company believes this approach has the potential to further enhance efficacy and durability while preserving the simplicity, tolerability, and office-based administration profile that may make detalimogene a preferred option for community urology practices, where approximately 80% of NMIBC patients receive treatment.

LEGEND Cohorts 2a, 2b and 3: As part of cash conservation efforts, the Company has stopped enrollment in these additional cohorts and plans to reevaluate its strategy for them following discussion with the FDA in 2H 2026.

Recent Corporate Updates

Reduction in Force and Executive Departures: In June 2026, enGene implemented a plan to reduce its workforce by approximately 50% to streamline operations and preserve cash. The Company has retained personnel and resources required to meet its key strategic goals and milestones, including completion of LEGEND Cohort 1; enrolling the detalimogene plus surfactant cohort; meeting with the FDA and planning for BLA initiation in 2H 2026; and completing necessary pre-commercial activities required to support the planned commercial launch of detalimogene in 2027.

In conjunction with its reduction in force, the following executive officers will depart from the Company, effective July 15, 2026: Ryan Daws, Chief Financial Officer, Lee Giguere, Chief Legal Officer and Alex Nichols, Chief Strategy and Operations Officer.

Anthony Cheung, Chief Scientific Officer, will continue in his role through September 30, 2026, after which, he will transition into a consulting arrangement.

Hussein Sweiti, M.D., Chief Medical Officer, stepped down from his position to pursue a new professional opportunity, effective June 14, 2026. Effective immediately, William Grossman, M.D., Ph.D., a member of enGene's Board of Directors, will act as interim Chief Medical Officer. He is the former Senior Vice President and Therapeutic Area Head of Oncology Clinical Development at Gilead Sciences Inc. where he oversaw the oncology portfolio (early and late-stage clinical development) and collaboration programs. Prior to that, he held several Chief Medical Officer roles including at Arcus Biosciences and Bellicum Pharmaceuticals. He has held additional leadership roles at Genentech/Roche, Merck, AbbVie, and Biothera. Dr. Grossman received his M.D. and Ph.D. in Immunology from Washington University School of Medicine's Medical Scientist Training Program and completed his medical and post-doctoral training in both the Divisions of Pediatrics and Medicine at Washington University School of Medicine. He also currently serves on several advisory boards and will continue to serve on enGene's Board of Directors as a non-independent Director during his interim CMO role.

Constantine Chinoporos, who joined the Company in May as a business development consultant, is expected to act as enGene's interim Chief Business Officer. Mr. Chinoporos brings deep experience across business development, licensing, and M&A in the biopharma sector. He is a member of the Board of Directors at Geron Corporation, and most recently served as Chief Operating Officer and Chief Business Officer of Applied Therapeutics. Prior to his role at Applied Therapeutics, Mr. Chinoporos served as Chief Business Officer at Albireo Pharmaceuticals, Inc. from 2021 until its acquisition by Ipsen S.A. in 2023. From 2015 to 2021, he served as Chief Business Officer at Boston Pharmaceuticals, Inc. Previously, he held senior positions in worldwide licensing, business development, corporate development, corporate finance and alliance management at Sanofi S.A., Genzyme Corporation, and Eli Lilly and

Company. Mr. Chinoporos holds an M.B.A. from the Johnson Graduate School of Management at Cornell University and a B.A. in History from Cornell University.

Anticipated Milestones

- 12-month complete response data for all of Cohort 1 and pre-BLA meeting in 2H 2026
- Initiation of BLA filing for detalimogene in 2H 2026
- Potential detalimogene FDA approval decision and platform designation in 2027

Second Quarter 2026 Financial Results

As of April 30, 2026, cash, cash equivalents and marketable securities were $285.2 million providing significant operational flexibility.

Total operating expenses were $32.0 million for the three months ended April 30, 2026, compared to $27.1 million for the three months ended April 30, 2025. Research and development expenses increased by $2.0 million, primarily driven by increased personnel and clinical costs related to our LEGEND trial, completion of PPQ batch manufacturing and preparation to initiate the submission of a planned Biologics License Application with the FDA in the second half of 2026. General and administrative expenses increased by $2.9 million, primarily driven by annualization of personnel-related costs and increased facility costs.

For the three months ended April 30, 2026, net loss attributable to common shareholders was approximately $30.2 million, or $0.43 per share, compared to approximately $25.8 million, or $0.51 per share, for the three months ended April 30, 2025. 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 Non-Muscle Invasive Bladder Cancer (NMIBC)

Non-muscle invasive bladder cancer (NMIBC) is a disease that poses a significant burden on both patients and clinics and has a massive economic impact on the healthcare system. NMIBC occurs when cancer cells grow in the tissues that line the interior of the bladder, but the cancer has not yet penetrated the muscle of the bladder wall. NMIBC can present as papillary outgrowths from the bladder wall, which are typically resected, or as carcinoma in situ (CIS), which consists of flat, multifocal lesions that cannot be resected. The two forms can also co-occur. About 75%-80% of new bladder cancer diagnoses are NMIBC. Patients suffering from high-risk NMIBC who are unresponsive to the standard of care, Bacillus Calmette-Guérin (BCG), face high rates of disease recurrence (50%-70%) and are potentially subject to full removal of the bladder (cystectomy) as a curative but life-altering next step.

