enGene Therapeutics Inc.

2025 Annual Report

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended October 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-41854

enGene Holdings Inc.

(Exact name of Registrant as specified in its Charter)

British Columbia, Canada	**N/A**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4868 Rue Levy, Suite 220	**H4R 2P1**
Saint-Laurent, QC, Canada	**(Zip Code)**
(Address of principal executive offices)	

Registrant's telephone number, including area code: (514) 332-4888

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares	ENGN	The Nasdaq Stock Market LLC
Warrants, each exercisable for one Common Share, at an exercise price of $11.50 per share	ENGNW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the common equity held by non-affiliates of the registrant, based on the closing price of the Common Shares on The Nasdaq Stock Market LLC on April 30, 2025 was $154,176,366.

The number of the registrant's Common Shares outstanding as of December 17, 2025 was 66,984,661.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement of enGene Holdings Inc. to be filed for its 2026 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Auditor Firm Id: 85 Auditor Name: KPMG LLP Auditor Location: Montreal, Canada

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K (the "Annual Report") may constitute "forward-looking statements" within the meaning of U.S. securities laws 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," "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 in this Annual Report may include, for example, statements about:

- our financial performance, including financial projections and business metrics and any underlying assumptions thereunder;
- our ability to maintain the listing of the Company's common shares ("Common Shares") and warrants to purchase Common Shares ("Warrants") on The Nasdaq Capital Market ("Nasdaq") or another national securities exchange;
- our success in recruiting and retaining, or changes required in, officers, key personnel or directors;
- our plans and ability to execute product development, manufacturing process development, preclinical and clinical development efforts successfully and on anticipated timelines;
- our ability to design, initiate and successfully complete clinical trials and other studies for detalimogene voraplasmid, or detalimogene, formerly referred to as EG-70, and any other product candidates we develop and our plans and expectations regarding our ongoing or planned clinical trials;
- the impacts and outcomes of our later-stage and pivotal clinical trials and their influence on obtaining the U.S. Food and Drug Administration (the "FDA") or comparable foreign regulatory approval to market detalimogene or any future product candidates;
- our plans and ability to seek, obtain and maintain marketing approval from the FDA and other regulatory authorities, including the European Medicines Agency (the "EMA"), for detalimogene or any other product candidates we develop;
- our plans and ability to commercialize detalimogene or any other product candidates we develop, if approved by applicable regulatory authorities;
- the degree of market acceptance of detalimogene or any other product candidates we develop, if approved, and the availability of third-party coverage and reimbursement;
- the ability of our external contract manufacturers to support the manufacturing, release testing, stability analysis, clinical labeling and packaging of detalimogene or any other product candidates that we develop;
- our future financial performance and the sufficiency of our cash and cash equivalents to fund our operations;
- our ability to obtain additional funding on a timely basis;
- our ability to effectively manage the transition of executive-level roles to new leaders, and to attract and retain key executives and employees;
- the outcome of any known and unknown litigation and regulatory proceedings, including any legal proceedings that may be instituted against us or any of our directors or officers; and
- our ability to implement and maintain effective internal controls.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. Certain assumptions made in preparing the forward-looking statements include:

- we are able to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials and acquire technologies complementary to, or necessary for, detalimogene or any other programs;
- we are able to enroll, in a timely manner, a sufficient number of patients in each cohort of the Phase 2 LEGEND trial to assess the efficacy and safety of detalimogene including the cohorts with the BCG-naïve patient population, the BCG-exposed patient population and the BCG-unresponsive, papillary-only Ta/T1 disease;
- we are able to file our planned Biologics License Application in second half of 2026 with the FDA for approval to market detalimogene in the United States as a monotherapy to treat BCG-unresponsive NMIBC with CIS;

- detalimogene's product profile can be integrated seamlessly into community urology clinics where the vast majority of NMIBC patients are treated;
- we are able to retain commercial rights to detalimogene in the United States and commercialize detalimogene independently, while selectively partnering outside of the United States;
- we are able to execute the "pipeline-in-a-product" development strategy for detalimogene; and
- we are able to utilize the DDX gene delivery platform to develop effective, new product candidates for the delivery of genetic medicines to mucosal tissues.

You should not place undue reliance on these forward-looking statements which speak only as of the date hereof. The forward-looking statements contained in this Annual Report are based primarily on current expectations and projections about future events and trends that may affect our business, financial condition and operating results. The following uncertainties and factors, among other things (including those described in "Risk Factors" in this Annual Report), could affect future performance and actual results to differ materially and adversely from those expressed in, anticipated or implied by forward-looking statements:

- risks applicable to our business, including the heavy dependence on the success of detalimogene and the extensive regulation of all aspects of our business, competition from other existing or newly developed products and treatments;
- risks associated with the protection of intellectual property, our ability to raise additional capital to fund our product development activity, and our ability to maintain key relationships and to attract and retain talented personnel;
- the possibility that we may be adversely affected by changes in domestic and foreign laws and regulations, including but not limited to resultant changes in business, market, financial, political, legal or geopolitical conditions, including tariffs, economic sanctions and economic slowdowns or recessions, or prolonged government shutdowns or defunding, and;
- the risk that any regulatory approvals are not obtained, are delayed or are subject to unanticipated conditions that could adversely affect our business; or
- other risks and uncertainties set forth in the section entitled "Risk Factors" in this Annual Report.

In addition, statements that "we believe" and similar statements reflect beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Annual Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

RISK FACTORS SUMMARY

Our business is subject to a number of risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report. The principal risks and uncertainties affecting our business includes, among other the following:

Risks Related to Our Business

- We depend heavily on the success of our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, which is currently in a clinical trial. Our clinical trial of detalimogene may not be successful. If we are unable to successfully develop, obtain regulatory approval for, and commercialize detalimogene, or experience significant delays in doing so, our business will be materially harmed.
- We expect to make significant investments in our continued research and development of detalimogene and other new product candidates, genetic medicines and services we may develop, which, if not successful, would limit our ability to achieve or sustain profitability in the future.
- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the foreseeable future.
- The estimates of market sizes and forecasts of market growth for the potential demand of our detalimogene product and any other product candidates we develop are based on a number of assumptions and may prove to be inaccurate. The actual market may be smaller than we believe, which would adversely affect our business and results of operations.
- If our internal controls over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the trading price of our common stock.
- To date, we have not generated any product revenue, have a history of losses and will need to raise additional capital to fund our operations. If we fail to obtain necessary financing, we will not be able to complete the development and commercialization of detalimogene or our other product candidates.
- We face significant competition from other entities, including biotechnology and pharmaceutical companies, which may result in our competitors discovering, developing or commercializing products before us or more successfully than we do. Our business and results of operations could be adversely affected if we fail to compete effectively.
- We are focusing our research and development efforts on detalimogene, as well as further development of our genetic medicine platform and other product candidates we may develop. As a result, we may forego or delay pursuit of other genetic medicine technologies or other therapeutic product candidates that provide significant advantages over our platform or product candidates, which could materially harm our business and results of operations.
- Detalimogene and our genetic medicine platform are based on proven novel technologies, which makes it difficult to predict the time and cost of development and the probability or timing of subsequently obtaining regulatory approval.
- Development of new therapeutics involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs, fail to replicate the positive results from our earlier preclinical or clinical studies of our product candidates in later preclinical studies or clinical trials or experience delays in completing or ultimately be unable to complete, the development and commercialization of any product candidates, including but not limited to detalimogene.
- Interim top-line and preliminary data from our clinical trials will change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Although we have conducted the Phase 1 portion of the LEGEND clinical study of detalimogene, we have not as an organization completed later-stage or pivotal clinical trials or submitted a BLA (as defined below), and we may be unable to do so for detalimogene or any future product candidates in a timely manner or at all.
- Our use of third parties to manufacture, develop and test our therapeutic product candidates for preclinical studies and clinical trials increases the risk that we will not have sufficient quantities of our product candidates or products, or necessary quantities of such materials on time or at an acceptable cost.
- Detalimogene is complex to manufacture, and the manufacturing process for any other product candidates we develop may be similarly complex or more complex, and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of our third-party manufacturers with whom we contract encounter these types of difficulties, our ability to supply detalimogene or any other product candidates we develop for clinical trials or as products for patients, if approved, could be constrained, delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

- The market opportunities for detalimogene and any other product candidates we develop may be limited to a small group of patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.
- We depend on our executive team and key personnel, and if we lose one or more of our executive officers or key employees or are unable to attract and retain highly skilled employees, such events could harm our business.
- Our research and development initiatives, manufacturing processes and business depend on our ability to attract and retain highly skilled scientists and other specialized individuals. We may not be able to attract or retain such qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses.
- Nearly all aspects of our activity and our products and services are subject to extensive regulation by various U.S. federal and state agencies and regulatory bodies in non-U.S. jurisdictions, and compliance with existing or future regulations could result in unanticipated expenses or limit our ability to offer our products and services. Regulatory approval is a lengthy, expensive, and inherently unpredictable process with uncertain outcomes and cost and is subject to the potential for substantial delays. We cannot give any assurance whether or when our product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- We cannot predict whether or when we will obtain regulatory approval to commercialize detalimogene or any other product candidate we may develop in the United States or any other jurisdiction and any such approval may be for a narrower indication than we seek.
- If we are not able to obtain or if there are delays in obtaining required regulatory approvals for detalimogene or any other product candidates that we may develop, our ability to generate revenue will be adversely affected. Even if we eventually gain approval for detalimogene or any other product candidates, we may be unable to commercialize them.
- We may not obtain or maintain regulatory approval of detalimogene or other product candidates we develop in all jurisdictions in which such approval may be required or otherwise desirable or beneficial from a business perspective, and failure to do so may have a material adverse effect on our business and results of operations.
- Our contract manufacturers are subject to significant regulation with respect to the manufacturing of our current and future product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements and/or may have limited capacity.
- Drug marketing, price controls and reimbursement regulations may materially affect our ability to market and receive coverage for our product candidates, if approved, in the European Union, the United Kingdom, Japan and other non-U.S. jurisdictions.
- Global economic uncertainty, changes in geopolitical conditions and weakening product demand caused by political instability, changes in trade agreements and disputes, such as armed conflicts between Russia and Ukraine and in the Middle East, and other macroeconomic factors, could adversely affect our business and results of operations.
- If we are unable to obtain and maintain, enforce and defend patent protection for any product candidates we develop or for our novel genetic medicine platform, or if the scope of the patent protection obtained is not sufficiently broad, our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.

Risks Related to our Common Shares and Warrants and to Being a Public Company

- Sales of Common Shares, or the perception of such sales, by us or the Selling Holders in the public market or otherwise could cause the market price for our Common Shares to decline and certain Selling Holders still may receive a significant rate of return.
- Certain existing securityholders acquired their securities in our Company at prices that may be below the current trading price of such securities, and may experience a positive rate of return based on such current trading price. Future investors in our Company may not experience a similar rate of return.
- There is no assurance that Warrants will be and/or remain "in the money" prior to their expiration or that the holders of Warrants will elect to exercise any or all of their Warrants for cash; the Warrants may expire worthless.
- We will continue to incur increased costs as a result of operating as a public company, and the requirements for public companies may strain resources and divert management's attention.
- We may be unable to satisfy Nasdaq's continued listing requirements in the future, which could limit investors' ability to effect transactions in our securities and subject us to additional trading restrictions.

PART I

Item 1. Business.

Background

enGene Holdings Inc. (together with its consolidated subsidiaries "enGene" or the "Company") formed in connection with the Merger Agreement (as defined below), was incorporated as 14963148 Canada Inc. under the federal laws of Canada on April 24, 2023 and changed its name to enGene Holdings Inc. on May 9, 2023. On October 31, 2023, enGene Holdings Inc. continued from being a corporation incorporated under and governed by the Canada Business Corporations Act to a company continued to and governed by the Business Corporations Act (British Columbia).

Forbion European Acquisition Corporation ("FEAC") was a special purpose acquisition company ("SPAC"), incorporated as a Cayman Island exempted company on August 9, 2021 and formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more business or entities. On October 31, 2023 (the "Closing Date"), the Company, FEAC, and enGene Inc., a subsidiary of the Company, consummated the merger (the "Reverse Recapitalization" or the "Business Combination") pursuant to a business combination agreement, dated as of May 16, 2023 (the "Merger Agreement").

As a result of the Reverse Recapitalization, the Company became a publicly traded company and listed its Common Shares and Warrants on the Nasdaq Global Market under the symbols "ENGN" and "ENGNW," respectively, commencing trading on November 1, 2023, with enGene Inc. continuing the existing business operations.

Overview

We are a clinical-stage biotechnology company mainstreaming 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, beginning with non-muscle invasive bladder cancer (NMIBC). We are developing non-viral genetic medicines based on our novel and proprietary dually derived chitosan, or "DDX", gene delivery platform, which allows localized delivery of complex genetic cargos directly to mucosal tissues and other organs. Our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, is a therapy designed to promote a pro-inflammatory, anti-tumor microenvironment throughout the bladder urothelium. We believe this enables the immune system to durably clear the tumor and develop memory to resist recurrence. Because this treatment is designed to work by delivering genetic cargo to the broader tumor tissue environment rather than tumor cells specifically, we believe it has the potential to be utilized across a variety of tumor types. Currently, we are developing detalimogene as a monotherapy to treat non-muscle invasive bladder cancer ("NMIBC") with carcinoma in situ ("CIS") with or without concomitant papillary disease in patients that have been unresponsive to treatment with Bacillus Calmette-Guérin, or "BCG," or what is referred to as "BCG-unresponsive NMIBC with CIS." BCG is established as the first-line therapy for patients diagnosed with high-risk NMIBC; however, supply constraints have resulted in a shortage of BCG in the United States for over a decade. We are also exploring the clinical application of detalimogene to various additional NMIBC patient populations, namely, high-risk papillary-only BCG-unresponsive NMIBC (i.e., high-risk NMIBC without CIS), as well as high-risk BCG-naïve NMIBC patients with CIS and high-risk BCG-exposed NMIBC patients with CIS (i.e., patients who have not received an adequate course of BCG and who do not qualify as BCG-unresponsive in accordance with FDA and urology practice guidelines).

In NMIBC, carcinoma in situ, or CIS, is a flat, high-grade tumor that can invade the deeper layers of the bladder wall if left untreated. A "high-" or "low-" tumor risk describes the degree to which the tumor pathology appears more likely to grow quickly and invade non-cancerous tissue. NMIBC with CIS, which is high-risk, is typically initially treated with a solution containing the bacterium BCG that is instilled into the bladder multiple times over the course of several months. Despite high initial response rates to this treatment, many of these patients will experience a recurrence that is unresponsive to additional BCG, allowing the cancer to spread throughout, and deeper into, the bladder, often requiring surgical removal of the bladder (this procedure is called a radical cystectomy). We believe patients with BCG-unresponsive NMIBC with CIS are currently underserved with limited FDA-approved treatment options, and that there is a market opportunity for detalimogene as a monotherapy for patients with this condition. While the potential market for detalimogene may not ultimately be limited to these patients, that is our current initial focus in working to bring detalimogene to market.

Within the United States, we estimate that there are approximately 85,000 new patients each year diagnosed with bladder cancer, of which up to 80% present with non-muscle invasive disease. Bladder cancer also poses a long-term management burden with an estimated 730,000 people living with disease. See *"- Lead Product Candidate and Pipeline Development - Lead Program: NMIBC Background and Unmet Need*" for further information.

Detalimogene is currently being studied in a combined Phase 1/2 open-label trial, referred to as "LEGEND" (ClinicalTrials.gov identifier NCT04752722). The Phase 2 portion of LEGEND is comprised of three cohorts: Cohort 1 is a pivotal cohort studying detalimogene in patients with high-risk BCG-unresponsive NMIBC with CIS with or without concomitant papillary disease for which we have completed enrollment with 125 patients; Cohort 2 is evaluating detalimogene in patients with high-risk BCG-naïve NMIBC with CIS (Cohort 2a, with 30 enrolled patients as of November 11, 2025) and patients with high-risk BCG-exposed NMIBC with CIS

(Cohort 2b, with 45 enrolled patients as of November 11, 2025); and Cohort 3 is evaluating detalimogene in patients with high-risk BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS, with 36 enrolled patients as of November 11, 2025). In addition, our preclinical research is focused on expanding the cancer indications that can be treated with detalimogene as well as discovering new opportunities to apply our DDX technology platform to treat other indications with high unmet medical needs.

Our Competitive Strengths

- **Detalimogene Product Candidate Demonstrated Compelling Preliminary Data in Phase 2 of LEGEND** - We are developing detalimogene, which has received FDA Regenerative Medicines Advanced Therapy (RMAT) and Fast Track designations, as a monotherapy for patients with BCG-unresponsive NMIBC with CIS who we believe are underserved with limited FDA-approved treatment options. In addition, the LEGEND study has been selected for the U.S. Food and Drug Administration' ("FDA") Chemistry, Manufacturing, and Controls ("CMC") Development and Readiness Pilot ("CDRP") Program. We have released preliminary data from the pivotal arm of the LEGEND study (Cohort 1) on two occasions; the first occasion in which we released Phase 2 LEGEND Cohort c1 data (cut-off date of September 13, 2024) demonstrated that detalimogene was generally well-tolerated across all patients dosed, with no patients experiencing a Grade 3, 4 or 5 treatment-related adverse event ("TRAE") and no drug-related discontinuations. Based on preliminary data corresponding to the September 13, 2024 data cut-off, detalimogene also demonstrated promising clinical activity. Across 21 patients included in the preliminary data, a 71% complete response rate ("CR" rate) at any time was observed (15/21), along with a 3-month CR rate of 67% (14/21), a 6-month CR rate of 47% (8/17), and a 6-month Kaplan-Meier CR rate estimate of 51%. Our most recent data update (released on November 11, 2025 and reflective of an October 24, 2025 data cut-off) provided an updated view of preliminary activity and tolerability following implementation of a protocol amendment designed to better align LEGEND with the standard of care amongst urological practitioners treating NMIBC with CIS. Among patients treated under the amended protocol, 62% of patients remained in CR at six months after initiation of treatment, with all evaluable patients at nine months also demonstrating continued CR. Detalimogene continued to demonstrate a generally well-tolerated safety profile in Cohort 1, with treatment-related adverse events primarily Grades 1-2 in severity and a limited number of Grade 3 events, and no Grade 4 or Grade 5 TRAEs reported at the time of data cut-off. We believe these updated results illustrate the intended benefits of the protocol amendments.
- **Product Profile Tailored to the Practical Needs of Clinicians and Patients** - Gene therapy and genetic medicines products, such as oncolytic viruses, have historically been associated with specific handling or dosing requirements designed for safety reasons to minimize patient, physician, or environmental exposure or risk. These can include use of enhanced personal protective equipment during preparation and administration, required virucidal decontamination of drug product-exposed bodily fluids, such as urine, after exposure to the genetic medicine product, preparative treatment of tissues with a solvent or wash agent, enhanced refrigeration/cold chain on-site storage requirements, and guidance to avoid close personal contact with the patient during the treatment period. By contrast, we believe detalimogene can be handled in accordance with biosafety level 1 guidelines, should not require the aforementioned precautions in handling or decontamination of fluids or bodily surfaces following dosing when handled in accordance with most institutional or standardized guidelines, and has no ultra cold chain on-site storage requirements. We believe these product characteristics, among others, will position detalimogene, if approved, as a preferred choice among both physicians and patients.
- **"Pipeline-in-a-Product" Potential** - Through the combined data generated in the LEGEND study and corresponding preclinical studies, we have demonstrated that detalimogene is able to traverse the mucosal barrier and transfect the underlying epithelial tissues, drive expression of multiple cargos in transfected tissues, and simultaneously activate multiple arms of the immune system. We have further demonstrated in preclinical models the potential for expanding detalimogene to treat solid tumors.
- **Scalable, Proprietary Manufacturing Process** - We developed the DDX platform in-house, and in addition, have developed manufacturing processes to produce detalimogene that we believe are robust, cost-effective, and scalable. These manufacturing processes, which involve incorporation of plasmid DNA with the DDX carrier at a defined concentration and mixing rate using commercially available equipment, are patent-protected and involve proprietary know-how. We also have a global, royalty-bearing, non-exclusive license to use certain patents and know-how relating to a proprietary plasmid DNA backbone for high-yield production and efficient transgene expression in target tissues. We believe we have scaled up our manufacturing processes to a level that will be able to meet the needs of a potential commercial launch for detalimogene. We believe our manufacturing process is in accordance with current Good Manufacturing Practice (cGMP) and quality system regulations for drugs and biologics.
- **Proprietary "Next-Generation" DDX Platform** - We believe our DDX platform has the potential to be the next-generation platform that takes genetic medicine beyond rare diseases and into the mainstream of patient care for larger disease indications. The platform has a high degree of payload flexibility, including the ability to conveniently deliver multiple genes (including DNA and RNA) in a single drug product, and has been demonstrated in preclinical animal and *in vitro* models to effectively induce expression of therapeutic genes in mucosal tissues following delivery to the urinary tract, lung, and gastrointestinal tract, among other organs, all without integration of the genetic cargo into the host's genomic DNA. We believe products developed using the DDX platform can overcome many of the significant challenges that have historically faced genetic medicines, including immunogenicity, safety concerns, limited efficacy, high cost of goods, lack

of commercially viable manufacturing technology, limited ability to effectively target localized diseases, systemic toxicity, and difficulties with effective administration.

- **Experienced Management Team** - Our management team has extensive experience across oncology, urology and multiple other therapeutic areas and modalities and is well-equipped to lead our drug development and commercialization efforts.

