



enGene Reports Third Quarter 2026 Financial Results and Provides Business Update

Data update on key regulatory endpoints, complete response (CR) at any time and maturing durability, as well as landmark CR rates from LEGEND's pivotal cohort planned for 4Q 2026

Pre-Biologics License Application (BLA) meeting with the FDA on track for 4Q 2026

Initiation of BLA submission for detalimogene planned for 4Q 2026

Detalimogene plus surfactant cohort safety run-in successfully cleared; Webinar on surfactant plus detalimogene preclinical data and cohort enrollment guidance planned for October 15, 2026

Well-capitalized with \$266 million in cash, cash equivalents, and marketable securities, supporting continued capital discipline and execution toward BLA filing and precommercial readiness

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 third quarter ended July 31, 2026, and provided clinical and corporate updates.

"As we move through the second half of 2026, our focus is on maturing regulatory endpoints data from LEGEND's pivotal cohort and our planned engagement with the FDA regarding a BLA filing for detalimogene," said Ron Cooper, President and Chief Executive Officer, enGene. "We believe the clinical profile observed to date, together with detalimogene's potential best-in-class tolerability and straightforward, office-based administration, supports it becoming an important treatment option for urologists and their patients with BCG-unresponsive NMIBC."

"We are pleased to have cleared the surfactant safety run-in period and are encouraged by the progress of the cohort, which is designed to explore whether we can further enhance efficacy and durability while preserving tolerability and the practical attributes that we believe differentiate detalimogene," added Mr. Cooper. "With a strong balance sheet, we remain focused on disciplined capital allocation to advance the program toward BLA submission and prepare for commercialization."

Recent Clinical and Corporate Updates

Detalimogene without Surfactant Pivotal Cohort 1: Detalimogene previously reported an interim 54% complete response (CR) rate at any time and a low rate of progression to muscle-invasive disease (3.2%) in LEGEND's pivotal Cohort 1, which is evaluating detalimogene without surfactant in patients with high-risk (HR), Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS). enGene expects to report updated data on key primary and secondary regulatory endpoints (CR at any time and Duration of Response (DOR) 12 months), as well as additional durability datapoints, from Cohort 1 and conduct a pre-BLA meeting with the FDA in 4Q 2026 to discuss its planned initiation of a BLA filing before yearend.

Detalimogene plus Surfactant Key Opinion Leader (KOL) Webinar: The Company is currently enrolling high-risk, BCG-unresponsive NMIBC patients with CIS in an additional LEGEND cohort incorporating a brief surfactant bladder rinse with an FDA-approved surfactant solution (generic name: polidocanol). Surfactants have been shown to enhance the efficacy of other intravesical gene therapies for NMIBC and have subsequently been incorporated into their clinical development. 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 where a brief surfactant rinse significantly increased the distribution of detalimogene nanoparticles throughout the bladder and IL-12 expression by over nine-fold. Preclinical data indicates that use of a surfactant bladder rinse not only raises the peak of transgene expression but makes transfection consistent across the bladder surface. In a disease that recurs multifocally, transfection coverage may matter as much as amplitude.

On October 15, 2026, at 10:00 a.m. ET, the Company will host a webinar to provide greater detail on the preclinical data supporting the incorporation of its surfactant bladder rinse into clinical development. In addition, the Company will be joined by two KOLs from Colorado Urology, David Cahn, MD, and Suzanne Merrill, MD, FACS, to review clinical case studies and discuss various treatment considerations.

Please click [here](#) to register for the event.

Emerging NMIBC Market Insights KOL Webinar: On August 11, 2026, the Company hosted a virtual KOL event featuring Neal Shore, MD, FACS, Medical Director for START-Carolinas Research, who joined management to discuss the evolving non-muscle invasive bladder cancer (NMIBC) treatment landscape. As a part of its broader pre-commercial preparation efforts, the Company shared highlights from its ongoing market research, including the future treatment paradigm where avoidance of radical cystectomy by sequencing multiple lines of therapy will become the norm, the prevalent population will continue to grow as a result of increased sequencing, and a new market price point has been established by recently launched products.

Dr. Shore emphasized the importance of a product profile that could address the various needs of community urology practices, including practice workflow constraints, while also providing a well-tolerated and effective therapy for patients. A replay of the webinar can be accessed [here](#).