About Detalimogene Voraplasmid

Detalimogene is a novel, investigational, non-viral gene therapy for patients with high-risk, non-muscle invasive bladder cancer (NMIBC), including Bacillus Calmette-Guérin (BCG)-unresponsive disease. It is designed to be instilled in the bladder and elicit a powerful yet localized anti-tumor immune response.

Detalimogene was developed using the Company's Dually Derivatized Oligochitosan® (DDX) platform, a technology designed to transform how gene therapies are accessed by patients and utilized by clinicians. Medicines developed with the DDX platform can potentially overcome the limitations of viral-based gene therapies, reduce complexities related to safe handling and cold storage, and streamline both manufacturing processes and administration paradigms.

Regenerative Medicine Advanced Therapy (RMAT) and Fast Track Designations

Detalimogene has received Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations from the U.S. Food and Drug Administration (FDA) based on its potential to address the high unmet medical need for patients with BCG-unresponsive carcinoma in situ (CIS) NMIBC with or without resected papillary tumors who are unable to

undergo cystectomy. These designations are intended to expedite the development and review of drugs intended to treat serious or life-threatening conditions and fill an unmet medical need. Detalimogene has also been selected for the FDA's Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) program, designed to facilitate CMC development for therapies with compressed clinical development timeframes based on the anticipated clinical benefits of earlier patient access to the therapy.

About the LEGEND Trial

Detalimogene is being evaluated in the ongoing, open-label, multi-cohort, Phase 2 LEGEND trial to establish its safety and efficacy in high-risk NMIBC. LEGEND's pivotal cohort (Cohort 1) consists of 125 patients with high-risk, BCG-unresponsive NMIBC with CIS (with or without papillary disease) and is designed to serve as the basis of the Company's planned Biologics License Application (BLA) filing. In addition to this pivotal cohort, LEGEND includes four additional cohorts, including NMIBC patients with CIS who are naïve to treatment with BCG (Cohort 2a); NMIBC patients with CIS who have been exposed to BCG but have not received adequate BCG treatment (Cohort 2b); BCG-unresponsive high-risk NMIBC patients with papillary-only disease (Cohort 3); and BCG-unresponsive high-risk NMIBC patients with CIS who receive polidocanol plus detalimogene.

About enGene

enGene Therapeutics Inc. is a clinical-stage biotechnology company mainstreaming non-viral genetic medicine 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) 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 trial, which includes a pivotal cohort studying detalimogene in high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive patients with carcinoma in situ (CIS) with or without concomitant papillary disease.

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.

To learn more, please visit enGene.com and follow us on LinkedIn, X and BlueSky.

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 relating to the Company's future plans, 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", "goal", "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: detalimogene's potential efficacy, durability, safety, tolerability and ease of use profile, the development of detalimogene, enGene's estimates regarding expenses, debt obligations and capital requirements necessary to fund its current operating plan, the expected period over which enGene estimates its cash and marketable securities will be sufficient to fund its current operating plan, the intended objectives and benefits of the reduction in force, including any estimated cost savings, the potential benefits of detalimogene, plans regarding regulatory interactions and a potential BLA submission for detalimogene, plans regarding updates on the LEGEND

study, including clinical data and engagement with the FDA, the potential benefits of combining a surfactant bladder rinse with detalimogene, plans for the additional cohorts of the LEGEND study, and the potential benefits of medicines developed with the DDX platform. Such statements are subject to numerous important factors, risks and uncertainties, many of which are beyond enGene's control, that may cause actual events or results to differ materially from enGene's current expectations. For example, there can be no guarantee that detalimogene will successfully complete necessary clinical development phases, including achieving positive results in the pivotal cohort of the LEGEND study, or that those results or any feedback from regulatory authorities will ultimately lead to a BLA submission for, and the approval of, detalimogene.

Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks, uncertainties and assumptions relating to a number of other factors, which 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 inability of preliminary clinical data to predict the final results of the trial, changes in the results from enGene's clinical trials, including due to new data collected from the ongoing LEGEND study or future studies, subsequent analysis of existing data, and audit and verification procedures; the content and timing of decisions made by the FDA and other regulatory authorities; 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 its 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, 2025 (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 Therapeutics 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,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 22,195	$ 20,209	$ 44,450	$ 40,183
General and administrative	9,773	6,915	18,703	13,554
Total operating expenses	31,968	27,124	63,153	53,737
Loss from operations	31,968	27,124	63,153	53,737
Total other income, net	(1,741)	(1,549)	(3,174)	(3,564)
Net loss before income tax	30,227	25,575	59,979	50,173
Provision for income tax	-	240	-	258
Net loss	$ 30,227	$ 25,815	$ 59,979	$ 50,431
Other comprehensive loss:				
Unrealized loss (gain) on available-for-sale investments	$ 299	$ (306)	$ 253	$ (450)
Total comprehensive loss	$ 30,526	$ 25,509	$ 60,232	$ 49,981
Net loss attributable to common shareholders, basic and diluted	30,227	25,815	59,979	50,431
Weighted-average common shares outstanding, basic and diluted	69,724,761	51,019,363	68,473,598	50,997,98
Net loss per share of common shares, basic and diluted	$ 0.43	$ 0.51	$ 0.88	$ 0.99

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

	April 30, 2026	**October 31, 2025**
Cash, cash equivalents and marketable securities	$ 285,174	$ 202,258
Total assets	307,524	221,468
Total liabilities	52,356	53,758
Total shareholders' equity	255,168	167,710

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