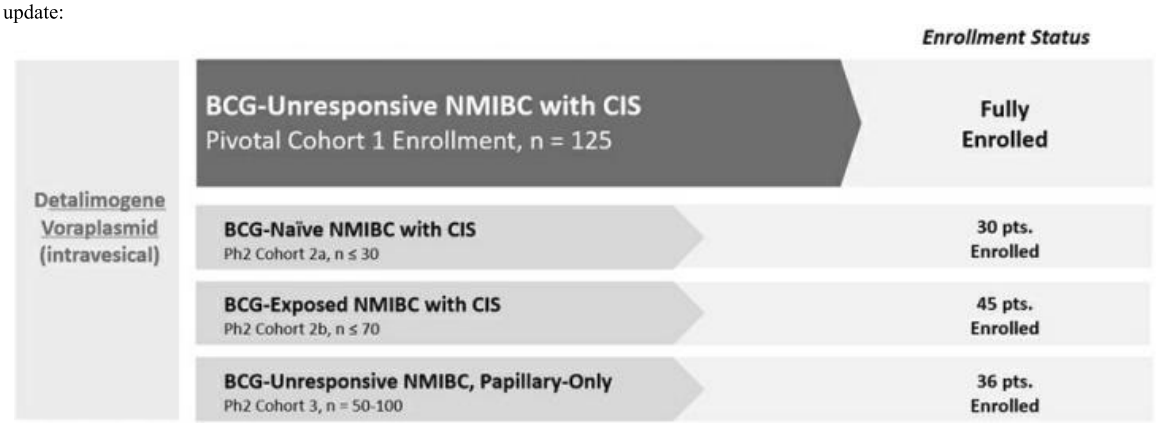
Our Strategy

- **Focus on advancing our lead product candidate detalimogene through late-stage clinical development and seek regulatory marketing approval in the United States**. We are focused on bringing detalimogene to market as a monotherapy for patients with BCG-unresponsive NMIBC with CIS who we believe are currently underserved by the recommended standard-of-care of radical cystectomy, a major surgery that carries a high mortality rate, a reduced quality of life, and other significant negative clinical outcomes. In response to this urgent unmet need, the FDA has issued guidance and subsequently updated and maintained this guidance for the design of clinical studies for development of novel NMIBC treatments for patients with CIS who are unresponsive to BCG, with a goal of encouraging development of alternative treatments to this drastic surgery. We have followed this guidance and discussed our detalimogene development plan with the FDA and, after these discussions, the FDA cleared us to initiate the Phase 2 portion of the LEGEND clinical trial, including the pivotal portion (Cohort 1). We currently plan to file a Biologics License Application ("BLA") with the FDA in the second half of 2026 for approval to market detalimogene in the United States as a monotherapy for BCG-unresponsive NMIBC with CIS, and we believe detalimogene's product profile will integrate seamlessly into community urology clinics where the vast majority of urologists practice.
- **Build a fully integrated company by independently commercializing approved products in indications and key geographies where we believe we can maximize the value of detalimogene and any other product candidates we develop**. We currently own all development and commercialization rights for our detalimogene. To bolster our potential return on investment, we currently plan to retain commercial rights to detalimogene in the United States and to commercialize detalimogene independently, while selectively partnering outside of the United States, with the goal of leveraging a potential partner's regional expertise and existing sales force to the extent appropriate.
- **Explore additional clinical applications of detalimogene within high-risk NMIBC**. Given the persistent high unmet need in high-risk NMIBC outside of the BCG-unresponsive population with CIS, the Phase 2 LEGEND trial is also assessing detalimogene in other indications such as BCG-Naïve NMIBC with CIS, BCG-exposed NMIBC with CIS, and BCG-unresponsive, papillary-only NMIBC.
- **We believe we can potentially develop detalimogene as a treatment for other forms and stages of bladder cancer, including applications within NMIBC and beyond.** For example, we have shown in a murine preclinical orthotopic model of locally advanced bladder cancer that i) administration of detalimogene drives profound and durable anti-tumor immunity, and ii) cured mice exhibit resistance to subsequent local or distal re-challenge with bladder tumor cells due to detalimogene's potentiation of a T-cell mediated response within the adaptive immune system. These preclinical observations support detalimogene's immunostimulatory mechanism of action and speaks to its potential in more aggressive or advanced diseases where the bladder remains intact, such as locally advanced or metastatic bladder cancer. We further believe that to the extent detalimogene proves to be both safe and effective in more aggressive, high-risk NMIBC populations, it also will have the potential for use in earlier stage low- and intermediate-risk NMIBC populations.
- **Apply our proprietary DDX platform to other mucosal tissues**. We believe that our clinical data to date demonstrate the value and breadth of our DDX platform in delivering genetic medicines to mucosal tissues, especially when combined with our preclinical proof-of-concept studies. We believe this could allow us to use our DDX platform to develop safe and effective new agents beyond detalimogene, thereby unlocking better outcomes for historically difficult-to-treat conditions. Our belief is driven by our DDX platform's numerous advantages and points of differentiation relative to other approaches to genetic medicine, which we believe will enable us to apply such medicines beyond their traditional tissues of application such as the liver, muscle, and central nervous system. Importantly, we have also developed a streamlined, end-to-end cGMP manufacturing process that we believe can support commercial launch of detalimogene and can be readily applied to new drug products.

Lead Product Candidate and Pipeline Development

Our lead product candidate is detalimogene voraplasmid, which we are developing as a monotherapy for the treatment of NMIBC via the LEGEND study, a multi-cohort Phase 2 open-label study comprised of single-arm cohorts (ClinicalTrials.gov identifier NCT04752722). Cohort 1 of LEGEND, which has enrolled BCG-unresponsive NMIBC patients with CIS, is pivotal, and we plan to incorporate the data from this study in a BLA that we plan to submit no later than immediately following the conclusion of the Phase 2 portion of Cohort 1. In addition to this pivotal cohort, LEGEND has two additional cohorts and three patient groups: Cohort 2a is evaluating detalimogene in patients with BCG-naïve NMIBC with CIS; Cohort 2b is evaluating detalimogene in patients with BCG-exposed NMIBC with CIS; and Cohort 3 is evaluating detalimogene in patients with BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS).

The following chart shows the enrollment status of each LEGEND cohort as of November 11, 2025, the date of our most recent LEGEND trial update:

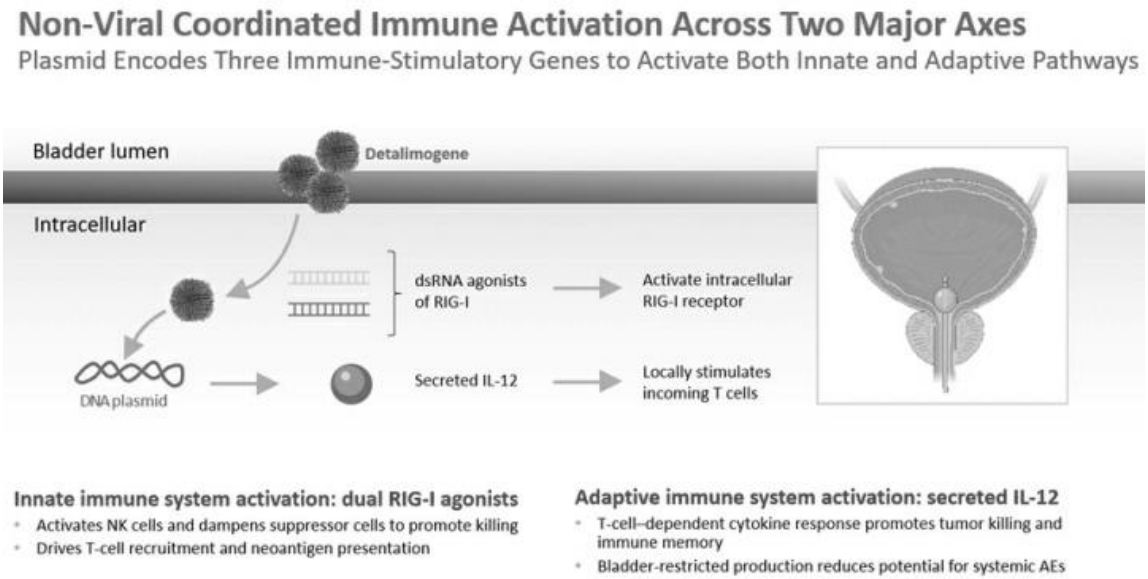


All NMIBC cohorts refer to high-risk NMIBC unless otherwise specified.

Detalimogene voraplasmid Mechanism of action

Detalimogene consists of a small plasmid DNA encapsulated in nanoparticles using enGene's proprietary DDX carrier. These nanoparticles are further coated with a modified polyethylene glycol (PEG) polymer, forming a reversible PEG corona that enhances diffusion through the glycosaminoglycan layer that lines the bladder wall while preserving the particles' potency. Detalimogene is formulated as an aqueous nanoparticle dispersion in mannitol, then filter-sterilized and lyophilized into a dry powder that can be stably stored under standard refrigeration or freezing conditions.

The DDX delivery vehicle is a novel chemical entity proprietary to enGene. It consists of a highly derivatized short-chain chitosan polymer which complexes with DNA to form consistent nanoparticles. The plasmid DNA drug substance encodes three distinct genes: a single-chain interleukin-12 (IL-12) protein and two non-coding RNAs, eRNA11a and VA1, which together activate the retinoic acid-inducible gene I (RIG-I) pathway. The coordinated effects of IL-12 secretion and RIG-I activation stimulate both innate and adaptive immunity, establishing a pro-inflammatory, tumor-killing environment:



Mechanistically, detalimogene's dual RIG-I agonists work by initiating a signaling cascade that results in the production of Type I interferons (IFN) and proinflammatory cytokines upon recognizing certain double stranded RNA molecules typically associated with cellular pathogens. This in turn stimulates a potent inflammatory response that results in direct tumor cell killing, cytokine-mediated activation of innate immune cells, and the recruitment and cross-priming of T cells. Detalimogene's third genetic cargo, IL-12, is an

immunomodulatory cytokine that signals primarily through the IL-12 receptor complex, which is expressed on natural killer (NK), NK-T, and activated effector CD4+ and CD8+ T cells. For these cells, receptor engagement of IL-12 enhances cytotoxicity, e.g., by driving T cell proliferation, polarization to a type 1 helper (Th1) phenotype, and interferon-gamma (IFNγ) production. In summary, the activation of RIG-I is intended to induce an innate immune response that will trigger T cell recruitment and cross-presentation of tumor antigens to T cells through induction of mediators such as C-X-C motif chemokine ligand 10 (CXCL10) and Type I IFNs, respectively. The expression of the IL-12 protein is intended to synergistically augment the anti-tumor activity of indwelling effector T cells. Together, RIG-I agonism and IL-12 receptor stimulation function in a two-step mechanism to recruit and activate immune cells to the tumor microenvironment ("TME"). Importantly, detalimogene does not need to transfect tumor cells specifically to drive the above effects and can exert its anti-tumor effect by transfecting healthy epithelial cells within the tumor or bladder microenvironment. Importantly, we believe restricting expression of IL-12 to the bladder and tumor microenvironment yields meaningful safety advances. This is important as historically, clinical trials using systemic administration of IL-12 to treat various solid malignancies have resulted in severe dose-limiting toxicities, resulting in a marginal therapeutic index. We believe the clinical data observed to date demonstrate that coupling the potent stimulation of the innate immune system by RIG-I agonism and stimulation of the adaptive immune response by IL-12 provides robust and persistent anti-tumor activity.

Lead Program: NMIBC Background and Unmet Need

Disease Background

Bladder cancer represents a serious, life-threatening condition. Based on data reported through 2020, bladder cancer was projected to result in an estimated 2.7% of all cancer deaths in 2023 while comprising an estimated 4.2% of all new cancer cases according to the National Institute of Health. Overall, according to the American Cancer Society and the National Institute of Health, the chance men will develop this cancer during their life is about 1 in 28; for women, the chance is about 1 in 91. Fortunately, due to early warning signals such as hematuria (the presence of blood in the urine), many instances of bladder cancer are diagnosed while still localized to the bladder urothelium. These tumors, referred to as non-muscle invasive bladder cancer (NMIBC), represent approximately 80% of newly diagnosed bladder tumors.

Unmet Medical Need

When diagnosed at the non-muscle invasive stage, the goal of treatment is to prevent further tissue invasion (i.e., into the muscle layers of the bladder or beyond), thereby potentially reducing the intensity of needed treatment regimens (e.g., allowing local/intravesical treatment versus systemic/intravenous treatment), improving disease prognosis, and forestalling surgical bladder removal, if indicated. Since the 1970s, the primary therapy for high-risk NMIBC has been intravesical BCG therapy and/or transurethral resection of bladder tumor surgery (TURBT), despite the adverse effects of both treatment approaches. Due to the increased use of BCG in the high-risk setting and loss of several manufacturers of BCG, supply constraints have resulted in a shortage of BCG for commercial use. To manage the limited supply available in the United States, as of February 2019, the American Urological Association and their collaborative physician groups have introduced rationing guidelines that limit use of BCG to high-risk NMIBC patients only. This situation is projected to continue late into the current decade and has brought urgency to the unmet medical need for effective intravesical treatments for patients with high grade NMIBC, according to the American Urological Association.

We estimate that there are approximately 85,000 new patients each year diagnosed with bladder cancer in the United States, of which up to 80% are initially diagnosed with NMIBC. Within this group, we estimate approximately 30% present with high-risk NMIBC (where risk level describes the risk of disease progression to muscle invasion), 35% present with intermediate-risk disease, and 35% present with low-risk disease. NMIBC lesions are further characterized as CIS, Ta, and T1 based on their physical attributes. Ta and T1 lesions are papillary urothelial carcinomas which have not yet penetrated the muscle wall of the bladder. These tumor types are not mutually exclusive within the bladder; at any given time, an NMIBC patient can have papillary lesions only, CIS and papillary lesions, or CIS lesions only. In general, while most NMIBC patients respond favorably to treatment (e.g., transurethral resection of bladder tumor surgery ("TURBT") and/or treatment with BCG), it is estimated that as many as 60% will experience a recurrence within one year, depending on the patient and tumor characteristics. For patients with BCG-unresponsive NMIBC, standard therapy has been radical cystectomy or treatment with systemic therapy, both of which have been associated with significant toxicities and complications, including a lower quality of life, and increased treatment-related morbidity and mortality. No salvage medical or intravesical treatments have been shown to have durable efficacy in BCG-unresponsive NMIBC patients and therefore, we believe there is an unmet medical need for novel non-systemic therapies to treat these patients. This recurrent population represents a population of patients with a need to keep their cancer from becoming invasive while being able to preserve their bladders.

Importantly, we believe that the frequency of newly incident high-risk NMIBC per year does not fully capture the number of patients living with this disease. This is because there are multiple channels through which a patient previously diagnosed with low- or intermediate-risk NMIBC may, through the course of their treatment and disease evolution, ultimately present with high-risk disease. For example, a patient whose tumor was initially diagnosed and treated as low- or intermediate-risk NMIBC may recur as high-risk NMIBC. Similarly, a patient treated for BCG-unresponsive high-risk NMIBC with CIS may recur a second time with another high-risk NMIBC lesion and be eligible for another round of treatment. Thus, we believe that the real-world high-risk NMIBC burden is best understood as a combination of both incident and prevalent disease. Unfortunately, for individuals with BCG-unresponsive NMIBC

with CIS, which represents the focus of LEGEND's pivotal cohort, FDA-approved non-surgical treatment options are few in number and each suffer from significant limitations.

Study Design

LEGEND is a Phase 1/2, open-label, multicenter global study with a pivotal Phase 2 study cohort focused on adult patients with NMIBC with CIS who have failed BCG therapy. The study consists of two phases, beginning with a (completed) Dose-Escalation Phase (Phase 1). The key objective for the Phase 1 portion of the study was evaluation of safety and tolerability and selection of a dose for the Phase 2 portion, and it was not designed to evaluate efficacy in a statistically meaningful way. While not statistically powered for efficacy, an evaluation of efficacy was a secondary objective, with a Phase 2 study to be conducted at the recommended dose. Eligible patients with BCG-unresponsive NMIBC with CIS were enrolled in Phase 1 and additional patients meeting these criteria were enrolled in Cohort 1 of Phase 2, which has now completed enrollment.

In addition to the pivotal cohort 1, the Phase 2 portion of LEGEND has two additional cohorts: Cohort 2 is evaluating detalimogene in patients with BCG-naïve NMIBC patients with CIS (Cohort 2a) and BCG-exposed NMIBC patients with CIS (Cohort 2b); and Cohort 3 is evaluating detalimogene in patients with BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS).

Phase 1

The Phase 1 portion of the study was an open-label, multi-dose study designed to evaluate the safety of detalimogene in high-risk BCG-unresponsive NMIBC patients with CIS, with or without co-occurring papillary disease, and to help determine an appropriate dose for the Phase 2 portion of LEGEND. This study enrolled a total of 24 patients across multiple dose groups.

Phase 1 Study Design

All patients in Phase 1 received at least one cycle of treatment with detalimogene. A cycle is 12 weeks or approximately three months in duration, which corresponds to the exploratory three-month efficacy endpoint of the Phase 1 study (see below). Those patients who experience CR or stable disease ("SD") at the end of the first three-month treatment cycle could (in association and consultation with their physician) optionally elect to continue receiving treatment for up to a total of four cycles, provided they did not have progressive disease ("PD") on evaluation for response at the end of each cycle. Patients who complete cycle 1 and the additional 3 cycles without PD are followed until PD or for approximately 2 years following their End-of-Treatment Visit, whichever occurs first. In general, we use the terminology "3-month," "6-month," "9-month," and "12-month" timepoint to refer to 12-week, 24-week, 36-week, and 48-week timepoints, respectively. We use these terms interchangeably.

Phase 1 Study Endpoints

The primary endpoint of the Phase 1 study was safety (i.e., characterizing the nature, incidence, relatedness and severity of all observed adverse events ("AEs") and severe adverse events ("SAEs")), with complete response at 3 months and pharmacodynamics of biomarkers assessed as exploratory endpoints.

Phase 1 Results: Safety

Twenty-four patients received at least one dose of detalimogene in the Phase 1 study, with the total number of treatment-related adverse events (TRAEs) and most commonly reported TRAEs across all 24 patients defined in the table below. The majority (75%) of TRAEs experienced by patients were Grade 1 or 2 and largely consistent with the same events seen with instrumentation, catheterization, and instillation of any intravesical agent. One Grade 3 TRAE was observed in Phase 1. However, on review, it was observed that the patient had a history of renal failure and recurrent obstructive uropathy prior to treatment that was present at screening, and the enrollment criteria for LEGEND were subsequently modified to exclude patients with similar medical history. There was no association between the severity or incidence of AEs and the dose level. In addition, TRAEs were not more frequent or severe in later cycles of dosing. The following table summarizes the Phase 1 safety results.

(n= 24)	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
Patients with ≥ 1 TRAE	**13 (54.2%)**	**11 (45.8%)**	**6 (25.0%)**	**1 (4.2%)***	**0 (0)**
TRAE Reported in >10% patients:					
Dysuria	**3 (12.5%)**	**3 (12.5%)**	**0 (0)**	**0 (0)**	**0 (0)**
Haematuria	**3 (12.5%)**	**3 (12.5%)**	**0 (0)**	**0 (0)**	**0 (0)**
Micturition Urgency	**4 (16.7%)**	**3 (12.5%)**	**1 (4.2%)**	**0 (0)**	**0 (0)**
Urinary Tract Infection	**3 (12.5%)**	**0 (0)**	**3 (12.5%)**	**0 (0)**	**0 (0)**

Phase 1 Results: Efficacy

Efficacy at 3 months was assessed by the standard three-criteria efficacy evaluation used for NMIBC, namely urinary cytology, cystoscopic appearance (i.e., an inspection with a cystoscope-a thin tube with video camera that is inserted into the bladder), and biopsy results of suspicious areas. Biopsies in the former area of CIS were required even if the appearance was normal. In Phase 1, patients without progressive disease were allowed to electively continue study drug after the 3-month visit. In total, 22 patients were dosed with the study drug and evaluable for efficacy at the 3-month visit. One patient included in evaluations for safety evaluation was excluded from efficacy.

Patients: BCG-Unresponsive, High-risk NMIBC with Cis

Dosing: 2 or 4 doses in 12-week cycle

Cohorts: 3+3 dose escalation (4 dose levels)

Endpoints: 1° - Safety; 2° - Efficacy

All Dose Groups (N = 22)	CR Rate (%)
Anytime	73%
3 Months	68%
6 Months	45%
Phase 2 Dose (n = 10)	
3 Months	70%
6 Months	60%

Overall, across all doses, patients dosed with detalimogene achieved a CR, corresponding to a CR rate at any time of 73%. At the 3-month timepoint, this CR rate was 68%, with 82% of patients continuing to receive additional doses of the study drug beyond 3 months. The 6-month CR rate across all doses was 45%. Within the dose selected for the pivotal portion of the study, the CR rates at 3 and 6 months were 70% and 60%, respectively, with 90% of patients continuing on the study drug beyond 3 months.

Phase 2 Study Design

The Phase 2 portion of the study is open-label and is comprised of three independent single arm cohorts of patients. Cohort 1, the pivotal cohort, enrolled 125 patients with high-risk BCG-unresponsive NMIBC with CIS, with or without co-occurring papillary disease. Cohort 2 is evaluating detalimogene in high-risk, BCG-naïve NMIBC patients with CIS (Cohort 2a) or high-risk BCG-exposed NMIBC patients with CIS (Cohort 2b). Cohort 3 is evaluating detalimogene in high-risk BCG-unresponsive papillary only NMIBC patients. Although the treatment is the same for each cohort, an independent set of analysis will occur for each cohort. As of November 11, 2025, Cohorts 2a, 2b, and 3 had enrolled 30 patients, 45 patients, and 36 patients, respectively.

In Phase 2, treatment cycles are 12 weeks in duration and dosing occurs at weeks 1, 2, 5 and 6 of each 12-week cycle. Patients are administered 800µg/ml intravesically at each dosing. In addition to urine cytology and cystoscopic inspection, a bladder mapping biopsy to confirm a CR is required at the 12-month evaluation.

For all subsequent evaluation cycles beyond week 12 (e.g., weeks 24, 36, 48, and beyond), the presence of any high-risk tumor in the bladder will render a patient ineligible to continue on-study. More specifically, (i) patients with no evidence of high-risk tumor will be classified as in CR, remain on-study, and enter the next 12-week course of therapy as specified in the protocol, whereas (ii) patients with biopsy-confirmed evidence of CIS, high-risk Ta, or high-risk T1 disease or greater will be classified as non-CR and will discontinue the study. Patients who remain in CR at week 48 will enter maintenance treatment for up to four 12-week cycles through week 96. Maintenance treatment will consist of 2 detalimogene instillations per 12-week cycle, administered at week 1 and at week 2. Patients in CR at the end of the 8 cycles (week 96) can choose to continue in maintenance treatment for up to 4 more cycles (through week 144) or enter a follow-up period for quarterly visits (every 12 weeks) through week 144 or until non-response.

Phase 2 Study Endpoints

In the second half of 2025, following discussions with FDA, the Company announced the primary endpoint for Cohort 1 will change to percentage of patients with CR at any time, based on cystoscopic exam, urine cytology, and biopsies, from its previous primary endpoint of landmark CR rate at 48 weeks. This updated primary endpoint is consistent with recently approved products for BCG-unresponsive NMIBC registered with FDA. Key secondary endpoints include duration of response of the responding patients and percentage of patients with duration of response ≥1 year, CR rates at landmark timepoints, progression-free survival, and cystectomy-free survival.

Phase 2 Study: Preliminary Efficacy

On September 26, 2024, we shared preliminary data from the first 21 patients who had reached their 12-week evaluation in the ongoing pivotal cohort of the LEGEND study, including 17 patients who were also assessed at six months. The CR rate at any time was 71%, the CR rate at three months was 67% and the CR rate at six months was 47% (Kaplan Meier estimate of 51%). The data cut-off date was September 13, 2024.

Phase 2 Study: Preliminary Safety

Detalimogene's overall tolerability profile as presented in September 2024 was favorable, and there were no drug-related discontinuations in the study as of this date. Of the 42 patients assessed for safety, inclusive of all Phase 2 cohorts, 48% experienced at least one treatment-related adverse event (TRAE), which were mainly Grade 1/2 in severity. The most common TRAEs were dysuria (21.4%), bladder spasm (19%), pollakiuria (11.9%) and fatigue (11.9%). There were no Grade 4 or Grade 5 TRAEs reported.

Phase 2 Study: Protocol Amendment

In conjunction with the preliminary data presented on September 26, 2024, we announced an important amendment to the LEGEND Phase 2 protocol that, among other changes, modified how patients are evaluated and treated at key points during the trial. The amended LEGEND protocol stipulates that patients who present with CIS plus T1 disease at screening must undergo an initial TURBT to remove the T1 lesion, followed by a secondary resection at the lesion site. Should residual T1 disease be present following the second resection, the patient is ineligible to enter the LEGEND trial. Regarding patient assessment at the end of the first 12-week cycle, patients will be evaluated as follows: (i) patients with no evidence of high-risk tumor will be classified as being in CR, will remain on-study, and will enter the next 12-week course of therapy; (ii) patients with disease that has not responded to therapy but not progressed in stage will be classified as not in CR, will have any papillary lesions resected via TURBT, will remain on-study, and will enter the next 12-week course of therapy; and (iii) patients with disease that has progressed in stage will be required to come off-study. If a patient is suspected of having persistent or recurrent disease at 6 months, or recurrent disease at 9 months, biopsy confirmation is required to remove a patient from the study.