Board Leadership Transition: In July 2026, Michael Heffernan, a member of enGene's Board of Directors since July 2025, assumed the role of Chairman of the Board, succeeding Dr. Richard Glickman, who had served as Chairman for over 14 years. The transition was made as the Company plans for potential regulatory milestones and to support commercial readiness for detalimogene, if approved.

Anticipated Milestones

- Data update on key regulatory endpoints, complete response (CR) at any time and maturing durability, as well as landmark CR rates from LEGEND's pivotal cohort planned for 4Q 2026
- Pre-BLA meeting with the FDA in 4Q 2026
- Initiation of BLA filing for detalimogene in 4Q 2026
- Potential FDA approval decision for detalimogene and platform designation in 2027

Third Quarter 2026 Financial Results

As of July 31, 2026, cash, cash equivalents and marketable securities were \$266.3 million providing significant operational flexibility.

Total operating expenses were \$34.0 million for the three months ended July 31, 2026, compared to \$29.9 million for the three months ended July 31, 2025. Research and development expenses decreased by \$2.5 million, primarily driven by timing of process validation manufacturing activities in preparation to initiate the submission of a planned Biologics License Application with the FDA in the fourth quarter of 2026, partially offset by increased workforce reduction-related costs. General and administrative expenses increased by \$6.6 million, primarily driven by workforce reduction-related costs and the annualization of personnel-related costs.

For the three months ended July 31, 2026, net loss attributable to common shareholders was approximately \$32.5 million, or \$0.47 per share, compared to approximately \$29.0 million, or \$0.57 per share, for the three months ended July 31, 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](https://www.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 "forecast", "intend", "develop", "expect", "anticipate", "appear", "approximate", "believe", "continue", "could", "estimate", "expect", "foresee", "goal", "intends", "may", "might", "plan", "possible", "potential", "predict", "project", "seek", "should", "strategy", "future", "potential", "opportunity", "target", "term", "will", "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, the potential benefits 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, 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, our current views and market research on the non-muscle invasive bladder cancer market, the depth, breadth and quality of our market research, our conclusions, implications or take-aways from the results of our market research, estimates, projections or forecasts of payer coverage of therapies, projected revenues for detalimogene at pricing parity with new therapies, the size of the addressable BCG unresponsive population, our expectations regarding the frequency or manner in which healthcare providers may use detalimogene, potential growth of the potential patient population, sequencing of products, the potential benefits of combining a surfactant bladder rinse with detalimogene, including the potential for increased efficacy and durability, estimates and forecasts of financial and performance metrics, projections of market opportunity and market share, the anticipated market acceptance of detalimogene, expectations and timing related to regulatory submissions and commercial product launches and the prospects for regulatory approval of 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 July 31,		Nine Months Ended July 31,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 20,090	\$ 22,575	\$ 64,540	\$ 62,758
General and administrative	13,924	7,372	32,627	20,926
Total operating expenses	34,014	29,947	97,167	83,684
Loss from operations	34,014	29,947	97,167	83,684
Total other income, net	(1,513)	(1,195)	(4,687)	(4,759)
Net loss before income tax	32,501	28,752	92,480	78,925
Provision for income tax	-	239	-	497
Net loss	\$ 32,501	\$ 28,991	\$ 92,480	\$ 79,422
Other comprehensive loss:				
Unrealized loss (gain) on available-for-sale investments	\$ 210	\$ 240	\$ 463	\$ (210)
Total comprehensive loss	\$ 32,711	\$ 29,231	\$ 92,943	\$ 79,212
Net loss attributable to common shareholders, basic and diluted	32,501	28,991	92,480	79,422
Weighted-average common shares outstanding, basic and diluted	69,734,610	51,097,711	68,898,554	51,031,618
Net loss per share of common shares, basic and diluted	\$ 0.47	\$ 0.57	\$ 1.34	\$ 1.56

enGene Therapeutics Inc.

Condensed Consolidated Balance Sheet Information

(unaudited)

(Amounts in thousands of USD)

	July 31, 2026	October 31, 2025
Cash, cash equivalents and marketable securities	\$ 266,320	\$ 202,258
Total assets	288,322	221,468
Total liabilities	58,032	53,758
Total shareholders' equity	230,290	167,710

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