Protocol Changes	Prior LEGEND Protocol	*Current LEGEND Protocol*
T1 disease at pre-enrollment screen	• Surgically resect lesion via TURBT • Enroll patient	• *Perform 2nd resection at lesion site and restage* • If residual T1 disease present, patient ineligible
Ta disease detected at 3 months	• Response deemed "Progressive Disease" • Discontinue patient from study	• Surgically resect lesion via TURBT • *Re-induce patient with detalimogene*
Assessment of Suspected CIS or other disease	• Patient may be discontinued from study based only on visual impression of CIS	• *Discontinuation requires biopsy confirmation* of disease

Phase 2 Study: Updated Preliminary Efficacy

On November 11, 2025, the Company announced updated preliminary efficacy data from two patient subpopulations of the intent-to-treat ("ITT") patient population of Cohort 1, which the Company defines as of (i) patients who received at least one dose of detalimogene and had at least one post-baseline disease assessment and were enrolled prior to the amendment of the protocol in the fourth quarter of 2024 (the "Pre-Protocol Amendment Patients") and (ii) patients who received at least one dose of detalimogene and had at least one post-baseline disease assessment and were enrolled following the amendment of the protocol in the fourth quarter of 2024 (the "Post-Protocol Amendment Patients"). As of October 24, 2025, the ITT population consisted of 31 Pre-Protocol Amendment Patients and 62 Post-Protocol Amendment Patients. An additional 10 patients who were enrolled prior to the protocol amendment in the fourth quarter of 2024 were included in the updated data for the Pre-Protocol Amendment Patient subpopulation. The table below summarizes preliminary efficacy results from the two separate patient subpopulations:

Post-Protocol Amendment

N=62 as of Oct. 2025		Any Time (N=62)	3 Month (N=62)	6 Month (N=37)**
ITT Population*	CR Rate	63% (CI: 51-74)	56% (CI: 44-68)	62% (CI: 46-76)
			KM Estimate	63%

Pre-Protocol Amendment

N=31 as of Oct. 2025		Any Time (N=31)	3 Month (N=31)	6 Month (N=27)**
ITT Population*	CR Rate	55% (CI: 38-71)	55% (CI: 38-71)	41% (CI: 25-59)
			KM Estimate	42%

Data as of October 24, 2025.
* ITT: Intent-To-Treat population includes all Pre-Protocol Amendment Patients and Post-Protocol Amendment Patients, respectively, who received at least 1 dose of treatment and had at least 1 post-baseline disease assessment.
** CR rates at 6 months include only patients who were evaluable at the 6-month timepoint or had disease progression prior to the 6-month assessment.
CI: 95% Confidence Interval

The preliminary efficacy data for Pre-Protocol Amendment Patients demonstrated a markedly lower 12-month CR rate than those of FDA-approved products for BCG-unresponsive NMIBC patients.

Among the Post-Protocol Amendment Patients, four patients that did not have a CR at the 3-month assessment converted to a CR at the 6-month assessment. In addition, of the 23 patients in this subpopulation that had a CR at the 6-month assessment, five patients remained in CR at the 9-month assessment, 17 patients were pending their 9-month assessment and one patient dropped out of the study prior to the 9-month assessment.

Phase 2 Study: Preliminary Safety Update

Detalimogene's overall tolerability profile was favorable. Of the 125 patients assessed for safety in Cohort 1, as of October 24, 2025, 42% experienced at least one TRAE, which were mainly Grade 1/2 in severity, except for three patients (2.4%) that experienced Grade 3 TRAEs. The following table contains an overview of this preliminary safety data:

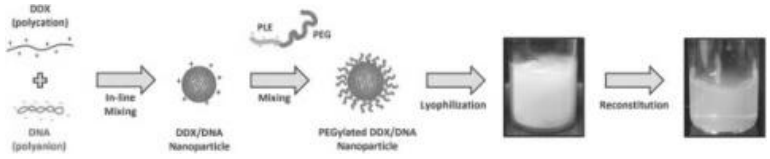
	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
Patients with ≥ 1 TRAE	**53 (42.4%)**	**47 (37.6%)**	**23 (18.4%)**	**3 (2.4%)***	**0 (0)**
TRAE Reported in >10% patients:					
Bladder Spasm	**13 (10.4%)**	**7 (5.6%)**	**7 (5.6%)**	**0 (0)**	**0 (0)**
Dysuria	**15 (12.0%)**	**14 (11.2%)**	**1 (0.8%)**	**0 (0)**	**0 (0)**
Fatigue	**21 (16.8%)**	**19 (15.2%)**	**2 (1.6%)**	**0 (0)**	**0 (0)**
Micturition urgency	**13 (10.4%)**	**8 (6.4%)**	**5 (4.0%)**	**0 (0)**	**0 (0)**
Pollakiuria	**13 (10.4%)**	**9 (7.2%)**	**4 (3.2%)**	**0 (0)**	**0 (0)**

TRAEs Leading to	Dose Interruptions	Dose Discontinuations
	2 (1.6%)	1 (0.8%)

* 2 patients experienced urinary tract infection, 1 experienced pyelonephritis.
Data as of October 24, 2025; Data collection and cleaning is ongoing, TRAE = Treatment-Related Adverse Event.

Detalimogene voraplasmid: Design and Mechanism of Action

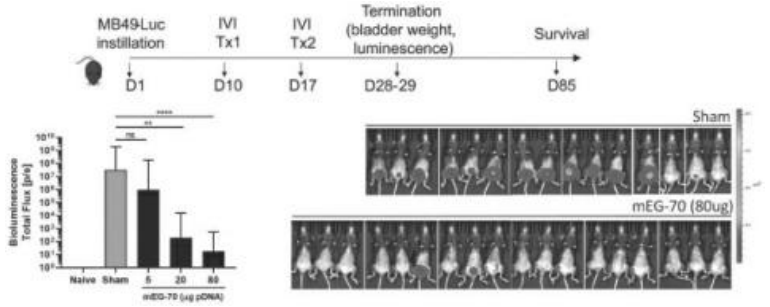
Detalimogene contains a non-integrative plasmid DNA (pDNA) packaged in our proprietary DDX delivery platform that is further combined with the excipient polyethylene glycol-b-poly-L-glutamic acid (PEG-b-PLE), a di-block co-polymer



The pDNA component of detalimogene encodes the two linked subunits (p40 and p35) of the human (h) IL-12 cytokine. Also encoded within the same plasmid are two RNA products (adenoviral VA RNA1 (VA1) and eRNA11a; annotated together as eRNA41H) that coordinate to activate RIG-I. The dsRNA directly agonizes the intracellular protein RIG-I, while VA1 is an inhibitor of adenosine deaminase acting on RNA (ADAR), an RNA editing enzyme, and the double-stranded RNA-dependent protein kinase (PKR), a protein translation inhibitor. Together, VA1 and eRNA11a synergistically boost RIG-I activity.

Analysis of intravesical mEG-70 treatment in an orthotopic bladder cancer model

To evaluate the therapeutic benefit of detalimogene preclinically, an orthotopic model of murine bladder cancer was established by implanting syngeneic MB49 urothelial carcinoma cells that stably express luciferase (MB49luc) into murine bladders. Baseline tumor burden was confirmed by bioluminescence using in vivo imaging before two weekly IVI of mEG-70, a murine-reactive surrogate for detalimogene voraplasmid, with the study design captured in the top panel of the figure below. mEG-70 mediated a dose-dependent reduction of pre-existing tumor burden as evidenced by diminished bioluminescent signal on Day 29 of the study. Note in the figure below, the right panel displays individual animals, with the color scale indicating the intensity of the tumor signal, from blue (lowest) to red (highest), and areas without color indicating a lack of tumor. The graph on the left displays the geometric mean across all animals, ± 95% confidence interval.

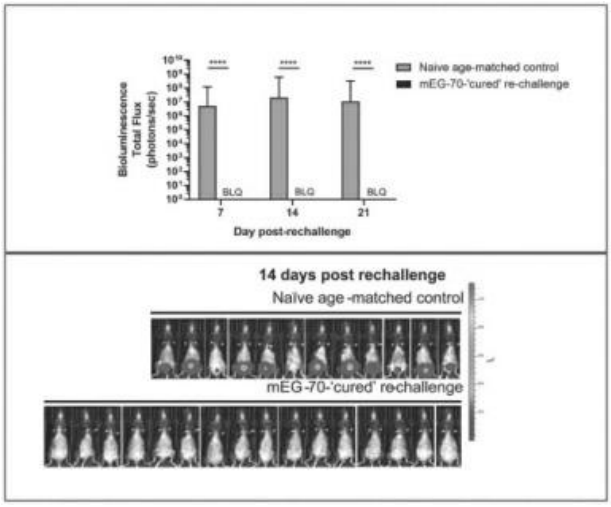


We further examined the durability of the anti-tumor response by monitoring long-term survival until all mice succumbed to bladder cancer or were deemed cured, which was defined as no evidence of bioluminescent signal with no clinical signs of bladder cancer, including palpable bladder mass and hematuria. Over 90% of mice treated with mEG-70 had durable anti-tumor responses as demonstrated by long-term disease-free survival with no disease relapse during the 100-day monitoring period. In contrast, about 90% of sham-treated animals had succumbed to disease during the same period. We believe these data demonstrate the rapid, robust, and durable anti-tumor effects of mEG-70 in the orthotopic model of bladder cancer.

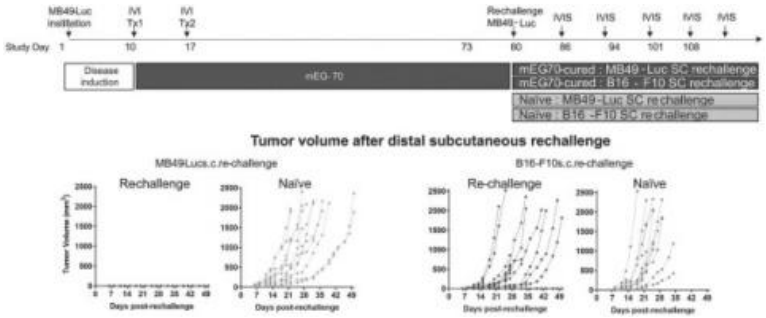
Long-term effects, immunological memory, and systemic immunity mediated by mEG-70

We believe that the long-term survival benefit and lack of relapse in mEG-70-treated animals suggested that immunological memory may have been established. To further explore this, we examined protective immunity against tumor re-challenge, wherein mEG-70-treated mice with complete disease regression and no relapse (‘mEG-70-cured’) were re-challenged orthotopically with MB49luc cells to assess protection from recurring disease. All mEG-70-cured mice were resistant to tumor recurrence, as shown by negative bioluminescence signal up to 3 weeks after re-challenge. In contrast, indicative of tumor burden, all age-matched naïve controls had positive bioluminescence signal following cell implantation (figure below; bottom panel displays luminescence from each individual animal reflecting tumor burden from luciferase expression with the color scale indicating the intensity of the tumor signal, from blue

(lowest) to red (highest), and areas without color indicating a lack of tumor; top panel reflects geometric means ± 95% confidence interval).



As shown in the figure below, to determine if local treatment to the bladder results in systemic anti-tumor immunity, mice cured of orthotopic bladder cancer by mEG-70 were challenged with MB49luc cells subcutaneously on the flank and tumor growth was monitored. Although age-matched naïve controls showed rapid tumor growth, all mEG-70-cured mice remained tumor free up to 50 days post-rechallenge. To investigate whether the abscopal anti-tumor immunity was specific to MB49luc cells, a separate cohort of mice was re-challenged with antigenically distinct melanoma tumor cells (B16-F10). Although mEG-70-cured mice were resistant to re-challenge with MB49luc cells, the B16-F10 tumors grew on the mouse flank, suggesting that long-term anti-tumor effect is antigen-driven and specific to the primary tumor.



Other Bladder Cancer Indications

Our preclinical data package utilizes the MB49 cancer cell line, which, when instilled into the bladder of a mouse, can generate tumors reflective of muscle invasive bladder cancer. We believe that the preclinical data we have gathered using this murine model system, especially the data suggesting mEG-70 drives a potent immune memory effect that renders the host resistant to tumor re-challenge, could potentially support the use of detalimogene in other forms of bladder cancer, such as muscle invasive disease, as well as other forms of NMIBC such as intermediate-risk disease.

Commercialization Strategy

In accordance with our clinical development plan, we are planning to file a BLA for detalimogene for the treatment of NMIBC patients who are BCG-unresponsive with CIS in the second half of 2026 based on the expected Phase 2 results from the pivotal cohort of the LEGEND study, if the results support filing. If the FDA grants us marketing approval for detalimogene in the United States, we currently plan to commercialize detalimogene in the United States ourselves. Our current plan is to establish a U.S.-focused sales and marketing organization to coordinate with high-prescribing community urology centers in the United States. As part of our commercialization strategy, our plan is to also establish a specialty urologic medical science liaison team to support scientific exchange

with and education of physicians and scientists about detalimogene. To proactively support these efforts, we will seek to continue expanding our relationships with key opinion leaders as well as our trial investigators while expanding physician and patient education about the potential benefits of detalimogene versus alternative therapies. We have not yet determined our commercialization strategy outside of the United States.

Manufacture and Supply

Detalimogene voraplasmid is a nanoparticle suspension containing the plasmid deoxyribonucleic acid (pDNA) drug substance encapsulated in a proprietary polymer, DDX, and further combined with a custom-manufactured methoxy-poly(ethylene glycol)-block-poly(L-glutamic acid) diblock co-polymer (abbreviated as PEG-b-PLE). DDX and PEG-b-PLE are novel excipients. The drug product is formulated as an aqueous nanoparticle dispersion, filter sterilized, lyophilized to a dry powder, and stored at -20°C.

We do not currently own or operate any manufacturing facilities for the clinical or commercial production of drug product.

We have leveraged our internal expertise and know-how to develop and scale up the manufacturing processes for our proprietary DDX and drug product before transferring them to qualified external contract manufacturers or contract manufacturing organizations ("CMO"). Additionally, we are conducting studies to understand and establish controls for all critical process parameters and critical quality attributes for our drug product. The PEG-b-PLE excipient and pDNA drug substance are custom manufactured and purchased from qualified cGMP manufacturers located in the European Union. All critical excipients, drug substance and drug product are currently manufactured at cGMP-compliant CMOs at a scale that we believe can meet our needs for a commercial launch of detalimogene for the BCG-unresponsive NIMBC indication in the United States if approved by the FDA.

We believe that our manufacturing processes are robust, cost-effective and scalable. These manufacturing processes are patent-protected and involve significant proprietary know-how. We also have a global, royalty-bearing, non-exclusive license to use certain patents and know-how relating to a proprietary plasmid DNA backbone for high-yield production and efficient expression of transgene in target tissues. Our manufacturing process is in accordance with current Good Manufacturing Practice (cGMP) and quality system regulations for drugs and biologics.

We currently rely on our commercial relationships with independent CMOs to supply our clinical trials. We have performed detailed quality audits in the past and will continue to conduct periodic quality audits of their facilities per existing quality agreements. We believe that our suppliers will be capable of providing sufficient quantities of each component to meet our clinical trial supply needs, as well as our commercial launch within the United States if and when approved by the FDA. We have supply agreements in place with multiple CMOs to support manufacturing, release testing, stability analysis, clinical labeling and packaging of detalimogene for the Phase 2 portion of the LEGEND study. We plan to enter into long term commercial supply agreements with selected qualified CMOs to supply detalimogene in the event that we are granted marketing approval in the United States. Other CMOs may be used in the future for commercial manufacturing.

Intellectual Property

Our commercial success depends in part on our ability to protect, obtain, enforce and maintain exclusivity around our gene delivery technology and product candidates through intellectual property protection, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary rights.

We strive to protect, maintain, enforce and enhance the proprietary technology, inventions and improvements that are commercially material to our business, including by seeking, maintaining and defending our patent rights. We have and are expecting to maintain granted patents, and we continue to file and prosecute patent applications directed to our modified oligomeric chitosan-based nanoparticle gene delivery technology independently or in combination with therapeutic genes in an effort to establish intellectual property positions relating to new compositions of matter and novel treatments of various indications.

We also rely, in part, on trade secrets and know-how to maintain exclusivity to our technology. We strive to protect our proprietary information that is not covered by registered intellectual property instruments by entering into confidentiality and invention assignment agreements with employees, collaborators and consultants. While protecting trade secrets and know-how presents challenges due to, for example, movement of personnel and the natural evolution of the knowledge in the field of our technology over time, we strive to actively manage exchanges of information with third parties to minimize the risks of dissemination.

Patent Portfolio

Our patent portfolio includes composition of matter, method of treatment and manufacturing process protection for our lead product candidate detalimogene. We have taken a multi-tiered approach to our patent strategy, and in doing so we have captured a series of sequential technical developments leading to and incorporated within detalimogene.

- First, as of October 31, 2025, we own two patent families comprising seven granted U.S. patents, two pending U.S. non-provisional applications, and 85 corresponding granted foreign patents and pending foreign patent applications in jurisdictions including Australia, Brazil, Canada, China, Eurasian Patent Organization, the European Patent Office, Austria, Belgium, Switzerland, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hong Kong, Hungary, Ireland, Italy, Luxembourg, Latvia, Macedonia, Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Slovakia, Turkey, Israel, India, Japan, Philippines, Republic of Korea, Mexico, New Zealand, Singapore and South Africa with claims directed to the dual-derivatization scheme that constitutes the core of our DDX-based gene delivery platform, including granted and pending composition of matter claims relating to the nature of the hydrophilic polyol used in the dual derivatization scheme, as well as methods of use and treatment. The U.S. and foreign patents directed to this subject matter will expire between 2033 and 2034, absent any applicable patent term extension or patent term adjustment.
- Second, as of October 31, 2025, we own one patent family comprising one U.S. non-provisional application and 15 corresponding granted foreign patents and pending foreign patent applications pending in jurisdictions including Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore and South Africa with claims directed to the non-covalent, reversible coating of our nanoparticle technology for enhanced delivery, which enhances transfection and gene expression in detalimogene. The pending claims include compositions of matter and methods of use, and the patents issuing from this patent family will expire in 2040, absent any applicable patent term extension or patent term adjustment.
- Third, as of October 31, 2025, we own one patent family comprising one U.S. non-provisional application and 15 corresponding foreign patent applications pending in jurisdictions including Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore and South Africa with claims directed to the unique combination of immunological cargos, IL-12 and RIG-1 agonists, that are delivered in detalimogene, including composition of matter claims relating to alternatives to our RIG-I agonists, as well as methods of using same in the treatment of mucosal cancers. The patents issuing from this patent family, if any, will also expire in 2040, absent any applicable patent term extension or patent term adjustment.
- Fourth, as of October 31, 2025, we own one patent family comprising one granted U.S. patent, one pending U.S. non-provisional application, and six corresponding granted foreign patents and pending foreign patent applications in jurisdictions including Australia, Canada, China, the European Patent Office, Israel and Japan with claims directed to the use of our chitosan-based nanoparticle gene delivery technology in the treatment of various inflammatory gut disorders. The patents issuing from this patent family will expire in 2037, absent any applicable patent term extension or patent term adjustment. In this patent family, U.S. Patent No. 11,603,398 received a patent term adjustment of 154 days thereby extending the expiry date to at least April 12, 2038.
- Fifth, as of October 31, 2025, we own one patent family comprising one U.S. non-provisional application and four corresponding foreign patent applications pending in jurisdictions including Australia, Canada, the European Patent Office and Hong Kong with claims directed to the use of our chitosan-based nanoparticle gene delivery technology in the treatment of various lung disorders. The patents issuing from this patent family, if any, will expire in 2041, absent any applicable patent term extension or patent term adjustment.
- Sixth, as of October 31, 2025, we own one patent family comprising one U.S. non-provisional application and 15 corresponding foreign patent applications pending in jurisdictions including Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore and South Africa with claims directed to the use of detalimogene in the treatment of various metastatic cancers, based on data obtained in one of the cancer models. The patents issuing from this patent family, if any, will expire in 2042, absent any applicable patent term extension or patent term adjustment.
- Seventh, as of October 31, 2025, we own one patent family comprising two granted U.S. patents and corresponding granted foreign patents in jurisdictions including Australia, the European Patent Office, Belgium, Switzerland, Germany, France, United Kingdom, Ireland, Liechtenstein, Netherlands, Hong Kong, and New Zealand with claims directed to the use of low molecular weight chitosan in oral gene delivery, including composition of matter and method of use claims. The US and foreign patents directed to this subject matter will generally expire in 2027, absent any applicable patent term extension or patent term adjustment. In this patent family, U.S. Patent No. 8,846,102 received a patent term adjustment of 1737 days thereby extending the expiry date to at least December 31, 2031, and U.S. Patent No. 9,404,088 received a patent term adjustment of 736 days thereby extending the expiry date to at least April 4, 2029.
- Eighth, as of October 31, 2025, we own one patent family comprising three granted U.S. patents and 28 corresponding granted foreign patents in jurisdictions including Australia, Canada, China, the European Patent Office, Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Ireland, Iceland, Italy, Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Hong Kong, Israel, Japan, Republic of Korea, Mexico, India and Singapore with claims

directed to certain methods of manufacturing our nanoparticles, including composition of matter, methods of making, and product-by-process claims. The US and foreign patents directed to this subject matter will expire in 2028, absent any applicable patent term extension or patent term adjustment. In this patent family, U.S. Patent No. 8,722,646 received a patent term adjustment of 327 days thereby extending the expiry date to at least August 19, 2029.

- Ninth, as of October 31, 2025, we have one pending PCT application directed to the optimized clinical treatment protocol for detalimogene in the treatment of bladder cancer, based on the LEGEND study (NCT04752722). The patents issuing from this patent family, if any, will expire in 2044, absent any applicable patent term extension or patent term adjustment.
- Tenth, as of October 31, 2025, we have one pending U.S. provisional application directed to improved compositions and methods for expressing genetic medicines in the bladder. The patents issuing from this patent family, if any, will expire in 2046, absent any applicable patent term extension or patent term adjustment.
- Finally, as of October 31, 2025, we have one pending U.S. provisional application directed to the treatment of bladder cancer with immunomodulatory antibodies. The patents issuing from this patent family, if any, will expire in 2046, absent any applicable patent term extension or patent term adjustment.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional patent application to which priority is claimed. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years beyond the expiration of the patent under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. There is no guarantee that the applicable authorities will agree with our assessment of whether any extensions should be granted, and if granted, the length of these extensions.

Our general filing strategy regarding registrable intellectual property is to seek patent protection in major markets. For example, our core DDX-based gene delivery technology is protected by issued patents in the United States, Europe (with country coverage within Europe), Japan, China, Hong Kong, India, Eurasia, South Korea, Canada, Australia, New Zealand, Brazil, Mexico and several other jurisdictions. Our filing strategy typically involves the filing of an international PCT patent application followed by national filings in specific countries. The selection of countries is made on a case-by-case basis.

Our patent portfolio currently comprises eleven patent families, which include approximately 135 issued patents and 64 pending patent applications, including 13 issued U.S. patents, four issued European patents (with country coverage within Europe), seven non-provisional pending U.S. applications, six European pending applications, one pending PCT application, and two pending U.S. provisional applications. enGene exclusively owns all eleven patent families in its patent portfolio.

The patent positions of companies like us are generally uncertain and involve complex legal, scientific, and factual questions. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents or will be commercially useful in protecting our commercial products and methods of using and manufacturing the same. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold or control may be challenged, circumvented or invalidated by third parties. In addition, our agreements and security measures protecting our trade secrets and know-how may be breached, and we may not have adequate remedies for any such breach. Further, our trade secrets may otherwise become known or independently discovered by competitors.

See "*Risk Factors-Risks Related to Our Intellectual Property"* for important information about risk related to our intellectual property.

Strategic License Agreement

On April 10, 2020, we entered into a non-exclusive license agreement (the "License Agreement") with Nature Technology Corporation ("NTC") pursuant to which NTC granted enGene a worldwide non-exclusive, royalty-bearing and sublicensable license to

certain patents and know-how relating to the Nanoplasmid™ vector backbone that is used in detalimogene voraplasmid to research, develop, make, use, import, sell and offer to sell, any gene and cell therapy products incorporating the Nanoplasmid™ vector backbone (excluding any such products in the field of dermatology). The licensed intellectual property includes 10 patent families (inclusive of all related divisional, continuation, continuation-in part, substitutes, counterparts and/or any foreign equivalents filed in any country within such family) and certain know-how. NTC is solely responsible for the preparation, filing, prosecution, cost and maintenance of all patent applications and patents included in the licensed intellectual property.

Unless terminated earlier, the License Agreement will continue until no valid claim of any licensed patent exists in any country. NTC may terminate the License Agreement if we fail to make any payments within a specified period after receiving written notice of such failure. Either party may terminate the License Agreement in the event either party commits a material breach and fails to cure such breach within a certain period. We can terminate the License Agreement for convenience with prior notice to NTC.

Under the License Agreement, we are obligated to make annual payments of $50 thousand until the first sale of a product for which a royalty is due and make a payment to NTC of $50 thousand upon assigning the License Agreement to a third-party. We are also required to make a one-time payment of $50 thousand for the first dose of a product covered by a valid claim of a licensed patent (a “Milestone Product”) in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a Milestone Product by the FDA. The first milestone related to the first dose of a Milestone Product was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a Milestone Product, has not been achieved as of the year ended October 31, 2025. We are also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by us, our affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the License Agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country. In the event that we or any of our affiliates or sublicensees manufacture any GMP lot of a licensed product, then we or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. Such manufacturing payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory. Under the License Agreement, enGene is permitted to sublicense our rights to third parties and we are not required to share any of the license revenue with NTC.

NTC was acquired by Aldevron, LLC in January 2022. The terms of the existing License Agreement described above remained the same. See "*Notes to the Financial Statements - Note 7, License Agreement and Clinical Research Organization*" for additional information about the License Agreement.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid innovation of new technologies, fierce competition, and strong defense of intellectual property. While we believe that detalimogene and our knowledge, experience and scientific resources provide us with competitive advantages, we may face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among other things.

Many of our competitors, either independently or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval for treatments and achieving widespread market acceptance. Merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be substantially limited if our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than products we may develop. In geographic locations that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of other drugs. The key competitive factors affecting the success of any products we may develop are likely to be their efficacy, safety, convenience, price and availability of reimbursement.

There are five FDA-approved products for the treatment of high risk NMIBC patients that are unresponsive to BCG, and multiple companies have therapies in clinical development for such treatment. While many of these products are neither intravesical nor monotherapy, they may nonetheless compete with us for patient recruitment in clinical trials as well as for commercial sales, if detalimogene is approved. Furthermore, to the extent Merck & Co. (“Merck”) or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as detalimogene in BCG-naïve or BCG-exposed patients. In addition, there are numerous companies that have commercialized or are developing treatments for NMIBC, including Aura Biosciences, Inc.,

AstraZeneca, Bristol Meyers Squibb, CG Oncology Inc., Hoffman-La Roche AG (Roche), ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc., and UroGen Pharma, Inc.

Competing products include, among other things, the following FDA-approved products:

- Adstiladrin® (nadofaragene firadenovec), a non-replicating adenoviral vector-based genetic medicine that is manufactured and marketed by Ferring Pharmaceuticals A/S.
- Keytruda® (pembrolizumab), a Merck product, for the treatment of patients with high-risk BCG-unresponsive NMIBC with CIS with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
- VALSTAR® (valrubicin), marketed by Endo Pharmaceuticals, an anthracycline topoisomerase inhibitor for intravesical treatment of BCG-refractory CIS of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.
- Anktiva® (nogapendekin alfa inbakicept-pmln), marketed by ImmunityBio, an engineered IL-15 superagonist protein complex that is approved for use in patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, when administered in combination with BCG.
- Inlexzo™ (gemcitabine intravesical system), marketed by Johnson & Johnson, intravesical drug-releasing system that is placed into the bladder and slowly releases gemcitabine, a chemotherapeutic agent, that is approved for use in patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors.

See "*Risk Factors - Risks Related to Our Business - We face significant competition from other biotechnology and pharmaceutical companies, which may result in our competitors discovering, developing or commercializing products before us or more successfully than we do. Our business and results of operations could be adversely affected if we fail to compete effectively*" for important information about risks respecting competition.

Regulatory Matters

The development, production, testing, distribution, and marketing of biologics like the ones we are developing are subject to strict regulations by various U.S. federal, state, and local agencies in addition to foreign regulatory authorities. These regulations cover a wide range of aspects, including research, safety, efficacy, labeling, packaging, storage, distribution, and advertising, as well as post-approval monitoring and reporting. Our Company, as well as our vendors, partners, contract research organizations (CROs), and manufacturers, will need to comply with these regulations. To gain approval for our product candidate, we need to comply with the regulatory requirements of various governing agencies, including those related to preclinical and clinical trials, manufacturing, and commercialization. This process requires a significant investment of time and financial resources. In the United States, our focus market, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and other federal, state, and local regulations also apply. Our lead product candidate, detalimogene, is not yet approved for marketing in the United States.

See "*Risk Factors - Regulatory Risks*" for important information about risks respecting regulatory matters.

To obtain approval for our product candidates for therapeutic use in the United States, we must follow a series of steps regulated by the FDA. This includes conducting preclinical studies in compliance with regulations, meetings with the FDA, submitting an investigational new drug application, or "IND," to the FDA, obtaining institutional review board, or "IRB," or ethics committee approval at each clinical trial site, conducting clinical trials in compliance with Good Clinical Practice ("GCP") requirements, preparing and submitting a BLA accompanied by fees, undergoing FDA pre-approval inspections of manufacturing facilities, and having potential FDA audits of the clinical trial sites. Finally, the FDA will review and approve the BLA and provide any recommendations before the biologic drug can be sold commercially in the United States.

Preclinical and clinical testing of biological drug products

In order to test a drug or biologic in humans, it must first undergo extensive preclinical testing, which includes laboratory evaluations and animal studies to determine safety and efficacy. These studies must comply with federal and state regulations, including Good Laboratory Practices ("GLP") requirements for safety and toxicology studies. The results of these studies, as well as manufacturing and analytical data, must be submitted to the FDA as part of an IND. The IND is a request for authorization to administer the product to humans and must be approved before clinical trials can begin. The IND submission focuses on the protocol for the initial clinical study and includes results of animal and *in vitro* studies, as well as any available human data to support the use of the investigational product. The IND becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the study, in which case a clinical hold is imposed until the concerns are resolved.

During the clinical stage of development, the product candidate is administered to patients or healthy volunteers under the supervision of qualified investigators in accordance with GCP requirements. Each clinical trial must be reviewed and approved by an IRB to ensure that the risks to individuals participating in the clinical trial are minimized and reasonable in relation to the anticipated benefits. The FDA, IRB, or sponsor may suspend or discontinue a clinical trial at any time on various grounds. Some studies also include

oversight by a data safety monitoring board. Clinical trials must be reported to public registries within specific timeframes. While international clinical trials can be conducted under an IND, the FDA does not require that all foreign clinical trials be conducted under United States INDs. The FDA will accept a well-designed and conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if necessary.

Clinical trials that are carried out to determine the safety and efficacy of a drug for the purpose of obtaining marketing approval through a BLA are typically carried out in three phases that can occur simultaneously, in combination, or staggered.

Phase 1: Phase 1 of clinical trials involves administering the investigational product to healthy human volunteers or patients with the target disease or condition for the first time. The primary objective of these studies is to evaluate the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, identify any side effects associated with increasing doses, and potentially gather preliminary evidence of effectiveness.

Phase 2: Phase 2 clinical trials usually involve giving the investigational product to a small group of patients with a particular disease or condition to assess its effectiveness, determine the best dosage and dosing schedule, and detect any potential risks or side effects. To gather data before conducting more extensive and costly Phase 3 trials, several Phase 2 studies may be conducted.

Phase 3: Phase 3 trials usually involve testing the investigational product in a larger group of patients to confirm its efficacy and safety. The trials are conducted at multiple locations and aim to establish the overall risk-benefit profile of the product. Typically, the FDA requires two well-controlled Phase 3 clinical trials to approve a BLA.

After marketing approval, Phase 4 clinical trials, also known as post-approval trials, may be conducted to gain more experience with the product in its intended use and to gather additional safety or efficacy data. The FDA may require these trials as a condition of approval. The results of clinical trials and safety reports for serious adverse events must be submitted to the FDA annually and within 15 days of the sponsor's determination. Fatal or life-threatening adverse reactions must be reported within seven days. Along with clinical trials, companies must complete additional animal studies, develop information about the product's biological characteristics, and establish a commercial manufacturing process that adheres to cGMP requirements. The manufacturing process must consistently produce quality batches of the product, and appropriate packaging and storage conditions must be identified through stability studies.

Expanded Access

Expanded access, also known as "compassionate use," refers to the use of investigational products outside of their intended clinical development to treat patients suffering from serious or life-threatening diseases or conditions when no satisfactory alternative treatment options are available. FDA regulations permit access to investigational products through an IND by the treating physician or the company for treatment purposes, including individual patients, intermediate-size patient populations, and larger populations for use under a treatment protocol or treatment IND application. It is important to note that companies are not obligated to provide expanded access to their investigational products.

BLA Submission and marketing authorization by the FDA

We plan to apply for either data exclusivity or market exclusivity for our product candidates. If the necessary clinical testing is completed successfully, we will submit the results of preclinical studies and clinical trials, as well as detailed information on the product's manufacturing, labeling, and other aspects, to the FDA in the form of a BLA. This application seeks approval to market a new biologic for one or more specific indications. The BLA must contain all relevant data from both positive and negative studies. The BLA should incorporate all important information accessible from relevant preclinical and clinical examinations, including negative or questionable outcomes as well as certain discoveries, along with itemized data on the product candidate's science, chemistry, manufacturing and controls, and proposed naming, in addition to other things. The data submitted must be of sufficient quality and quantity to satisfy the FDA regarding the investigational product's safety, purity, and potency in order to support marketing approval. A BLA must be approved by the FDA before a biologic can be sold in the United States.

A BLA or supplement to a BLA must also include data to assess the biological product candidate's safety and effectiveness for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, as required by the Pediatric Research Equity Act, or PREA. An initial Pediatric Study Plan (PSP) must be submitted within sixty days of an end-of-Phase 2 meeting or as agreed upon between the sponsor and FDA by a sponsor planning to submit a marketing application for a biological product that includes a new clinically active component, new indication, new dosage form, new dosing regimen, or new route of administration. PREA does not apply to any biological product for an indication for which an orphan designation has been granted, unless otherwise required by regulation.

In some cases, the FDA may also request additional information before deciding whether or not to accept the BLA for filing. Within 60 days of receiving a BLA, the FDA must decide whether or not to accept it for filing. This decision may include refusing to file. The FDA begins a comprehensive substantive review of the BLA as soon as the submission is accepted for filing. A BLA is reviewed by the FDA to see, among other things, if the product is safe, pure, and effective, and if the facility where it is manufactured,

processed, packaged, or stored satisfies standards designed to guarantee the product's continued safety, quality, and purity. Under the objectives and policies consented to by the FDA under the Prescription Drug Users Fee Act, or PDUFA, once a BLA has been submitted, the FDA's goal for novel biological products generally is to review the application within ten months after it accepts the application for filing, or, if the application is granted priority review, six months after the FDA accepts the application for filing. The FDA does not always meet its PDUFA goal dates, and the review process may be extended. For example, the review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional data, analysis or information that the FDA deems a major amendment.

Further, under PDUFA, as changed, each BLA should be joined by a client charge, and the patron of an endorsed BLA is likewise dependent upon a yearly program expense. FDA changes the PDUFA client expenses on a yearly premise. In some cases, fees may be reduced or waived. For example, a small business may not have to pay the application fee for the first time. In addition, unless the product also includes a non-orphan indication, there are no user fees associated with BLAs for products designated as orphan drugs. See "*Orphan drug designation and exclusivity*" below.

The FDA might refer an application for a biologic to any advisory committee, which is a panel of independent experts, such as clinicians and other scientific experts. It reviews, evaluates, and offers a recommendation, such as whether the biologic is sufficiently safe and effective in a particular indication for a particular population and under what conditions. While an advisory committee's recommendations do not bind the FDA, they are carefully taken into consideration when deciding whether or not to grant marketing approval.

The FDA will typically conduct an inspection of the facility or facilities where the product is manufactured prior to approving a BLA. The FDA will not approve an application unless it finds that the manufacturing facilities and processes are adequate to guarantee consistent product production in accordance with the required specifications. Furthermore, prior to approving a BLA, the FDA might investigate at least one clinical preliminary destination to guarantee consistence with GCP and different necessities and the uprightness of the clinical information submitted to the FDA.

The FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to be submitted as a condition for approving a BLA to ensure that the product's benefits outweigh its risks. The REMS may include medication guides, communication plans, assessment plans, or other risk-minimization tools.

Once the BLA and all related information, including advisory committee recommendations and inspection reports, have been evaluated, the FDA may issue an approval letter or a Complete Response Letter. A Complete Response Letter indicates that the application is not ready for approval and lists all deficiencies found in the BLA, which need to be addressed to achieve approval. Even with additional information, the FDA may still reject the application.

If the FDA approves a product, it may impose restrictions, require additional studies, or limit approved indications for use. The FDA can also impose distribution and use restrictions or other risk management mechanisms under a REMS, which may affect the product's market and profitability. Post-marketing studies or surveillance programs may result in the FDA limiting or preventing further marketing of the product. Changes to the approved product may also require further testing and FDA review and approval.

Expedited drug development and review programs at the FDA

The FDA has programs to speed up the development, review, and potential approval of new drugs and biologics for serious or life-threatening diseases. These programs include Regenerative Medicine Advanced Therapy (RMAT) designation, the CMC Development and Readiness Pilot (CDRP) Program, Fast Track designation, Breakthrough Therapy designation, priority review, and Accelerated Approval.

The RMAT program is intended to expedite the development and review of regenerative medicine therapies for serious or life-threatening conditions, where preliminary clinical evidence suggests potential to address unmet medical needs. This designation provides several regulatory advantages, including early and frequent engagement with the FDA, and potential for rolling review and priority review.

The FDA's CDRP Program is designed to support accelerated development of products addressing serious conditions by providing enhanced, earlier CMC engagement during the clinical development lifecycle. The program enables sponsors to obtain timely feedback on manufacturing strategy, analytical readiness, control systems, and comparability plans to reduce CMC-related delays at the time of marketing application. Participation is limited and prioritized for products with significant potential public health impact, with the goal of ensuring CMC readiness aligns with expedited clinical and regulatory pathways.

A biologic can get Fast Track designation if it is meant to treat a serious or life-threatening disease and has the potential to address unmet medical needs for that disease. This applies to the product and the specific indication for which it is being studied. Similar to RMAT, Fast Track designation also allows sponsors to interact more with the FDA during preclinical and clinical development. There

is also potential for rolling review, where the FDA can review parts of the BLA on a rolling basis if the sponsor provides a schedule, the FDA accepts the schedule, and the sponsor pays required fees when submitting the first section of the BLA.

There can be no assurance that detalimogene's RMAT or Fast Track designations or participation in the CDRP program will lead to a faster development, regulatory review or approval process or increase the likelihood that detalimogene will receive marketing approval. Breakthrough Therapy designation is given to drugs that demonstrate a substantial improvement over existing therapies on clinically significant endpoints, and this designation provides intensive guidance for an efficient development program.

Products with Fast Track or Breakthrough Therapy designation may also be eligible for priority review and Accelerated Approval. Priority review is given to drugs that provide significant improvement in safety or effectiveness for serious or life-threatening diseases or conditions. Under priority review, FDA's PDUFA goal for the review of the application is shortened to six months from the application filing date.

Accelerated Approval is given when a drug has an effect on a surrogate or early clinical endpoint that is likely to predict clinical benefit. Sponsors must agree to conduct additional post-approval studies to verify clinical benefit, and the FDA may withdraw approval if those studies fail.

While these programs may expedite the development or review process, they do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval.

Post-Approval Requirements

The FDA heavily regulates drugs and biologics that are manufactured or distributed with their approval. This includes requirements related to recordkeeping, reporting, and product distribution. Companies must comply with promotion and advertising restrictions and are prohibited from marketing or promoting products for unapproved, off-label uses. Failure to comply with these requirements can result in penalties and liability under the False Claims Act (the "FCA"). Post-approval requirements may include post-market testing and surveillance to assess the product's safety and effectiveness. Manufacturers and their subcontractors must register with the FDA and undergo periodic inspections for compliance. Changes to the manufacturing process may require FDA approval. Failure to comply can result in legal or regulatory action, and the FDA can withdraw approval if regulatory standards are not maintained. Revisions to approved labeling and other restrictions may also be imposed.

In addition, post approval, a pediatric study is typically required unless a waiver is granted. In the case of detalimogene, due to the rare incidence of bladder cancer in children, we plan to request a waiver of this requirement.

The consequences of failing to comply with FDA regulations include various restrictions such as limitations on marketing or manufacturing, product recalls, safety alerts, and mandated modifications of promotional materials and labeling. Companies may also face fines, warning letters, untitled letters, or holds on clinical trials and refusal of FDA approvals. The FDA can also take more serious actions such as product seizure or detention, injunctions, or civil or criminal penalties. In addition, companies may face consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs.

Orphan drug designation and exclusivity

The Orphan Drug Act allows the FDA to give orphan drug designation ("ODD") to drugs or biologics meant to treat rare diseases or conditions, which are defined as having a patient population of fewer than 200,000 individuals in the United States or a patient population greater than 200,000 individuals in the United States when it is not reasonable to expect that the cost of developing and making the drug available in the United States will be recovered from sales in the United States. To receive ODD, it must be requested before submitting a BLA, and the identity of the therapeutic agent and its potential orphan use are publicly disclosed after ODD is granted.

If a product receives ODD and later becomes the first FDA-approved drug for a particular clinically active component for the disease it was designated for, it is entitled to orphan drug exclusivity, meaning the FDA cannot approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years from the approval of the BLA, except under specific circumstances. These circumstances include showing clinical superiority to the product with orphan drug exclusivity or if the holder of the exclusivity cannot assure the availability of sufficient quantities of the drug for patients.

Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. ODD also offers benefits like tax credits for certain research and a waiver of the BLA application user fee. However, a product with ODD may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. Moreover, the exclusive marketing rights in the United States may be lost if the FDA later finds that the request for designation was materially defective or if the manufacturer can't assure sufficient quantities of the product for patients with the rare disease or condition.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act ("BPCIA"), which simplified approval process for biological products that are similar to an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining how to review and approve biosimilars. Biosimilarity requires that the biological product and the reference product be the same in terms of safety, purity, and potency. This can be proven through analytical studies, animal studies, and clinical studies. Interchangeability requires that a product be biosimilar to the reference product and that the biologic, and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy.

An application for a biosimilar product cannot be submitted to the FDA until four years after the reference product was licensed by the FDA. Also, the approval of a biosimilar product cannot be made effective until 12 years after the reference product was licensed. During this period, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product that shows the safety, purity, and potency of its product. The BPCIA also created exclusivity periods for biosimilars approved as interchangeable products. It is not yet clear if products deemed "interchangeable" by the FDA will be readily substituted by pharmacies, which are governed by state pharmacy law.

In the United States, a biological product may receive additional market exclusivity for six months if the manufacturer voluntarily completes a pediatric study in accordance with an FDA-issued "Written Request." The BPCIA, which created an abbreviated approval pathway for biosimilar products, is complex and continues to be interpreted and implemented by the FDA. Recently, government proposals have sought to decrease the 12-year reference product exclusivity period. Some aspects of the BPCIA, which could affect its exclusivity provisions, have been the subject of litigation. Therefore, the impact, implementation, and regulatory interpretation of the BPCIA remain uncertain.

Regulation of combination drug products in the US

Combination products are those that are made up of different components, such as biological and device components, that are typically regulated by different FDA centers. According to FDA regulations, a combination product can be a single entity made up of two or more regulated components that are combined in some way, two or more separate products packaged together, or a product that requires the use of an approved drug, device or biological product to achieve the intended effect. The FDA assigns a lead center for review of combination products based on the product's primary mode of action. The Office of Combination Products has been established to address issues related to combination products and provide guidance and regulations for their regulation. Combination products with a biologic primary mode of action are generally reviewed through the biologic approval process, with input from the device center to ensure the device component meets safety and performance requirements. Combination products are subject to current Good Manufacturing Practice (cGMP) regulations for drugs, biologics, and devices, including quality system regulations for medical devices. Our manufacturing process is cGMP compliant.

Other regulatory considerations for drug products

After a product candidate has been approved or commercialized, its manufacturing, sales, promotion, and other related activities are subject to regulation by various regulatory bodies in the United States. In addition to the FDA, these regulatory authorities may include the Centers for Medicare & Medicaid Services (the "CMS"), other divisions of the Department of Health and Human Services (the "HHS"), the Drug Enforcement Administration (the "DEA"), the Consumer Product Safety Commission, the Federal Trade Commission (the "FTC"), the Occupational Safety & Health Administration, the Environmental Protection Agency, as well as state and local governments and agencies.

Drug coverage and reimbursement

In the United States and many other countries, patients rely on third-party payors to cover part or all of the costs of their treatment. Having sufficient coverage and reimbursement from government healthcare programs and private insurers is critical for the success of new products. The availability of coverage and reimbursement will impact our ability to commercialize our product candidates, and the amount of reimbursement provided may not be enough for us to make a profit. Government authorities and third-party payors determine which medications they will pay for and at what level. New products may not be covered or may have limited coverage, and the reimbursement level may be lower than necessary to cover our costs. The COVID-19 pandemic has also caused uncertainty regarding insurance coverage, as many people have lost their employer-based coverage. The factors that payors consider when determining reimbursement include whether the product is covered by the plan, safe, effective, medically necessary, appropriate for the patient, and cost-effective. Discounts and rebates required by government programs and private payors may reduce the net price for drugs, and there is increasing pressure on drug companies to offer predetermined discounts. We cannot be certain that reimbursement will be available for our products or what the reimbursement level will be, and we may be subject to penalties if we do not report pricing metrics accurately and in a timely manner. We also cannot be certain that if we obtain reimbursement arrangements with payors that such arrangements will not be subject to recoupment actions or overpayment challenges, which can be time-consuming and expensive to resolve.

Health care laws and regulations in the United States

Pharmaceutical companies must comply with various healthcare regulations enforced by the federal government and state and foreign authorities where they do business. These regulations limit financial arrangements and relationships involving the research, sale, marketing, and distribution of products authorized for sale. The laws include the federal Anti-Kickback Statute ("AKS"), which prohibits offering or receiving remuneration for referrals or purchases that may be paid under federal and state healthcare programs. The FCA and Civil Monetary Penalties Law prohibit submitting false claims for payment to the government. The federal Health Insurance Portability and Accountability Act of 1996 imposes liability for executing schemes to defraud healthcare benefit programs or falsifying information related to healthcare delivery and payment. The "Sunshine Act" requires manufacturers of reimbursable drugs, devices, biologics, and medical supplies to report physician payments and other transfers of value. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes privacy and security obligations on certain healthcare providers, health plans, and healthcare clearinghouses. Similar state laws may apply to sales and marketing arrangements involving healthcare items or services reimbursed by non-governmental third-party payors, reporting requirements related to financial arrangements with clinicians, and state privacy and security laws governing health information can be different from HIPAA. Noncompliance with these laws can lead to significant penalties, including administrative, civil, and criminal penalties, damages, fines, disgorgement, restructuring of operations, oversight and reporting obligations, and exclusion from participation in federal and state healthcare programs.

Healthcare legislative development

Healthcare payors, whether they are government or private entities, are using more sophisticated methods to control costs, but these methods are not always suitable for new technologies like genetic medicine and treatments for rare diseases. Legislative and regulatory changes to the healthcare system in the United States and many other countries could affect our ability to sell our products profitably. The ACA, which became law in 2010, introduced a range of changes, including subjecting biologic products to competition from lower-cost biosimilars, increasing minimum Medicaid rebates, and imposing new annual fees and taxes on certain branded prescription drugs. The ACA has faced legal and political challenges. Other healthcare reform measures may also impact our business. Since the ACA was enacted, other legislative changes have been proposed and adopted in the United States, including spending reductions under the Budget Control Act of 2011 and the Right to Try Act, which provides a federal framework for certain patients to access investigational new drug products. There has also been growing interest in specialty drug pricing practices and efforts to control pharmaceutical and biological product pricing at the federal and state levels, including transparency measures and importation from other countries.

Facilities

Our corporate headquarters are located in Montreal, Canada, where we lease and occupy approximately 10,620 sq. feet of laboratory and office space at 4868 Rue Levy, Montreal, QC H4R 2P1. We also maintain office space in the United States at 99 High Street, 26th Floor, Boston, Massachusetts 02110 and 200 5th Street Waltham, Massachusetts 02451.

We believe that our current facilities are sufficient for our current needs. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Employees

As of October 31, 2025, we had 82 employees, including 81 full-time employees, 51 of whom were primarily engaged in research and development activities. Of these employees, 22 are based in Canada and 60 in the United States. None of our employees are represented by a labor organization or are party to a collective bargaining arrangement. We consider our relationship with our employees to be excellent.

Legal Proceedings

From time to time, we may be involved in legal proceedings that arise in the regular course of our business. Our management believes that we are not currently involved in any legal proceedings that are likely to have a significant negative effect on our business. However, legal proceedings can negatively affect our business, financial condition, results of operations, and future prospects, regardless of the outcome, due to costs associated with defense and/or settlement, as well as the diversion of management attention and resources, among other factors.

Item 1A. Risk Factors.

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Special Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described in this Annual Report or our other filings with the U.S. Securities and Exchange Commission (the "SEC") are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risks Related to Our Business

We depend heavily on the success of our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, which is currently in a clinical trial. Our clinical trial of detalimogene may not be successful. If we are unable to successfully develop, obtain regulatory approval for, and commercialize detalimogene, or experience significant delays in doing so, our business will be materially harmed.

We currently only have one product candidate, detalimogene, in clinical development. We invested and continue to invest a significant portion of our efforts and financial resources in the research and development of detalimogene. Our ability to generate revenues from the sale of drugs that treat bladder cancer and other diseases in humans, which may not occur for several years, if ever, will depend heavily on the successful clinical development, regulatory approval for, and eventual commercialization of detalimogene. This may make an investment in our Company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. The success of detalimogene will depend on several factors, including:

- successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- acceptance of regulatory submissions by the FDA or comparable foreign regulatory authorities for the conduct of clinical trials of detalimogene and of our proposed designs of planned clinical trials of detalimogene, including protocol amendments or other changes we may make to ongoing clinical trials;
- the frequency and severity of adverse events observed in clinical trials and preclinical studies;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of detalimogene, and the ability of such CROs and clinical sites to comply with clinical trial protocols, GCPs and other applicable requirements;
- demonstrating the safety, purity and potency (or efficacy) of detalimogene to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities;
- receipt and maintenance of regulatory approvals from applicable regulatory authorities, including approvals of BLAs from the FDA;
- maintaining relationships with our third-party CMOs and the CMOs' ability to comply with cGMPs as well as entering into agreements with our third-party CMOs for, or establishing our own, commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;
- establishing sales, marketing and distribution capabilities and launching commercial sales of detalimogene, if and when approved by the FDA, whether alone or in collaboration with others;
- obtaining, maintaining, protecting and enforcing patent and any potential trade secret protection or regulatory exclusivity for detalimogene;
- maintaining an acceptable safety profile of detalimogene following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell detalimogene; and
- acceptance and coverage of our products, if approved, by patients, the medical community and federal healthcare programs and other third-party payors.

If we are unable to develop, obtain regulatory approval for, or if approved, successfully manufacture and commercialize detalimogene, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed.

We expect to make significant investments in our continued research and development of detalimogene and other new product candidates and genetic medicines and services we may develop, which may not be successful, and if they are not successful, we may not be able to achieve or sustain profitability in the future. As an organization, we do not have experience in any such new lines of business, and failure to identify other product candidates and/or execute on the expansion of our business would adversely affect our business and results of operations.

Biotechnology product development is expensive, takes years to complete, and has uncertain outcomes. Failure can occur at any stage of product development. In addition, if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. We expect to incur significant expenses to advance our genetic medicine development efforts, which may be unsuccessful. Developing new product candidates, such as detalimogene, is a speculative, risky and highly competitive endeavor. Product candidates that initially show promise may fail to achieve the desired results in development and clinical studies and may ultimately not prove to be safe and effective or meet expectations for clinical utility. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. We may need to alter our offerings in development and repeat clinical studies before we develop a potentially successful product. If, after development, a product appears successful, we will still need to obtain FDA and other regulatory approvals before we can market it. The FDA's approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA may not clear, authorize or approve any product we develop. Even if we develop a product that receives regulatory clearance, authorization or approval, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development or announcement of competing products or services, which could occur at any time. Because of the numerous risks and uncertainties associated with developing product candidates, we are unable to predict whether or when our therapeutics business may successfully commercialize a product candidate.

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the foreseeable future.

We are a clinical-stage biotechnology company and have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through third-party investments in our debt and equity instruments. Our net losses were $117.3 million and $55.1 million for the fiscal years ended October 31, 2025 and October 31, 2024, respectively. As of October 31, 2025, we had an accumulated deficit of $372.0 million. Our lead product candidate, detalimogene, is in clinical trials. Our other programs are in preclinical research. Although we could potentially achieve our first commercial product as early as the second half of 2027, there is no guarantee we will do so, and delays or successful development efforts could prevent or significantly postpone commercialization. As a result, we may not generate revenue from product sales for some time, if at all. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial costs for commercialization as well as substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the pace of our development activities and the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our Common Shares.

The estimates of market sizes and forecasts of market growth for the potential demand of detalimogene and any other product candidates we develop, as provided in this Annual Report and as may be provided in our future public filings and press releases are based on a number of assumptions and may prove to be inaccurate. The actual market may be smaller than we believe, which would adversely affect our business and results of operations.

We make estimates of total addressable markets and forecasts of market growth for detalimogene and any other product candidates we develop in this Annual Report, and we may also make such estimates and forecasts in future public filings and press releases. Our estimates, forecasts and key performance indicators are based on a number of complex assumptions, internal and third-party estimates in published literature, and other business data, including assumptions and estimates relating to our ability to manage operating expenses of, invest in, and develop and generate revenue from detalimogene or any other product candidates we develop in the future. While we believe our assumptions and the data underlying our estimates and key performance indicators are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and metrics. Consequently, our estimates of the total addressable markets and our forecasts of market growth may prove to be incorrect. For example, if the annual total addressable markets or the potential market growth is smaller than we have estimated or if the key business metrics we utilize to forecast commercial opportunities are inaccurate, it may have an adverse effect on our business, financial condition, results of operations and prospects.

If our internal controls over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the trading price of our common stock.

As a public company, we are required to maintain internal control over financial reporting and disclosure controls and procedures. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Our management has performed an evaluation of our internal controls over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, however, an independent registered public accounting firm has never performed an evaluation because no such evaluation is currently required. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses may have been identified. If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to certify that our internal control over financial reporting is effective, our consolidated financial statements may contain material misstatements and we could be required to revise or restate our financial results. This could materially and adversely affect our business, results of operations and financial condition, restrict our ability to access the capital markets, require us to expend significant resources to correct the material weakness, subject us to fines, penalties or judgments, harm our reputation, adversely affect the trading price of our common stock, or otherwise cause a decline in investor confidence. See "*Item 9A. Controls and Procedures-Remediation Efforts to Address Material Weakness*" of this Annual Report for information related to material weakness remediation and mitigation.

To date, we have not generated any product revenue, have a history of losses and will need to raise additional capital to fund our operations. If we fail to obtain necessary financing, we will not be able to complete the development and commercialization of detalimogene or our other product candidates.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to conduct further research and development and preclinical or nonclinical testing and studies and clinical trials of our current and future programs, to seek regulatory approvals for our product candidates and to prepare for potential launch and commercialization of any products for which we may receive regulatory approval. As of October 31, 2025, we had $50.2 million in cash and cash equivalents and $152.1 million in marketable securities. Although we have a detailed current operating plan, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. We will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for product development and any approved marketing and commercialization activities. Our funding requirements, both near- and long-term, as well as the timing and amount of our operating expenditures, will depend largely on:

- the initiation, progress, scope, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable regulatory authorities outside of the United States;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of resolving intellectual property disputes, including any patent infringement actions that may be brought by third parties in the future against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of formulation development and manufacturing of our product candidates, including the completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or with a partner; and
- the costs related to any domestic and/or international expansion.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity

offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty revenues, sales or monetization of future revenue streams, marketing or distribution arrangements or other strategic transactions. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. Further, to the extent that we raise additional capital through the sale of our Common Shares or securities convertible or exchangeable into our Common Shares, your ownership interest will be diluted. We are party to the Amended Loan Agreement (as defined herein) with Hercules Capital, Inc. ("Hercules" or the "Lender"), as agent and lender, and several financial institutions. The Amended Loan Agreement subjects us to fixed payment obligation covenants that limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For additional information, see "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations-Hercules Loan Agreement*" and "*Notes to the Financial Statements-Note 18, Subsequent Events*" for additional information on the Hercules Loan Agreement. If we raise additional capital through debt financing, we may be subject to similar or more restrictive conditions than the conditions of the Amended Loan Agreement. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, licensing arrangements, royalty revenues, sales or monetization of future revenue streams, or strategic transactions with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research or development initiatives. Any of the above events could significantly harm our business, financial condition, results of operations and prospects and cause the price of our common shares to decline.

We face significant competition from other entities, including biotechnology and pharmaceutical companies, which may result in our competitors discovering, developing or commercializing products before us or more successfully than we do. Our business and results of operations could be adversely affected if we fail to compete effectively.

The biotechnology and pharmaceutical industries, including the development of non-viral genetic medicines for administration into mucosal tissues as well as the development of novel therapies for bladder cancer and non-muscle invasive bladder cancer, or "NMIBC," specifically, are characterized by rapid growth, a dynamic landscape of competitive product candidates and a strong reliance on intellectual property. We face competition from a variety of organizations, including larger pharmaceutical companies, specialty biotechnology companies, specialty medical device companies, academic research institutions, governmental agencies, as well as public and private institutions. There are several companies that are currently developing gene-based therapeutics for use in a variety of indications, from cancer (including bladder cancer and NMIBC specifically) to rare disease, to regenerative medicine. There are also companies and institutions developing non-gene based therapies such as, but not limited to, drug/device combinations that may be effective in the clinical indications we choose to pursue and oncology drugs.

DDX is our proprietary carrier for genetic medicines to mucosal tissues and is the foundation for our nanoparticle formulations. We developed DDX and our patented non-viral genetic medicines to penetrate mucus barriers and to deliver genes to mucosal epithelial cells in a way that is re-dosable, scalable, and designed to integrate into existing clinical practice. Our genetic medicine platform's leading program, detalimogene, is in the area of immuno-oncology. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of indications for which we are developing detalimogene, including NMIBC. Competitors using genetic medicines for mucosal tissues include CG Oncology, Inc. and Ferring Pharmaceuticals Inc, both of which are developing products that will compete directly with detalimogene, if approved. More generally, if detalimogene or any future product candidates that we develop are approved, they will compete with surgery, radiation, and drug therapy, including chemotherapy, BCG, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, antibody-drug conjugates, radiopharmaceuticals, immunotherapy, cell-based therapy, and targeted therapy, or a combination of any such methods, either approved or under development, which are intended to treat the same indications that we are targeting or may target, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer or have other advantages over detalimogene and any future product candidates that we develop. To the extent Merck or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as detalimogene, if approved, in earlier lines of treatment for NMIBC. There are numerous companies that have commercialized or are developing treatments for NMIBC that detalimogene will compete with, if approved, including Bristol Meyers Squibb, Gilead Sciences, Inc., Hoffman-La Roche AG (Roche), CG Oncology, Inc., Ferring Pharmaceuticals Inc., ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc., Aura Biosciences Inc., and UroGen Pharma, Inc.

In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for and participation in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer,

more effective, have fewer or less severe side effects, are more convenient, are more shelf-stable or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, if we successfully enter it at all. The key competitive factors affecting the success of all of our programs, including detalimogene, are likely to be their efficacy, safety, convenience and availability of reimbursement. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make detalimogene or any future product candidates we develop obsolete or noncompetitive before we generate sufficient revenue to recover the expense of their development and commercialization. If we are unable to compete effectively, our opportunity to generate revenue from the sale of detalimogene or any future product candidates we may develop, if approved, could be adversely affected.

If detalimogene or other product candidates that we may develop are approved for the indications for which we are currently conducting or planning clinical trials, they may compete with other products currently under development. We may not be aware of all competitive or potentially competitive products under development by other market participants, and information relating to such products may not be publicly accessible. Competition with other related products currently under development may include competition for clinical trial sites, patient recruitment and product sales. See "*Item 1. Business-Competition*" for additional information.

The genetic medicine field is relatively new and evolving rapidly. Because of our limited technical, financial and human resources, we are focusing our research and development efforts on detalimogene, as well as further development of our genetic medicine platform and other product candidates we may develop. As a result, we may forego or delay pursuit of other genetic medicine technologies or other therapeutic product candidates that provide significant advantages over our platform or product candidates, which could materially harm our business and results of operations.

Genetic medicine is an emerging field of product development with only a small number of genetic medicines having received FDA or EMA approval to date. Our genetic medicine research programs are still at an early stage, and there remain several areas of product development risk, which pose particular uncertainty for our programs given the relatively limited development history of, and our limited prior experience with, genetic medicines. Translational science, manufacturing materials and processes, safety concerns, regulatory pathway and clinical trial design and execution all pose particular risk to our product development activities. Furthermore, the medical community's understanding of the causes of many diseases continues to evolve and further research may change the medical community's views on what therapies and approaches are most effective for addressing certain diseases.

As an organization, we have limited experience conducting IND-enabling studies or clinical trials, including later stage or pivotal clinical trials. In pursuing our new technologies, we have begun to establish our own genetic medicine technical capabilities, but we will need to continue to expand those capabilities by either hiring internally or seeking assistance from outside service providers. Genetic medicine is an area of significant investment by biotechnology and pharmaceutical companies and there may be a scarcity of talent available to us in these areas. If we are not able to expand our genetic medicine capabilities, we may not be able to develop in the way we intend or desire any promising product candidates that emerge from our program, including detalimogene, which would limit our prospects for future growth. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of detalimogene or other product candidates that we may develop. We may also rely on third-party vendors or service providers, including CROs, among others who may fail to meet their commitments to us or deliver their products to us. We may also be forced to rely on a single such provider with no redundancy or alternative. Failure to commence or complete, or delays in our clinical trials, could prevent us from or delay us in commercializing detalimogene or other product candidates that we may develop.

Because we have limited financial and managerial resources, we focus on research programs and on genetic medicine technologies and product candidates that we identify for specific indications among many potential options, such as detalimogene in high-risk BCG-unresponsive NMBIC with CIS or other NMIBC indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential, or we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. For example, in June 2024, we announced that, as a result of our prioritization of exploring potential bladder cancer indications for detalimogene, we deprioritized preclinical development of another product candidate, EG-i08 for cystic fibrosis. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to pursue opportunities with greater commercial potential or relinquishing valuable rights to product candidates may have a material adverse effect on our business, financial condition, results of operations and prospects.

Detalimogene and our genetic medicine platform are based on novel technologies that are unproven, which makes it difficult to predict the time and cost of development and the probability or timing of subsequently obtaining regulatory approval.

We have concentrated our research and development efforts on our genetic medicine platform, and our future success depends on the successful development and maintenance of our platform.

However, the technologies that comprise our platform and detalimogene are new and largely unproven. These technologies have been neither extensively studied nor extensively clinically tested, and the scientific and clinical evidence to support the feasibility of developing product candidates based on those technologies in pursuit of regulatory approval and potential commercial viability and success may be considered preliminary and limited. Successful development of product candidates by us will require solving several issues, including proving the safety and efficacy of detalimogene for BCG-unresponsive NMIBC and expanding our mucosal tissue delivery system to treat patient tissues beyond the bladder, such as urogenital and gastrointestinal mucosal tissues. There can be no assurance we will be successful in solving any or all of these issues. We have concentrated our research efforts to date on developing the components of our genetic medicine platform, and our future success is highly dependent on the successful development of our proprietary carrier for genetic medicines to mucosal tissues, therapeutic applications of such technology and the advancement of additional programs focused on diseases of the urogenital and gastrointestinal mucosal tissues. We may decide to alter or abandon our initial programs as new data become available and we gain experience in developing our therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in any indication we pursue.

There can be no assurance that any development problems we experience in the future related to our genetic medicine platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring such processes to any commercial partners, which may prevent us from initiating or conducting clinical trials or commercializing our products on a timely or profitable basis, if at all. We may also fail to build redundancy in these manufacturing processes, such that we will be vulnerable to third-party provider failures that may impair the supply of or manufacture of critical materials, products, or reagents. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. FDA's regulatory guidance documents, including those that may be applicable to our programs, may change, be cancelled or evolve. Only a small number of genetic medicines have successfully reached the clinical trial phase of development or beyond, limiting insight into the regulatory review process for this field of genetic medicine. As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals in either the United States or the European Union for any product candidates we may develop or how long it will take to commercialize any product candidate that receives marketing approval.

Development of new therapeutics involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs, fail to replicate the positive results from our earlier preclinical or clinical studies of our product candidates in later preclinical studies or clinical trials or experience delays in completing or ultimately be unable to complete, the development and commercialization of any product candidates, including, but not limited to, detalimogene.

To obtain the requisite regulatory approvals to commercialize detalimogene or any other product candidate that we may develop, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective. Our product candidates are in preclinical development and clinical trial stages and thus their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our filed and planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including detalimogene, we must conduct extensive clinical trials to demonstrate the safety and efficacy of any of these product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during, or even after, the clinical trial process and our ongoing and future clinical results may not be successful. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful and a clinical trial can fail at any stage of testing. Similarly, if regulatory authorities agree, implicitly or explicitly, that a certain set of clinical endpoints is clinically meaningful or adequate to demonstrate safety and efficacy, they may change their determination at a later date. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials and interim or preliminary results of a clinical trial do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA and similar marketing applications to other regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will be completed on schedule, if at all.

We may experience delays in initiating or completing clinical trials and preclinical studies. We also may experience numerous unforeseen events during, or as a result of, any ongoing and future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that:

- we may be unable to generate sufficient preclinical, toxicology, *in vivo, in vitro*, or other data to support the initiation of clinical trials;
- we may experience delays in our discussions with the FDA and other regulatory authorities regarding trial design or other aspects of our trial and study;
- regulators or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- positive results from our preclinical studies of our product candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials and positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results;
- clinical trials of any product candidates may fail to show safety or efficacy, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the FDA or other regulatory authorities may require us to enroll more patients in clinical trials than we had planned, including if they determine that patients we have enrolled did not meet the eligibility criteria for the clinical trial or, in the case of detalimogene for BCG-unresponsive NMIBC with CIS, did not meet the requirements of the FDA's 2018 Guidance Document entitled "Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry" (the "Guidance Document") and the FDA's August 2024 update in draft form of the Guidance Document;
- we may need to add new or additional clinical trial sites; and
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial.

We could also encounter delays if a clinical trial is suspended, placed on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities or recommended for suspension or termination by the Data Safety Monitoring Board, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals, which will correspondingly increase our operating costs. Our preclinical studies or clinical trials may not begin as planned, may need to be restructured or may not be completed on schedule, or at all. Significant preclinical studies or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or clinical development programs may harm our business, financial condition, results of operations and prospects.

Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time will change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim, topline and preliminary data from our clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues, data is further analyzed, and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary, topline or interim results also remain subject to audit and verification procedures that may result in the final data being materially different from the data we have previously published. As a result, interim, topline and preliminary data should be expected to change as additional patient data become available and as such new data and/or existing data is audited and verified; all data should be viewed with caution until the final data and analyses are available. Adverse differences between preliminary, topline or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common shares to fluctuate significantly.

In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program (for example, detalimogene), the approvability or commercialization of the particular product candidate or product, and our Company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions we reached, our ability to obtain approval for, and commercialize detalimogene and any future product candidates we develop may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We have from time to time experienced and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the availability of a sizeable population of eligible patients;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions as to the potential advantages and side effects of our product candidate being studied in relation to other available therapies or surgical procedures;
- our ability to obtain and maintain patient consents;
- the failure of patients to complete a clinical trial;
- the availability of approved therapies that are similar in mechanism to our product candidates;
- the cost to, or lack of adequate compensation for, prospective patients; and
- the risk that patients enrolled in clinical trials will not complete such trials for any reason, including due to health crises, including pandemics, geopolitical conflicts, acts of terrorism, and/or "acts of God" that affect our contract manufacturing organizations ("CMOs"), suppliers, clinical investigator sites and governing regulatory bodies.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which would reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Although we have conducted the Phase 1 portion of the LEGEND clinical study of detalimogene, we have not as an organization completed later-stage or pivotal clinical trials or submitted a BLA, and we may be unable to do so for detalimogene or any future product candidates in a timely manner or at all.

We will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market detalimogene or any future product candidates we develop. Carrying out pivotal and later-stage clinical trials and the submission of a successful BLA or other comparable foreign regulatory submission are complicated processes. As an organization, we have conducted the Phase 1 portion of the combined Phase 1/2, open-label study of detalimogene referred to as the "LEGEND" study and are conducting the Phase 2 multi-cohort portion of the LEGEND study consisting of three cohorts, including the pivotal cohort evaluating detalimogene in patients with BCG-unresponsive NMIBC with CIS. We have not yet completed any later-stage or pivotal clinical trials for detalimogene or any other product candidate. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted a BLA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of detalimogene or any other product candidates we develop will be required or how such additional trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of a BLA and regulatory approval of detalimogene or any of the other product candidates we develop. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of detalimogene or any of other product candidates we develop. Failure to commence or complete, or delays in, our ongoing or future clinical trials could prevent us from or delay us in submitting BLAs or other comparable foreign regulatory submissions for and commercializing detalimogene or any of other product candidates we develop.

Use of our novel genetic medicine platform, detalimogene and other therapeutic product candidates we may develop could result in or be associated with harmful side effects, adverse events or other safety risks, which could cause us to delay, suspend or discontinue their clinical trials and/or development or abandon them, delay or prevent their regulatory approval, limit their commercial potential, if approved, or result in other significant negative consequences (including voluntary corrective actions or agency enforcement actions) that could severely harm our business and results of operations. In addition, these harmful side effects, adverse events or other safety risks may not be appropriately recognized or managed by our treating staff, which could result in litigation and reputational damage.

Detalimogene and other product candidates we may develop may be associated with harmful side effects, adverse events or other safety risks. Results of clinical trials could reveal severe or recurring side effects, toxicities or unexpected events, including death. There may also be delayed adverse events that may not be appropriately recognized or managed by our treating staff, which could result in litigation and reputational damage. We expect to have to train medical personnel using detalimogene or any other product candidates we may develop to understand the side effect profiles for our clinical trials and upon any commercialization of such product candidates. Inadequate training in recognizing or managing the potential side effects of such product candidates could result in patient injury or death.

If any such events occur, clinical trials or commercial distribution of detalimogene or any other product candidates or products we develop could be suspended or terminated, and our business and reputation may be substantially harmed. Treatment-related side effects could affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of or require us to cease selling detalimogene or any other product candidates or products we develop for any or all targeted indications. If we elect, or are required, to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated.

Additionally, if we successfully develop detalimogene or any other product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we and others later identify undesirable side effects caused by any product that we develop. Such identification could also have several additional significant negative consequences, such as:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts, "Dear Healthcare Provider" letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional trials;
- the product may become less competitive;

- we may decide to remove the product from the marketplace;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we could be sued and be held liable for harm caused to patients; and
- our reputation could be harmed.
- Any of these events could prevent us from achieving or maintaining market acceptance of any potential product.

Even if detalimogene or any other therapeutic product candidates that we develop receives regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors (including government health administration authorities and private health insurers) and others in the medical community necessary for commercial success, in which case we may not generate significant revenues and become profitable, which could adversely affect our ability to conduct our business and our results of operations.

The commercial success of detalimogene or any other product candidates that we develop will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if detalimogene or any other product candidates developed by us receives regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of detalimogene and any other product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the wider acceptance by patients of products derived from or involving RNA or DNA manufacturing processes;
- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials published in peer-reviewed journals or otherwise made available to the public (e.g., through FDA advisory committee meetings);
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices and to obtain coverage by third-party payors;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of handling, dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, EMA or other comparable non-U.S. regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA or other comparable non-U.S. regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the effectiveness of marketing and distribution efforts by us and other licenses and distributors;
- shortages or lack thereof of competitive or potentially competitive products, or products utilized in the standard-of-care for our patients, such as BCG;
- sufficient governmental third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If detalimogene or any other product candidate developed by us does not achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue and may not become or remain profitable. The failure of detalimogene or any other product candidates we develop to find market acceptance could harm our business, financial condition, results of operations and prospects.

Independent of any actions taken by us, negative developments in the field of genetic medicine, intravesical or NMIBC therapeutic development could damage public perception of detalimogene and any other product candidates that we develop, which could adversely affect our ability to conduct our business and our results of operations, or to obtain and retain regulatory approvals for such product candidates.

Our novel genetic medicine platform and detalimogene are comprised of new and largely unproven technologies, and we have no gene therapeutic product candidates approved to date. Gene therapeutics may not gain the acceptance of the public or the medical community and/or they may not gain the acceptance of the public or medical community within our indications of interest or

development areas. To date, several other efforts to leverage genetic medicine technologies have generally demonstrated an inability to generate predictable results or to manufacture products at suitable scale to treat more than a small number of patients.

Our success will depend on our ability to demonstrate that our genetic medicine platform, detalimogene and any other product candidates we develop and related services can overcome these challenges.

If detalimogene or any other product candidate that we develop is unable to successfully treat the intended organ or lesion and establish proof of concept in a certain disease, it may indicate that we will not be able to apply our genetic medicine platform to other diseases affecting the intended tissue area or other areas. This may also indicate a decrease in the probability of our success for other targets using the same modality in the same or different cell types, as well as our engineered approach and delivery approach, more generally. Such failures could negatively affect the public or medical community's perception of our genetic medicine platform and gene therapeutics in general.

Additionally, our success will depend upon physicians who specialize in the treatment of diseases targeted by detalimogene or any other product candidates that we develop, if approved, prescribing treatments that involve the use of those product candidates, if approved, in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of detalimogene or any other product candidates that we develop or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of gene therapeutics, could result in a decrease in demand for detalimogene, if approved, or any other product that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of, or modification to, our clinical trials. Any future negative developments in the field of genetic medicine could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for detalimogene or any other product candidates that we develop.

We may not be successful in our efforts to utilize our novel genetic medicine platform to identify and develop additional product candidates. Due to our limited technical, financial and human resources and access to capital, we may choose to prioritize development of certain product candidates, such as our initial focus on developing detalimogene, which may prove to be the wrong choice and may adversely affect our business and results of operations.

An important element of our strategy is utilizing our genetic medicine platform to generate multiple product candidates. Although we intend to develop numerous product candidates targeting various cell types and indications and carrying different biologically active drug molecules, in addition to detalimogene, we may fail to identify viable new product candidates for clinical development for a number of reasons. For example, while we believe our genetic therapy platform is capable of transfecting many different tissue types with varied genetic cargos, such as nucleic acid therapeutics (e.g., DNA), antisense oligonucleotides, siRNA, miRNA, mRNA, genetic medicine and gene editing mechanisms, we have not yet successfully advanced any proprietary enGene-developed drug candidate incorporating these cargoes into clinical trials beyond detalimogene, and we may not be successful in developing products to effectively employ these types of cargoes or molecules. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our product candidates and using our genetic medicine platform to design and identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our genetic medicine platform and research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs, or that make the product candidates impracticable to manufacture, unmarketable or unlikely to receive marketing approval; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

If any of these events occur, we may be forced to abandon our research or development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful, which would be costly and time-consuming.

Our use of third parties to manufacture, develop and test our therapeutic product candidates for preclinical studies and clinical trials increases the risk that we will not have sufficient quantities of our product candidates or products, or necessary quantities of such materials on time or at an acceptable cost.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture drug supplies for our ongoing clinical trials or any future clinical trials that we may conduct, and we lack the resources to internally manufacture detalimogene or any other product candidates we develop on a commercial scale. We rely, and expect to continue to rely, on third-party manufacturers to produce detalimogene or other product candidates that we may identify for clinical trials, as well as for commercial manufacture if detalimogene or any other product candidates we develop receive marketing authorization and approval. We rely entirely on numerous third-party suppliers to provide us with various product components. We may not have alternative suppliers for certain of these product components. Any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer or testing laboratory could considerably delay the clinical development and potential regulatory authorization and commercial launch of such product candidate, which could harm our business, financial condition, results of operations and prospects. We currently do not have relationships with alternate third-party contract manufacturers and testing laboratories for our critical raw materials and product candidates that could sustain our operations in the event we experience a disruption of service from our existing third-party contract manufacturers and testing laboratories. As a result, we are materially reliant on our existing contract manufacturers and testing laboratories and susceptible to material operational disruptions due to factors that may be unknown to us and unforeseeable. Our providers may also materially change the terms of our commercial arrangements for any reason or no reason, which could adversely affect our materials costs, ability to manufacture the drug at a sustainable cost, and profit margin on any sales.

We may be unable to identify and appropriately qualify third-party manufacturers and testing laboratories or establish agreements with third-party manufacturers and testing laboratories or do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers and testing laboratories, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for sourcing of raw materials, components, testing and such other goods as may be required for execution of our overall manufacturing process;
- risk of single sourced critical raw materials, drug substance and drug product, where secondary back-up vendors are not yet available;
- risk of increased and/or extended lead times for critical raw materials, reagents and equipment, thus requiring significant investment in building adequate inventory to avoid significant disruptions to manufacturing processes;
- reliance on third-party to ensure availability of adequate manufacturing capacity to meet product demand based on the needs of their other clients;
- reliance on the third-party for regulatory compliance and quality assurance for the manufacturing and/or testing activities each performs;
- reliance on third-party to adequately validate processes for timely approval of the BLA required for commercialization of product;
- the possible breach of the manufacturing and/or testing agreement by the third-party;
- the possible misappropriation of proprietary information, including trade secrets and know-how; and the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Furthermore, our contract manufacturing organizations ("CMOs") and testing laboratories are engaged with other companies to supply and/or manufacture and/or test materials or products, which exposes our manufacturers and testing laboratories to regulatory risks for the production and testing of such materials and products. The facilities used by our CMOs to manufacture and/or test detalimogene or any other product candidates we develop are subject to review by the FDA and other non-U.S. authorities pursuant to inspections that will be conducted after we submit a BLA, or other marketing application to the FDA and other non-U.S. authorities. We do not directly conduct the manufacturing and testing of any material or products. Therefore, we are materially dependent on our CMO partners and contract testing laboratories to operate in compliance with the regulatory requirements, known as current good manufacturing practice ("cGMP") requirements for manufacture of drug and device products or similar requirements outside the United States. If our CMOs and contract testing laboratories cannot successfully manufacture and/or test material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory authorization for detalimogene or any other product candidates we develop that are manufactured at these manufacturing facilities, resulting in delay or failure in the clinical development and commercialization of our products, which would have a material adverse effect on us. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or another non-U.S. regulatory agency does not approve these facilities for the manufacture and/or testing of detalimogene or any other product candidates we develop, if any agency withdraws its approval in the future, or if we identify material gaps in quality control and compliance at our selected CMOs, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop and deliver our products to markets around the world could delay product supply to patients in clinical studies or to commercial customers for any approved products, and may increase the overall cost of manufacturing our products.

Detalimogene or any other product candidates we develop may compete with other product candidates and marketed products for access to manufacturing and/or testing facilities. Any performance failure on the part of our existing or future CMOs could delay clinical development, marketing approval or commercialization. Our current and anticipated future dependence upon others for the manufacturing of detalimogene or any other product candidates we develop may adversely affect our future profit margins and our ability to commercialize detalimogene or any other product candidates we develop that receive marketing approval on a timely and competitive basis.

Detalimogene is complex to manufacture, and the manufacturing process for any other product candidates we develop may be similarly complex or more complex, and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of our third-party manufacturers with whom we contract encounter these types of difficulties, our ability to supply detalimogene or any other product candidates we develop for clinical trials or as products for patients, if approved, could be constrained, delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacturing processes used to produce detalimogene are complex and novel and have not been validated for clinical or commercial production. The manufacturing processes used to produce any future product candidates that we develop may be similarly or more complex and novel. As a result of these complexities, the cost to manufacture our product candidates is generally higher than traditional biopharmaceutical compounds and the manufacturing processes may prove to be less reliable and may be more difficult to reproduce. For example, for detalimogene we must separately manufacture a novel plasmid DNA drug substance (DS), a novel co-polymer excipient (DDX) and a novel block co-polymer excipient (PEG-b-PLE). We then combine those ingredients in the drug product manufacturing process. There are many points throughout this process, and the manufacturing processes of other product candidates we develop, that can lead to failure. Failure in the production of any of our product components or candidates could have a material adverse effect on our business, financial condition, results of operations and prospects. Some examples of manufacturing challenges and potential failure we may encounter follow:

- As part of the manufacturing process of DS, bacterial cells are inoculated to a fermenter and expanded.
- These bacteria produce the plasmid DNA DS, which is purified from the cells by an extensive purification process. At any stage, any or all of these processes can fail, including the biological or purification processes, which would result in batch failure. These processes can fail due to contamination, inadequate purification or other reasons.
- The manufacture of DDX and PEG-b-PLE involves multiple complex chemical synthesis and purification steps to produce final products with target specifications and yield. At any stage, any or all of these processes can fail, including the chemical or purification processes.
- The manufacture of detalimogene requires careful and complex combination of DS with DDX and PEG-b-PLE followed by sterile filtration, filling and lyophilization to yield the drug product. At any stage, any or all of the processes involved can fail, including the mixing, sterilization, filling, lyophilization or storage processes.

Our manufacturing processes are also susceptible to product loss or failure due to logistical issues associated with multiple outsourced activities across the range of manufacturing, shipping of materials to analytical laboratories, cold chain distribution to where products will be administered to patients, interruptions in the manufacturing processes, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability of product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other contaminations are discovered in detalimogene or other product candidates we develop or in the manufacturing facilities in which detalimogene or those other product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could result in our inability to timely produce or ship product. Further, as product candidates are developed through preclinical to later-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Although we continue to optimize our manufacturing processes, doing so is difficult and uncertain. There are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among other things, cost overruns, production delays, potential problems with process scale-out, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up our manufacturing processes with our current manufacturing partners, we will need to transfer such processes to another manufacturing partner and complete the manufacturing validation process, which can be a lengthy process. We ultimately may not be successful completing the transfer of our manufacturing processes to one or more of the manufacturers on whom we rely. The manufacturers who become responsible for our processes may not have the necessary capabilities to complete the implementation and development processes to our specifications or standards. If we are able to adequately validate and scale-up a particular manufacturing process for detalimogene and other product candidates we develop with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on commercially reasonable terms, or at all. As a result, we may ultimately be unable

to manage the cost of goods for detalimogene or other product candidates we develop to levels that will allow for an attractive return on investment if and when detalimogene or those other product candidates are approved and commercialized.

The manufacturing processes and facilities used for any products that we may develop are subject to the FDA and non-U.S. regulatory authority approval processes, and we will need to contract with manufacturers who we believe can meet applicable FDA and non-U.S. regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or if the facilities used to manufacture our products are found to be non-compliant for any reason, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications and under required good manufacturing practices acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and prospects.

Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

In addition, the FDA, the EMA and other non-U.S. regulatory authorities may require us to submit samples of any lot of any approved product, together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other non-U.S. regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in our manufacturing processes, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing processes could restrict our ability to meet market demand for our products.

Any problems in our manufacturing processes or facilities at our CMOs, or the perception of the possibility of problems in such processes or facilities, could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

We have no experience in developing a manufacturing facility for our biologic products and may never be successful in developing our own manufacturing facility or capability.

We expect to evaluate the possibility of establishing our own capabilities and infrastructure, including a manufacturing facility. If we choose to build our own manufacturing facility, we will need significant funding and will need to select an adequate location. We expect that development of our own manufacturing facility would provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. If we determine to establish our own manufacturing capabilities and infrastructure, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if approved, of our product candidates. If we fail to select the correct location, complete the construction in an efficient manner, recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or could prove costly. Even if we are successful, any manufacturing capabilities we develop could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in the manufacturing or formulation of detalimogene or any other product candidate we develop may result in additional costs or delay, which could adversely affect our business and results of operations.

As product candidates are developed through preclinical studies to later-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods or formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause detalimogene or any other product candidates that we develop to perform differently and affect the results of ongoing or planned clinical trials or other future clinical trials conducted with the altered materials. In addition, such changes and any other similar changes in the future may also require additional testing or notification to or approval by the FDA or other regulatory authorities. This could delay completion of clinical trials, require

the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of detalimogene or any other product candidates that we develop and/or jeopardize our ability to commence product sales and generate revenue.

Detalimogene is, and any other product candidates we develop may be, complex to analyze and we may encounter difficulties in product release testing, particularly with respect to bioassay potency testing. If we or any of our contract testing laboratories encounter difficulties, our ability to provide supply of detalimogene or any other product candidates that we develop for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The analytical methods used to test detalimogene are complex and many are novel and have not been validated for clinical or commercial production. The manufacturing processes used to produce any future product candidates that we develop may be similarly complex and novel. For example, in addition to several complex physio-chemical tests for detalimogene, drug substance (DS) and novel excipients, we also test detalimogene and the DS for biological potency using multiple unique cell-based assays. We rely on third-party laboratories to develop and conduct these assays. These assays may be subject to inherent variability and limitations such as, but not limited to, variations in assay conditions, reagents, equipment, or interpretation of results that could lead to inconsistent or inaccurate measurements of potency. Inaccurate potency assessments may affect our ability to demonstrate adequate control of the efficacy and safety of our drug product to regulatory authorities, potentially resulting in regulatory delays, additional testing requirements, or even rejection of our product. Furthermore, changes in regulatory guidelines or evolving scientific understanding may necessitate modifications to the biological potency assays, requiring additional validation studies and potential delays in the development or commercialization of detalimogene or any other product candidates we develop. It is important to note that despite our efforts to ensure the accuracy and reliability of these assays, there may be factors beyond our control that could impact their effectiveness, thereby affecting the overall success of our product candidates.

Although we continue to optimize our testing methods, doing so is a difficult and uncertain task, and there are risks associated with developing these methods to the level required for advanced clinical trials and commercialization, including, among other things, cost overruns, potential problems with reproducibility, stability issues, consistency and timely availability of reagents or raw materials needed to execute the testing. If we are unable to adequately validate testing methods with our current testing laboratories, we will need to transfer to another laboratory and repeat the analytical validation process, which can be a lengthy process. We ultimately may not be successful in transferring the analytical methods to contract testing laboratories and the selected contract laboratories may not have the necessary capabilities to complete the implementation and validation process for the assays. If we are able to adequately transfer and validate testing methods for detalimogene or any other product candidates we develop with a contract laboratory, we will still need to negotiate a service agreement with that contract laboratory and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to manage the cost of goods for detalimogene or any other product candidates we develop to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized.

The analytical testing methods for any products that we may develop are subject to the FDA and non-U.S. regulatory authority approval processes, and we will need to contract with laboratories we believe can meet applicable FDA and non-U.S. regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably test products in a manner acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for detalimogene or any other product candidates we develop, there is no assurance that either we or our CMOs will be able to test the approved product in a manner required by good manufacturing practices acceptable to the FDA or other regulatory authorities, to test products with sufficient throughput to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of detalimogene or any other product candidates we develop, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and prospects.

Our future success depends on our ability to test our products on a timely basis with acceptable costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we could incur higher testing costs if testing methods or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditure. Specifically, because detalimogene or any other product candidates we develop may have a higher testing requirement than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

The market opportunities for detalimogene and any other product candidates we develop may be limited to a small group of patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer and other disease therapies are sometimes characterized as first-line, second-line or third-line and the FDA often approves new therapies initially only for third-line use. When cancers are detected they are treated with first-line of therapy with the intention of

curing the cancer. This treatment generally consists of chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. If the patient's cancer relapses, then the patient is given a second-line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Generally, the later the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations. Initial approvals for new cancer and other disease therapies are often restricted to later lines of therapy for patients with advanced or metastatic disease, limiting the number of patients who may be eligible for such new therapies, which may include our product candidates.

Our lead product candidate, detalimogene, is being developed to treat patients with BCG-unresponsive NMIBC with CIS with or without concomitant papillary disease. Our projections of both the number of people who have the disease we are targeting, as well as the subset of people with these diseases in a position to receive our therapies, if approved, are based on our beliefs, research and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations or secondary market research databases and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for detalimogene or any other product candidates we develop may be limited or may not be amenable to treatment with such product candidates. Even if we obtain significant market share for detalimogene or any other product candidates we develop, because certain of the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. If the market opportunities for detalimogene or any other product candidates we may develop are smaller than what we believe they are, our potential revenues may be lower than projected and our business may be harmed.

We depend on our executive team and key personnel, and if we lose one or more of our executive officers or key employees or are unable to attract and retain highly skilled employees, such events could harm our business.

Our success depends on the skills, experience and performance of members of our senior management team and key personnel as well as their continued service. The individual and collective efforts of our senior management team and key personnel are important as we continue to develop product candidates, establish strategic partnerships, build out our operations and prepare for potential regulatory approval and commercialization of detalimogene, if approved. In the past two years, we have had several transitions of our executive officers, including our Chief Executive Officer transition in July 2024, the departure of our Chief Medical Officer in June 2025 and the hiring of a new Chief Medical Officer in September 2025. If we are unable to effectively manage such transitions or if we have any future transition or loss of the services of any of our executives or highly skilled technical and managerial personnel, it could have a disruptive impact on our ability to implement our business strategy and to meet our financial and operational goals, and as a result our strategic plans and financial performance may be adversely impacted. The loss or incapacity of existing members of our executive management team and key personnel could adversely affect our operations if we experience difficulties in hiring qualified successors. If we are not successful in attracting and retaining highly qualified personnel, our business, financial condition, results of operations and prospects may be harmed.

Our research and development initiatives, manufacturing processes and business depend on our ability to attract and retain highly skilled scientists and other specialized individuals. We may not be able to attract or retain such qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses.

Our research and development initiatives, laboratory operations and manufacturing processes depend on our ability to attract and retain highly skilled and experienced scientists, clinical personnel, technicians, engineers, quality-control and manufacturing personnel. We may not be able to attract or retain qualified scientists, clinical personnel, technicians or engineers in the future due to the competition for qualified personnel among life science and technology businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, we may be unable to identify, hire and retain the experienced scientific, quality-control and manufacturing personnel needed to transfer our manufacturing processes and test methods to CMOs and external testing laboratories. Further, if we endeavor to conduct manufacturing processes internally, we may be unable to identify, hire or retain the personnel needed to conduct our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. We may have difficulties locating, recruiting or retaining qualified personnel across functions that we deem critical to our success. Recruiting, training and retention difficulties can limit our ability to support our research and development and commercialization efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory and commercialization strategy. Our consultants and advisors may provide services to other organizations and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current consultants or advisors might impede the achievement of our research, development, regulatory and commercialization objectives.

We cannot assure you that we will be able to adequately address these additional risks. If we are unable to do so, our operations might suffer.

We face risks related to epidemics and other outbreaks of communicable diseases which could significantly disrupt our operations, including our clinical trials and preclinical studies, and adversely affect our business and results of operations.

Public health crises could have an adverse effect our business. Quarantines, travel restrictions and other public health and safety measures implemented in response to a pandemic could adversely impact our operations, and the ultimate impact is highly uncertain and cannot be predicted with confidence. Effects of a pandemic that may delay or otherwise adversely affect our ongoing and planned preclinical activities, our planned clinical trials as well as our business generally, include:

- delays related to disruptions at CROs and contract manufacturers, or in the supply chain;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff who, as healthcare providers, may have heightened exposure;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;
- difficulties interpreting data from clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and interruptions, difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely.

Any of these effects, and other effects of a pandemic could have a material adverse effect on our business, financial condition, results of operations and prospects. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States, Canada, and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

We or the third parties upon whom we depend may be adversely affected by risks beyond our control, such as natural disasters, political crises, acts of terrorism, epidemics and other outbreaks of communicable diseases, war or other catastrophic events and our business continuity and disaster recovery plans may not adequately protect us from the adverse effects of such events.

We, our suppliers and third-party service providers are vulnerable to damage from natural disasters, including but not limited to earthquakes, fires or floods, power loss, communications failures, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict and similar events. If any such disaster were to occur, our ability to operate our business at any of our or our third party facilities could be adversely affected.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

For example, since February 2022, Russian military forces have continued their significant military invasion of Ukraine. Since October 2023, with the launch of the Israel-Hamas war, there has been increased hostilities in the Middle East. The impact to these countries and regions, as well as actions taken by other countries, including new and stricter sanctions by the United States, Canada, the United Kingdom, the European Union and other countries and organizations against certain officials, individuals, regions, and industries in the affected areas, and each country's potential response to such sanctions, tensions, and military actions could continue to have a material adverse effect on the global economy and political situation.

As of the date of this Annual Report, we (i) are not conducting clinical or nonclinical studies in Ukraine, Belarus, Russia, or the Middle East, (ii) are not relying upon service providers or vendors from any of these regions to advance our product development programs, (iii) do not source biomanufacturing critical raw materials, equipment, or other supplies directly from these regions, and (iv) are not aware nor have we received notification from our supply vendors that the sourcing of any general laboratory or manufacturing materials may be negatively impacted due to such conflict and related sanctions.

The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

Regulatory Risks

Nearly all aspects of our activity and our products and services are subject to extensive regulation by various U.S. federal and state agencies and regulatory bodies in non-U.S. jurisdictions, and compliance with existing or future regulations could result in unanticipated expenses or limit our ability to offer our products and services. Once developed, detalimogene, and any future product candidates developed using our genetic medicine platform will require regulatory approval, which is a lengthy, expensive, and inherently unpredictable process with uncertain outcomes and cost and is subject to the potential for substantial delays. We cannot give any assurance whether or when detalimogene or any other product candidates we develop will receive regulatory approval, which is necessary before they can be commercialized.

Regulatory requirements governing gene and cell therapy products, and in particular any novel genetic medicine products we may develop, have changed frequently and may continue to change in the future. We are aware of a limited number of genetic medicine products that have received marketing authorization from the FDA and EMA. Even with respect to more established products in the genetic medicine field, the regulatory landscape is still developing. In 2016, the FDA established the Office of Tissues and Advanced Therapies ("OTAT") within its Center for Biologics Evaluation and Research to consolidate the review of genetic medicine and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products ("OTP") and elevation of OTP to a "Super Office" to meet its growing cell and genetic medicine workload. Genetic medicine clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health ("NIH"), also are potentially subject to review by the Office of Biotechnology Activities' Recombinant DNA Advisory Committee ("RAC"); however, the NIH announced that the RAC will only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks.

The same applies in the European Union. The EMA's Committee for Advanced Therapies ("CAT"), is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. The role of CAT is to prepare a draft opinion on an application for marketing authorization for a genetic medicine medicinal candidate that is submitted to the Committee for Medicinal Products for Human Use ("CHMP"), before CHMP adopts its final opinion. In the European Union, the development and evaluation of a genetic medicine medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for genetic medicine medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to genetic medicine products and cell therapy products may be applied to any product candidates we may develop, but that remains uncertain at this point.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of detalimogene and any other product candidates we may develop, or lead to significant post-approval limitations or restrictions. As we advance detalimogene and any other product candidates we may develop, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of these product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

Although the FDA decides whether individual genetic medicine protocols may proceed, the RAC public review process, if undertaken, can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an IND on a clinical hold even if the RAC has provided a favorable review or an exemption from in-depth, public review. If we were to engage an NIH-funded institution to conduct a clinical trial, now or in the future, that institution's institutional biosafety committee, as well as its IRB would need to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of genetic medicine products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of detalimogene or any other product candidates we may develop. Similarly, the EMA, FDA, and other regulatory bodies may issue new guidelines concerning the development and marketing authorization for genetic medicine products and require that we comply with these new guidelines.

As we are initially seeking to identify and develop product candidates to treat diseases using novel technologies, there is heightened risk that the FDA, the EMA or other regulatory authority may not consider the clinical trial endpoints that we propose to provide clinically meaningful results. Even if the endpoints are deemed clinically meaningful, we may not achieve these endpoints to a degree of statistical significance, particularly because many of the diseases we are targeting with our platform have small patient populations, making development of large and rigorous clinical trials more difficult.

Adverse developments in post-marketing experience or in clinical trials conducted by others of genetic medicine products or products developed or marketed for indications of interest to us, such as NMIBC, may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of detalimogene or any other product candidates we may develop or limit

the use of products utilizing non-viral genetic medicine technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as detalimogene or other product candidates we may develop can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing non-viral genetic medicine technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products.

In addition, ethical, social and legal concerns about genetic medicine, genetic testing and genetic research could result in additional regulations or prohibiting the processes we may use. Federal and state agencies, congressional committees and non-U.S. governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that detalimogene and any other product candidates we may develop are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of detalimogene and any other product candidates we may develop. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

As we advance detalimogene and any other product candidates we may develop through clinical development, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of detalimogene and any other product candidates we may develop or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue.

We have designed and are currently conducting the clinical trials for detalimogene in accordance with the Guidance Document. This document, which was updated in draft form in August 2024, sets forth guidance for patient selection and describes a potentially abbreviated regulatory path for approval provided certain recruitment, efficacy, and safety data are met. The FDA may review, revoke, or otherwise modify these guidelines at any time, for any reason, which would have a material adverse effect on our approval timelines or process. In addition, the Guidance Document is in draft form subsequent to FDA's 2024 revisions, and it is possible that some or all of its key provisions may be modified prior to the document's finalization. Furthermore, approval of other competitive products treating the same indication may reduce the agency's propensity to support abbreviated approval pathways, which could cause our programs to be delayed in achieving regulatory approval or contribute to our failure to achieve approval at all.

We cannot predict whether or when we will obtain regulatory approval to commercialize detalimogene or any other product candidate we may develop in the United States or any other jurisdiction and any such approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate and our application to commercialize it. Even if detalimogene or any other product candidates we may develop meet their safety and efficacy endpoints in clinical trials, regulatory authorities may not complete their review processes in a timely manner or we may not be able to obtain regulatory approval. Additional delays may result if an FDA panel of experts ("Advisory Committee") or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions, boxed warnings or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials.

In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of detalimogene or any other product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for detalimogene or any other product candidates we may develop and materially adversely affect our business, financial condition, results of operations and prospects.

If we are not able to obtain or if there are delays in obtaining required regulatory approvals for detalimogene or any other product candidates that we may develop, we will not be able to commercialize or will be delayed in commercializing detalimogene or any other product candidates that we may develop and our ability to generate revenue will be adversely affected. Even if we eventually gain approval for detalimogene or any of other product candidates, we may be unable to commercialize them.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize detalimogene or any other product candidates that we may develops, we must obtain marketing approval. Detalimogene or any other product candidates that we may develop in the future, require research and development, preclinical studies, nonclinical testing, and clinical trials prior to seeking regulatory approval, and commencing commercial sales. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that neither detalimogene nor any other product candidates we may seek to develop in the future will ever obtain regulatory approval. In certain instances, we may need to rely on third-party CROs and/or regulatory consultants to assist us in this process, and we may have limited control over those third parties and their conduct with respect to our development programs and product candidates. To date, we have focused substantially all of our efforts and financial resources on identifying and developing our product candidates, including conducting lead optimization, nonclinical studies, preclinical studies and clinical trials, and providing general and administrative support for these operations. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the manufacturing processes for the biologic product candidate to, and inspection of manufacturing facilities by, the relevant regulatory authority. Manufacturing facilities must comply with cGMP regulations, which include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports. In addition, given the novelty of our therapeutics approach and technologies, detalimogene and any other product candidates that we may develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use of such products if approved.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. FDA and other regulatory bodies may continually change the requirements for Chemistry, Manufacturing and Controls (CMC) and other aspects of product manufacturing such that the approval to continue a clinical trial and/or commercially sell a product may never occur. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted IND, BLA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Detalimogene and any other product candidates that we may develop could be delayed in receiving or fail to receive regulatory approval for many reasons, including the following:

- the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that detalimogene or any other product candidates that we may develop is safe and effective for its proposed indication or that a potential related companion diagnostic, should we develop one, is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory authorities for biologic product approval or continued clinical development;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of detalimogene or any other product candidates that we may develop may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or other authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs and biologics in development, only a small percentage successfully complete the FDA or non-U.S. regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of clinical trial

results may result in our failing to obtain regulatory approval to market detalimogene or any other product candidates that we may develop, which would significantly harm our business, financial condition, results of operations and prospects.

We expect the novel nature of detalimogene or any other product candidates that we may develop to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be adversely affected.

For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well-controlled, Phase 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize the requirements defined in the FDA's guidance for industry on developing detalimogene or other product candidates for BCG-unresponsive high-risk NMIBC given the limited alternatives for treatments for cancer and other serious diseases, but the FDA may not agree with our plans or permit us to proceed under such alternative guidance.

The FDA may also require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support BLA approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of detalimogene or any other product candidates that we develop based on the completed clinical trials.

Moreover, approval of genetic or biomarker diagnostic tests may be necessary in order to advance some of our product candidates to clinical trials or potential commercialization. In the future, regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy and approval may not be obtained.

In addition, even if we were to obtain approval, regulatory authorities may approve detalimogene or any other product candidates that we may develop for fewer or more limited indications than we request, may not approve the price we intend to charge for our products (where such regulatory approvals are required), may grant approval contingent on the performance of costly post-marketing clinical trials or may approve that product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for detalimogene or any other product candidates that we may develop.

If we experience delays in obtaining approval or if we fail to obtain approval of detalimogene or any other product candidates that we may develop, the commercial prospects for those product candidates may be harmed and our ability to generate revenues will be materially harmed.

We may not obtain or maintain regulatory approval in all jurisdictions in which such approval may be required or otherwise desirable or beneficial from a business perspective. Obtaining and maintaining regulatory approval of detalimogene or any other product candidates we develop in one jurisdiction does not mean that we will obtain and/or maintain regulatory approval of such product candidates in other jurisdictions, while a failure or delay in obtaining or maintaining regulatory approval of such product candidates in one jurisdiction may have a material adverse effect on the regulatory approval or maintenance process in other jurisdictions.

Obtaining and maintaining regulatory approval of detalimogene or any other product candidates that we may develops in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in non-U.S. jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many non-U.S. jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for us and could require additional preclinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of our products in certain countries. The non-U.S. regulatory approval process involves all of the risks associated with FDA approval, and may not offer certain potentially expedited development and approval pathways that exist in the United States. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and/or obtain and maintain applicable marketing

approvals, our target market will be reduced and our ability to realize the full market potential of detalimogene or any other product candidates that we may develop will be harmed.

Fast Track designation and Regenerative Medicine Advanced Therapy designation by the FDA for detalimogene and our participation in the FDA's Chemistry, Manufacturing, and Controls Development and Readiness Pilot ("CDRP") Program may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that detalimogene or any future product candidate that may receive these designations or is selected for the CDRP Program will receive regulatory approval.

The FDA has granted a Fast Track designation and Regenerative Medicine Advanced Therapy ("RMAT") designation for detalimogene for the treatment of BCG-unresponsive, high-risk NMIBC patients with CIS, and we may seek such designations for other indications or future product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Similarly, RMAT designation is a dedicated program designed to expedite the drug development and review processes for promising regenerative medicine products, including genetic therapies. A regenerative medicine advanced therapy is eligible for RMAT designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or therapy has the potential to address unmet medical needs for such disease or condition. Similar to breakthrough therapy designation, RMAT designation provides the benefits of intensive FDA guidance on efficient drug development, including the ability for early interactions with the FDA to discuss surrogate or intermediate endpoints, potential ways to support accelerated approval and satisfy post-approval requirements, potential priority review of a BLA, and other opportunities to expedite development and review. In addition, the LEGEND study has been selected for the FDA's Chemistry, Manufacturing, and Controls ("CMC") Development and Readiness Pilot ("CDRP") Program, a voluntary program designed to accelerate the development of certain drugs and biologics that have expedited clinical development pathways by increasing communication between the FDA and sponsors. The program's stated goal is to align and derisk CMC strategies early in the process, which can lead to faster patient access to new treatments.

The FDA has broad discretion whether or not to grant these designations or select a development program for participation in the CDRP Program. Even if we believe a particular product candidate or development program is eligible for these designations or the CDRP Program, we cannot assure you that the FDA would decide to grant any of them. Although we have received Fast Track designation and RMAT designation for detalimogene for the treatment of BCG-unresponsive, high-risk NMIBC patients with CIS and the LEGEND study has been selected for the CDRP Program, and even if we receive additional Fast Track or RMAT designations or are selected for the CDRP Program for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track and RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. The FDA may also decide that we are no longer eligible for the CDRP Program. Furthermore, these designations and the CDRP Program do not increase the likelihood that detalimogene or any future product candidate that may be granted Fast Track or RMAT designation or selected for the CDRP Program will receive marketing approval in the United States. Many product candidates that have received Fast Track designation and/or RMAT designation or other designations have ultimately failed to obtain approval.

We may seek priority review designation for detalimogene or any other product candidates we develop, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness of the treatment, the FDA may designate the marketing application for that product candidate for priority review. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications and to shorten the goal for the FDA to review an application to six months, rather than the standard review period of ten months. We may request priority review for one or more original BLAs for detalimogene or any other product candidates that we may develop s in the future. The FDA has broad discretion with respect to whether or not to grant priority review status to a marketing application, so even if we believe an application for a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle, or at all. Many product candidates that have received priority review designation have ultimately failed to obtain approval.

Even if we receive regulatory approval of detalimogene or any other product candidates or therapies that we may develop, we will be subject to ongoing regulatory obligations, reporting requirements and continued regulatory review, which may result in significant additional expenses. If we fail to comply with regulatory requirements or experience unanticipated problems with our products or product candidates, we may be subject to substantial penalties, fines, delays, suspensions, refusals and withdrawals of approvals.

If detalimogene or any other product candidates that we may develop are approved, they will be subject to ongoing regulatory requirements and reporting requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, recordkeeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable non-U.S. regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Facilities of CMOs and testing laboratories are required to comply with extensive FDA, and non-U.S. regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases, current Good Tissue Practices ("cGTP"), regulations. As a result, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work with must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for detalimogene or any other product candidates that we may develop may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require that we implement a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable non-U.S. regulatory authority approves detalimogene or any other product candidates that we may develop, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and establishment registration.

The FDA may seek consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers, manufacturing processes or testing laboratories, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Changes in regulatory requirements could result in delays or the discontinuation of development of detalimogene or other product candidates or therapies that we may develop, or unexpected costs in obtaining or maintaining regulatory approval, and thereby adversely affect our business and results of operations.

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products.

Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy and durability of effect must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Because we are developing novel genetic medicine product candidates, the regulatory requirements that we will be subject to are continually evolving and may not be clear. Even with respect to more established products that fit into the category of genetic medicines, the regulatory landscape is still developing. For example, regulatory requirements governing genetic medicine products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing cell therapy products.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union a special committee called the CAT was established within the EMA in accordance with Regulation ("EC") No 1394/2007 on advanced-therapy medicinal products ("ATMPs") to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include genetic medicine products. These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our genetic medicines and product candidates is new, we may face even more cumbersome and complex regulations than those emerging for cell therapy products.

Furthermore, even if detalimogene or other product candidates that we may develop obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

Our contract manufacturers are subject to significant regulation with respect to the manufacturing of our current and future product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements and/or may have limited capacity.

Contract manufacturers and their facilities are required to comply with extensive regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. These regulations cover all aspects of manufacturing relating to our product candidates and components used in clinical studies and commercial production. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational product candidates and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We and our contract manufacturers must supply all necessary documentation in support of a BLA or Market Authorization Application ("MAA") on a timely basis and must adhere to Good Laboratory Practices ("GLP") and cGMP regulations enforced by the FDA and other regulatory authorities through their facilities inspection program. The facilities and quality systems of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential product candidates.

In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. Moreover, if our contract manufacturers fail to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or there are substantial manufacturing errors, this could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns, revocation of regulatory approvals, or other problems that could seriously harm our business.

Ongoing healthcare legislative and regulatory reform measures, including the U.S. federal government's determination that any of our product candidates, including detalimogene, is an "essential" biologic medicine, may have a material adverse effect on our business and results of operations.

The United States and many non-U.S. jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription products. In recent years, Congress has considered reductions in Medicare reimbursement levels for products administered by

physicians. The CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some products. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the ACA expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic products, expanded the 340B program, and revised the definition of average manufacturer price, which could increase the amount of Medicaid rebates manufacturers are required to pay to states. The legislation also extended Medicaid rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those products. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the ACA. These regulations became effective on April 1, 2016. Since that time, there have been significant ongoing efforts to modify or eliminate the ACA. The Tax Cuts and Jobs Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the United States Internal Revenue Code of 1986, as amended (the "Code") or the individual mandate.

Other legislative changes have been proposed and adopted since the passage of the ACA. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction (the "Joint Select Committee"), to provide recommendations and legislative language that would significantly improve the short-term and long-term fiscal imbalance of the U.S. federal government. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022. Under the Consolidated Appropriations Act, 2023, the 2% Medicare sequester is extended for the first six months of fiscal year 2032 and revises the sequester percentage up to 2% for fiscal years 2030 and 2031. These across-the-board spending cuts could adversely affect our future revenues, earnings, and cash flows.

In August 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA"). The IRA contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of the IRA on our business and the pharmaceutical industry in general is not yet known.

The ACA, has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the ACA remain possible but it is unknown what form any such changes or any law proposed to replace or revise the ACA would take, and how or whether it may affect our business in the future. We expect that changes to the ACA, the Medicare and Medicaid programs and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and non-U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, including detalimogene, if approved, or additional pricing pressures.

Any product candidates we develop, including detalimogene, may become subject to unfavorable or unprofitable third-party coverage and reimbursement practices, as well as pricing regulations.

Patients rely on insurance coverage by third-party payors (third-party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as Blue Cross Blue Shield, Humana, Cigna, etc.), to pay for products. The availability and extent of coverage and adequate reimbursement by third- party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors.

Private insurance companies, commercial payors and various other healthcare intermediaries such as pharmacy benefit managers may take steps to thwart physician and/or patient access to our products including not covering the product, blocking access to our products or adding step edits or prior approval requirements before reimbursing patients or health care providers for using our products. This could result in reduced or failure to achieve revenues and/or margins. In addition, third-party organizations that purport to study and issue reports regarding the pricing of certain therapeutic medicines may issue reports regarding our products that negatively affect pricing and our product use and uptake by physicians and patients. Additionally, private insurance companies are increasingly imposing utilization management tools, such as requiring prior authorization for a proprietary product if a generic product or less expensive product is available or requiring the patient to first fail on one or more generic or less expensive products before permitting access to a proprietary medicine.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

No uniform policy exists for coverage and reimbursement in the United States. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

As U.S. federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Such other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in the European Union, the United Kingdom, Japan and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates, including detalimogene, from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future or subject to recoupment or overpayment challenges.

Drug marketing, price controls and reimbursement regulations may materially affect our ability to market and receive coverage for our product candidates, if approved, in the European Union, the United Kingdom, Japan and other non-U.S. jurisdictions.

We intend to seek approval to market our product candidates, including detalimogene if approved, in both the United States and in selected non-U.S. jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some countries outside of the United States, particularly those in the European Union and United Kingdom, the pricing of pharmaceutical products is subject to governmental control and other market regulations,

which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If required to execute such a trial, we cannot be sure of a favorable outcome. In general, product prices under such systems are substantially lower than in the United States. Price controls in non-U.S. jurisdictions or changes in pricing regulations in such jurisdictions could reduce the amount we are able to charge for our product candidates. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal AKS prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products are also prohibited in the European Union and United Kingdom. The provision of benefits or advantages to physicians is governed by both the rules on medicinal products and the national anti-bribery laws in the relevant countries, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, their competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most countries outside of the United States, including the European Economic Area ("EEA") and United Kingdom, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, and in some countries include retrospective rebates to the government. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally, prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us and the potential profitability of any of our product candidates in those countries would be negatively affected.

Guidelines and recommendations published by various organizations may impact the use or reimbursement of detalimogene, if approved, as well as other future products.

Government authorities promulgate regulations and guidelines that may be directly applicable to us and any approved products. However, professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payors, as well as patient communities.

Recommendations by government authorities or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review ("ICER"), which publish their findings and offer recommendations relating to the products' reimbursement by government and private payors. On December 17, 2020, ICER published its final report assessing the effectiveness and value of nadofaragene firadenovec and oportuzumab monatox for BCG-unresponsive NMIBC, both of which are potential competitors to detalimogene. The guidance was updated on January 15, 2021. Nadofargene firadenovec, sold under the brand name Adstiladrin, is a FDA-approved genetic medicine approved in 2022 for the treatment of adult patients with high-risk BCG-unresponsive NMIBC with CIS with or without papillary tumors; oportuzumab monatox, also known as Vicineum, is an experimental therapy that has been studied in a highly similar patient group. The findings of this or any future ICER report or similar recommendations or guidelines from ICER or similar third parties may affect our reputation as well as the perception of our value, and any recommendations or guidelines that result in decreased use or reimbursement of detalimogene, if approved or adopted into commercial or clinical practice, could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of detalimogene, if approved, could adversely affect the market price of our securities. The effect, if any, of any ICER report, recommendations or guidelines on our any of our products relating to usage, dosage, administration, pricing, reimbursement or other

matters is not foreseeable and we make no assurance regarding the effect of any current or future ICER report, recommendations or guidelines on our business.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business and results of operations.

We are subject to data privacy and protection laws, rules and regulations, as well as contractual obligations, that apply to the collection, transmission, storage, use and other processing of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

There are numerous U.S. federal and state laws, rules and regulations governing the collection, sharing, use, retention, disclosure, security, transfer, storage and other processing of personal information, including federal and state data privacy and security laws, data breach notification laws, and data disposal laws. In particular, at the federal level, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future. At the federal level, we are also subject to, among other laws and regulations, the rules and regulations promulgated under the authority of the FTC (which has the authority to regulate and enforce against unfair or deceptive acts or practices in or affecting commerce, including acts and practices with respect to data privacy and security), as well as the Electronic Communication Privacy Act. The United States Congress also has considered, is currently considering, and may in the future consider, various proposals for comprehensive federal data privacy and security legislation, to which we may become subject if passed. If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached certain contracts or obligations. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

At the state level, we are subject to similar and sometimes more onerous data protection and privacy laws and regulations such as the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (the "CPRA") (collectively, the "CCPA"). The CCPA imposes many requirements on certain businesses that process the personal information of California residents, including requirements similar to those found in the General Data Protection Regulation ("GDPR"). For example, the CCPA requires covered businesses to provide notice to California residents regarding the information collected about them and how such information is used and shared, provides California residents the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of certain "sales" of their personal information. The CCPA provides for significant civil penalties and statutory damages for companies that violate its requirements, and also provides for a private right of action for certain data breaches that result in the loss of unencrypted personal information. This private right of action is expected to increase the likelihood of, and risks associated with, data breach litigation. The CPRA significantly expands the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. These provisions may apply to some of our business activities. In addition, other states, including Virginia and Colorado, already have passed comprehensive state-level data privacy and security laws, rules and regulations that share similarities with the CCPA. Other states are in the process of enacting or will be considering these laws in the future. Moreover, laws in all 50 U.S. states require businesses to provide notice under certain circumstances to consumers whose personal information has been disclosed as a result of a data breach. These laws, and other similar laws that may be enacted in the future, may impact our business activities, including our identification of research subjects and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA is regulated by the GDPR, which went into effect in May 2018 and imposes obligations on companies that operate in our industry with respect to the processing of

personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations, including requiring data controllers and processors to maintain a record of their data processing and policies. Following the withdrawal of the United Kingdom from the European Union, the United Kingdom's Data Protection Act 2018 (the "U.K. GDPR"), which "implements" and complements the GDPR and achieved formal approval by United Kingdom's monarchy on May 23, 2018, applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the GDPR and U.K. GDPR remain substantially similar for the time being, the U.K. government has announced that it would seek to chart its own path on data protection and reform its relevant laws, including in ways that may differ from the GDPR. While these developments increase uncertainty with regard to data protection regulation in the United Kingdom, even in their current, substantially similar form, the GDPR and U.K. GDPR can expose businesses to divergent parallel regimes that may be subject to potentially different interpretations and enforcement actions for certain violations and related uncertainty. If our or our service providers' privacy or data security measures fail to comply with the GDPR and U.K. GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros (or GBP17.5 million under the U.K. GDPR) or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the EEA to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the EEA to other countries. Similar complexities and uncertainties also apply to transfers from the U.K. to third countries. In July 2020, the Court of Justice of the European Union ("CJEU"), invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU's decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses ("SCCs"), for transfers of personal data from the EEA to the United States. While we were not self-certified under the EU-U.S. Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors. While we may take steps to mitigate the impact on us, such as implementing SCCs, the efficacy and longevity of these mechanisms remains uncertain. Moreover, in 2021, the European Commission adopted new SCCs, which impose on companies additional obligations relating to personal data transfers out of the EEA, including the obligation to update internal privacy practices, conduct transfer impact assessments and, as required, implement additional security measures. The new SCCs may increase the legal risks and liabilities under European Union laws associated with cross-border data transfers, and result in material increased compliance and operational costs. While the European Commission announced in March 2022 that an agreement in principle had been reached between European Union and U.S. authorities regarding a new transatlantic data privacy framework, no formal agreement has been finalized, and any such agreement, if formalized, is likely to face challenge at the CJEU. Moreover, while the U.K. GDPR is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR. The United Kingdom has already determined that it considers all European Union and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the European Union and EEA remain unaffected. In addition, a decision from the European Commission appears to deem the United Kingdom as being "essentially adequate" for purposes of data transfer from the EEA to the United Kingdom, such that SCCs are not required for the transfer of personal data from the EEA to the United Kingdom, although such decision will sunset in June 2025 unless extended and it may be revoked in the future by the European Commission if the United Kingdom data protection regime is reformed in ways that deviate substantially from the GDPR. Adding further complexity for international data flows, in March 2022, the United Kingdom adopted its own International Data Transfer Agreement for transfers of personal data out of the United Kingdom to so-called third countries, as well as an international data transfer addendum that can be used with the SCCs for the same purpose. The European Union has also proposed legislation that would regulate non-personal data and establish new cybersecurity standards, and other countries, including the United Kingdom, may similarly do so in the future. If we are otherwise unable to transfer data, including personal data, between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Beyond the GDPR and U.K. GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow the GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and any eventual sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Any failure, actual or perceived, to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, any failure, actual or perceived, to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations

into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations and prospects.

Cyber-attacks or other failures in our or our third-party vendors', contractors' or consultants' telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We, our programs, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology ("IT"), systems and networks to process, transmit and store electronic information, including but not limited to intellectual property, proprietary business information and personal information, in connection with our business activities. Our internal IT systems and those of current and future third parties on which we rely may fail and are vulnerable to breakdown, breach, interruption or damage from cyber incidents, employee error or malfeasance, theft or misuse, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromises. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e.g., ransomware), viruses, spamming, phishing attacks, denial-of-service attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency, intensity, and sophistication. These threats pose a risk to the security of our, our programs', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data, and health-related information. There can be no assurance that we or any of our third-party partners will be successful in preventing cyberattacks or successfully mitigating their effects.

Advances in computer and software capabilities, encryption technology, and other discoveries increase the complexity of our technological environment, including how each interacts with our various software platforms. Such advances could delay or hinder our ability to conduct business or could compromise the integrity of our data, resulting in a material adverse impact on our financial condition and results of operations. The risk of system disruption is increased when significant system changes are undertaken. If we fail to timely integrate and update our information technology systems and processes, we may fail to realize the cost savings or operational benefits anticipated to be derived from these initiatives. We also may experience occasional system interruptions and delays that make our information technology systems unavailable or slow to respond, including the interaction of our information technology systems with those of third parties. A lack of sophistication or reliability of our information technology systems could adversely impact our operations and consumer service and could require major repairs, replacements or remodelings, resulting in significant costs.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, non-U.S. governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, varying parts of our workforce are currently working remotely on a part or full time basis. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile non-U.S. governments or agencies. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Similarly, there can be no assurance that our CROs, third-party logistics providers, distributors and other contractors, consultants and third parties will be successful in protecting our clinical and other data that is stored on their systems. Any loss of clinical trial data from our completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. We have experienced and expect to continue to experience actual and attempted cyberattacks of our IT networks, such as through phishing scams and ransomware. Although we do not believe that we have experienced any significant system failure, accident or security incidents to date, we cannot guarantee that we will not experience such incidents in the future.

Any cyberattack that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding clinical trial participants or employees, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws and regulations, require us to notify affected individuals or supervisory authorities, subject us to litigation and governmental investigations, proceedings and regulatory actions by federal, state and local regulatory entities in the United States and by international regulatory entities, cause our exposure to material civil and/or criminal liability and cause us to breach our contractual obligations, which could result in significant legal and financial exposure and reputational damages. Further, we could be forced to expend significant financial and operational resources in response to a security breach, including repairing system damage, increasing security protection costs by deploying additional personnel and modifying or enhancing our protection technologies, investigating and remediating any information security vulnerabilities and defending against and resolving legal and regulatory claims, all of which could divert resources and the attention of our management and key personnel away from our business operations and adversely affect our business, financial condition and results of operations. As cyber threats continue to evolve, we may be required to incur significant additional expenses in order to implement further data protection measures or to remediate any

information security vulnerability. Further, we do not maintain separate cyber liability insurance and our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability.

There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks and the mishandling of data by our employees and third-party service providers, then our business, financial condition, results of operations and prospects could be adversely affected.

Inadequate funding for, or changes in leadership at, or disruptions at the FDA, the SEC and other government agencies could hinder their ability to hire and retain key personnel, prevent new products and services from being developed, approved or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, passage of federal FDA user fee legislation every five years, ability to hire and retain key personnel and accept the payment of user fees, public health emergencies, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or for the FDA to take action with respect to other regulatory matters, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including for 43 days beginning in October 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown or other disruption occurs again in the future, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown or other disruption could prevent the timely review of patent applications by the United States Patent and Trademark Office, or USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our employees, independent contractors and contract manufacturers, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA, the Office of Inspector General at HHS ("HHS-OIG"), the U.S. Department of Justice ("DOJ") and other regulatory bodies in non-U.S. jurisdictions, fails to provide true, complete and accurate information to the FDA, CMS, HHS-OIG, DOJ and other similar regulatory bodies in non-U.S. jurisdictions, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar non-U.S. laws, or fails to report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly and our costs associated with compliance with these laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Our relationships with healthcare providers and physicians and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and result in diminished profits and future earnings and thereby adversely affect our business and results of operations.

We are subject to applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the AKS and the FCA, which may constrain our business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e.g., healthcare providers, physicians and third-party payors), are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. We also may be subject to patient information and privacy and security regulation by both the federal

government and the states and non-U.S. jurisdictions in which we conduct our business. The applicable federal, state and non-U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The AKS, which prohibits the knowing and willful offer, solicitation, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including but not limited to cash, improper discounts, and free or reduced price items and services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the AKS is violated. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of anti-kickback and other applicable laws can result in exclusion from participation in federal health care programs, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, and substantial civil and criminal sanctions.
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. Some state law equivalents of the above federal laws, such as the AKS and FCA, apply to items or services regardless of whether the good or service was reimbursed by a government program, so called all-payor laws. These all-payor laws could apply to our sales and marketing activities even if the AKS and FCA laws are inapplicable.
- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information also implicate our business. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition to other federal laws, state laws and non-U.S. laws, such as the General Data Protection Regulation in the European Union, create the potential for substantial penalties in the event of any non-compliance with the applicable data privacy and data protection laws.
- The federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. For the data submitted on or after January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. States may also have similar reporting requirements related to payments made to clinical providers, and failure to comply with such requirements can adversely impact the business.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulatory guidance. Federal and state enforcement bodies have

recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from our business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA or an all-payor law, then we could be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, loss of eligibility to obtain approvals from the FDA, the exclusion from participation in federal and state healthcare programs, suspension and debarment from government procurement and non-procurement programs, refusal of orders under existing government contracts, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs.

State and federal authorities have aggressively targeted pharmaceutical companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements with pharmacies and other healthcare providers that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines, have been ordered to implement extensive corrective action plans, and have in many cases become subject to consent decrees severely restricting the manner in which they conduct their business, among other consequences. Additionally, federal and state regulators have brought criminal actions against individual employees responsible for alleged violations. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the U.S. Foreign Corrupt Practices Act ("FCPA") and similar worldwide anti-bribery laws, including the Canadian Corruption of Foreign Public Officials Act, generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, partners or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation. For additional information regarding the compliance of our operations with the FCPA and non-U.S. laws and regulations, see the Risk Factor entitled "*Additional laws and regulations governing international operations may preclude or delay us from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs*."

We are subject to certain U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations thereof.

Among other matters, U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, the "Trade Laws") prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of the Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time, including when and if we conduct clinical trials outside the United States. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, even if we do not explicitly authorize or have prior knowledge of such activities.

Risks Related to International Operations

We are an international organization and we plan to expand operations internationally where we have limited operating experience and where we may be subject to increased regulatory risks and local competition. If we are unsuccessful in any efforts to expand internationally, our business and results of operations may be adversely affected.

We are already an international organization and we plan to further expand our operations internationally. We currently source drug product excipients and other product components that are critical to our manufacturing processes from CMOs located in the European Union. In the future, we expect to opportunistically engage with CMOs located in other non-U.S. jurisdictions to facilitate the manufacture of our products on a basis that is cost effective and responsive to customer demand. As part of our business strategy, we plan to commercialize detalimogene and other products we may develop for sale in the United States and non-U.S. jurisdictions. Our business strategy incorporates potential international operational expansion, independently and through third parties as we seek to obtain

regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including, but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of non-U.S. clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing non-U.S. operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to non-U.S. currency exchange rate fluctuations;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including a COVID-19 resurgence, and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; certain expenses including, among other things, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and recordkeeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

Global economic uncertainty, changes in geopolitical conditions and weakening product demand caused by political instability, changes in trade agreements and disputes, such as the armed conflicts between Russia and Ukraine and in the Middle East and other macroeconomic factors, could adversely affect our business and results of operations.

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years, including due to recent global economic uncertainty and turbulent financial market conditions. The armed conflict in the Middle East has created volatility in the global capital markets and is expected to have further global economic consequences. Russia's ongoing military invasion of Ukraine has triggered significant sanctions from U.S. and European leaders and disruptions to financial markets around the world. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." In addition, changes in political conditions in China and changes in the state of China-U.S. relations, including any tensions relating to potential military conflict between China and Taiwan, are difficult to predict and could adversely affect our business. Furthermore, if other countries, including the United States, become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. For example, increasing inflation has raised operating costs for us and many businesses, and, in the future, could impact demand, pricing or the cost we incur to manufacture our product candidates, foreign exchange rates (including in particular U.S. dollar and Canadian dollar exchange rates) or employee wages. Among other potential effects, continued increased inflation or interest rates may result in reduced liquidity and limits on our ability to access credit or otherwise raise capital. The Federal Reserve has previously raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks and creating new, unforeseen risks to our operations.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

These conditions make it extremely difficult for us to accurately forecast and plan future business activities. The above factors, including a number of other known and unknown economic and geopolitical factors in the United States and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations and prospects.

We expect certain of our research and development and manufacturing activities may take place in non-U.S. jurisdictions, such as China, through third-party CROs, collaborators or manufacturers. A significant disruption in the operation of those CROs, collaborators or manufacturers could materially adversely affect our business and results of operations.

We may contract many of our research, manufacturing and preclinical activities to third parties outside the United States, including without limitation, in China. Any disruption in the operations of such third parties or in their ability to meet our needs, whether as a result of a natural disaster, war or other causes, could impair our ability to operate our business on a day-to-day basis and to continue development of our programs. Furthermore, since many of these third parties are located outside the United States, we are exposed to the possibility of disruption and increased costs in the event of changes in the policies of the United States or non-U.S. governments, war, political unrest or unstable economic conditions in any of the countries where we conduct such activities. For example, a war or trade war could lead to tariffs, embargoes, sanctions or other limitations on trade, including without limitation those placed on Russia as a result of its ongoing military invasion of Ukraine, that may affect our ability to source from affected third parties the reagents and raw materials used in our product candidates. Additionally, a natural disaster, war, civil or political unrest or similar circumstances could hinder our ability to maintain or initiate clinical studies at our preferred sites, causing trial initiation or implementation delays. Any of these matters could materially and adversely affect our product development timelines, business, financial condition, results of operations and prospects.

Additional laws and regulations governing international operations may preclude or delay us from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.

As an international company with operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any non-U.S. official, political party or candidate for the purpose of influencing any act or decision of the non-U.S. entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees are considered non-U.S. officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we continue to expand our presence outside of the United States, we will need to dedicate additional resources to complying with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. securities exchanges for violations of the FCPA's accounting provisions.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain, enforce and defend patent protection for any product candidates we develop or for our novel genetic medicine platform, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products or technology similar or identical to ours and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.

Our success depends in large part on our and our licensors' ability to seek, obtain and maintain patent and other intellectual property protection in the United States, Canada and other jurisdictions with respect to any product candidates we may develop and our

technology, including our genetic medicine platform, manufacturing processes and their respective components, formulations, combination therapies, methods of treatment, processes and development that are important to our business, as well as successfully defending these patents and other intellectual property against third-party challenges. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future. We have sought, and will seek, to protect our proprietary position by filing patent applications in the United States and abroad related to certain technologies and our genetic medicine platform that are important to our business. However, elements of our patent portfolio are at an early stage and there can be no assurance as to whether or when such patent applications will issue as granted patents. Our ability to stop third parties from making, using, selling, marketing, offering to sell, importing and commercializing any product candidates we may develop and our technology is dependent upon the extent to which we and our licensors have rights under valid and enforceable patents and other intellectual property that cover our genetic medicine platform and proprietary technology. If we are or our licensors are unable to secure, maintain, defend and enforce patents and other intellectual property with respect to any product candidates or technology that we may develop, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

We own certain granted patents and pending patent applications which cover our genetic medicine platform, use and/or function, product candidates and their use, and manufacturing processes, as applicable. Our pending Patent Cooperation Treaty ("PCT") patent application, and any PCT application we may file in the future, is not eligible to become issued patents until, among other things, we file one or more national stage patent applications within 30 to 32 months, depending on the jurisdiction, from such application's priority date in the jurisdictions in which we are seeking patent protection. Similarly, should we in the future file a pending provisional patent application such application would not be eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of such provisional patent application's filing date. If we do not timely file such national stage patent applications or non-provisional patent applications, we may lose our priority date with respect to such PCT or provisional patent applications, respectively, and any patent protection on the inventions disclosed in such PCT or provisional patent applications, respectively. While we and our licensors intend to timely file national stage and non-provisional patent applications relating to our PCT and provisional patent applications, respectively, we cannot predict whether any such patent applications will result in the issuance of patents. If we or our licensors do not successfully obtain issued patents, or, if the scope of any patent protection we or our licensors obtain is not sufficiently broad, we will be unable to prevent others from using any product candidates we may develop or our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Any failure to obtain or maintain patent protection with respect to genetic medicine platform, manufacturing processes or our product candidates and technology would have a material adverse effect on our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive, time-consuming and complex, and we and our licensors may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We and our licensors may not be able to obtain, maintain or defend patents and patent applications due to the subject matter claimed in such patents and patent applications being in the public domain. For example, in some cases, the work of certain academic researchers in the genetic medicine field has entered or will enter the public domain, which may compromise our and our licensors' ability to obtain patent protection for certain inventions related to or building upon such prior work. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we would not be able to prevent any third-party from using any of our technology that is in the public domain to compete with our product candidates and technology.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not result in patents being issued which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and products or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent others from competing with us or otherwise provide us with any competitive advantage. In addition, the scope of claims in a patent application can be significantly reduced before the patent is issued, and such scope of an issued patent can be reinterpreted after issuance, and changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection. Furthermore, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Third parties have developed technologies that may be related or competitive to our own technologies and product candidates and may have filed or may file patent applications, or may have obtained or may obtain issued patents, claiming inventions that may overlap or conflict with those claimed in our owned or licensed patent applications or issued patents. We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates and technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are

typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know for certain whether the inventors of our owned or licensed patents and patent applications were the first to make the inventions claimed in any owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third-party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable.

We may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, inventorship disputes may arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and other jurisdictions. For example, we may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office ("USPTO") challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, re-examination, inter partes review, post-grant review or interference proceedings and similar proceedings in non-U.S. jurisdictions (for example, opposition proceedings) challenging the validity, priority or other features of patentability of our owned or licensed patent rights. In addition, a third-party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any litigation or patent office proceeding could put one or more of our owned or licensed patents at risk of being invalidated, ruled unenforceable or interpreted narrowly and could allow third parties to commercialize products identical or similar to any product candidates we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a non-U.S. patent office, that challenge priority of invention or other features of patentability. Such challenges and proceedings may result in loss of patent rights, exclusivity, freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the scope and duration of the patent protection of our technology and any product candidates we may develop. Such challenges and proceedings may also result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other interim proceedings or developments related to such challenges and proceedings and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares.

We may in the future co-own intellectual property rights relating to our genetic medicine platform and our future product candidates with third parties. In addition, our licensors may co-own the patent rights we in-license with other third parties with whom we do not have a direct relationship. If we or our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patent rights or we or our licensors are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties and such cooperation may not be provided to us. Further, any such co-owner may be able to license a co-owned patent to a third-party we believe infringes such patent, preventing us from obtaining compensation or other remedies from such third-party through litigation or settlement arrangements. We may also become engaged in disputes with our co-owners related to patent prosecution strategy or the apportionment of costs associated with the prosecution, maintenance or enforcement of co-owned patents or patent applications. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Issued patents covering our product candidates or genetic medicine platform could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other jurisdictions.

If we initiated legal proceedings against a third-party to enforce a patent covering our genetic medicine platform, product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in non-U.S. jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of,

or amendment to our patents in such a way that they no longer cover our product candidates or other technologies or prevent third parties from competing with us. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third-party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the genetic medicine platform, our product candidates or other technologies. Such a loss of patent protection would have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various non-U.S. government patent agencies over the lifetime of our owned or licensed patents and patent applications. In certain circumstances, we may rely on our licensing partners to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and non-U.S. patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We may also be dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technologies, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in either patent laws or interpretation of the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and genetic medicine platform.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Prior to March 2013, in the United States, the first to invent an invention was entitled to a patent claiming the invention, while outside the United States, the first to file a patent application was entitled to the patent, assuming that other requirements for patentability were met. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act") enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention, regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after the date of invention but before the filing date of our owned or in-licensed patent application could therefore be awarded a patent covering an invention of ours, even if we had made the invention before it was made by the third-party. This will require us and our licensors to be aware going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technologies and the prior art allow our technologies to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (1) file any patent application related to our technologies or product candidates or (2) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submissions of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because the evidentiary standard in USPTO proceedings is lower than the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid, even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use USPTO proceedings to invalidate our owned or in-licensed patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the enforcement or defense of our owned and in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our owned or in-licensed patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Patent terms may be inadequate to protect our competitive position, product candidates or genetic medicine platform for an adequate amount of time, and we may need to obtain patent term extension and equivalent extensions outside of the United States for our product candidates or genetic medicine platform.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest filing date of the first U.S. non-provisional patent application to which the patent claims priority. Various adjustments and extensions may be available, but the life of a patent and the protection it affords is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidates or genetic medicine platform, one or more U.S. patents that we own or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In Europe, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and can be extended for an additional six months if data from clinical trials is obtained in accordance with an agreed-upon pediatric investigation plan. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and so supplementary protection certificates must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be provided at all.

We may not be granted any extensions for which we apply in the United States or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third-party, we would need the cooperation of that third-party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may be able to enter the market sooner, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Further, recent judicial decisions in the U.S. raised questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted.

Our rights to develop and commercialize our product candidates and genetic medicine platform may be subject, in part, to the terms and conditions of licenses.

We are reliant upon licenses to certain intellectual property and proprietary technologies from third parties that are important or necessary to the development of our technologies and product candidates. We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain or maintain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technologies, product candidates, or the methods for manufacturing them or to develop or license replacement technologies, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, or may be significantly delayed in doing so, which could significantly harm our competitive position, business, financial condition, results of operations and prospects. We cannot provide any assurances that third-party patents do not exist which might be enforced against our technologies and product candidates resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Our current and future licenses may not provide exclusive rights to use such intellectual property and proprietary technologies in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technologies and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technologies that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business or in compliance with applicable laws

and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technologies. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate our license agreements, thereby removing our ability to develop and commercialize products and technologies covered by these license agreements. If these license agreements are terminated for this reason or any other reason, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business and results of operations.

We may be unable to acquire or in-license intellectual property rights from third parties relating to, or necessary for, the development of our product candidates on commercially reasonable terms, or at all. In that event, we may be unable to develop or commercialize such product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable non-U.S. regulatory authorities to provide a companion diagnostic test or tests with our product candidates, which test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth may be harmed.

If we fail to comply with our obligations under the agreements pursuant to which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the rights to intellectual property that are important to our business.

We have a non-exclusive license under certain patents and/or know-how to develop and commercialize certain elements or components of our potential product candidates which may not be available elsewhere. Our existing license agreements impose, and we expect that any future license agreements will impose on us, various obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. If any of our licenses are terminated and we are not able to negotiate other agreements for use of the intellectual property protections underlying these product candidates, we would not be able to

manufacture and market these potential products, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

- Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:
- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any licensors or partners' licensors; and
- the priority of invention of patented technology.

In addition, certain provisions in our license agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. In addition, certain of these license agreements, may not be assignable by us without the consent of the respective licensor, which may have an adverse effect on our ability to engage in certain transactions. Moreover, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside of the United States and Canada are less extensive than those in the United States and Canada. In addition, the laws of countries outside the United States and Canada may not protect our or our licensors' rights to the same extent as the laws of the United States and Canada, even in jurisdictions where we or our licensors do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States and Canada, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our inventions in and into the United States, Canada or other jurisdictions. Competitors may use our technologies in jurisdictions where we and our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States and Canada. These products may compete with our products and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our or our licensors' intellectual property and proprietary rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly, could put our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be harmed and our business, financial condition, results of operations and prospects may be adversely affected. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries and we will not have the benefit of patent protection in such countries,

which could have an adverse effect on our operations or commercial prospects within those countries or ability to pursue action against potential competitors.

Further, in Europe, a new unitary patent system came into effect on June 1, 2023. Under the unitary patent system, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC). European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

We may be involved in legal proceedings in relation to intellectual property rights and to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming, and we may not have the financial resources to do so. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office ("EPO"), or another non-U.S. patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications are typically not published in the United States until 18 months after their respective filing dates. Further, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours and that those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome in an interference proceeding could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be adversely affected.

In addition to the protection afforded by patents, we rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some countries outside of the United States do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. Some courts both within and outside the United States and Canada are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our genetic medicine platform and product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that certain information and data concerning our business made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. However, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed to publicly or to competitors. If any of the employees, consultants, outside scientific collaborators, sponsored researchers and other advisors who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Competitors or third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside the scope of our intellectual property rights. We will have limited recourse if this occurs. Furthermore, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our novel genetic medicine platform, our product candidates and other technologies.

The field of biotherapeutics, including the development of genetic medicines, is competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed and other third-party intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our licensors' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including

interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in jurisdictions outside of the United States. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S., Canadian and other foreign issued patents and pending patent applications owned by third parties exist relating to genetic medicine technologies and products and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our genetic medicine platform, product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot be sure that our genetic medicine platform, product candidates and other technologies that we have developed, are developing or may develop in the future do not infringe existing patents or will not infringe future patents owned by third parties. Many companies and institutions have filed, and continue to file, patent applications related to genetic medicine and related manufacturing methods. Some of these patent applications have already been allowed or issued and others may issue in the future. It is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our genetic medicine platform, product candidates and other technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our genetic medicine platform, product candidates and other technologies might assert are infringed by our current or future product candidates, genetic medicine platform or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our genetic medicine platform, product candidates and other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our genetic medicine platform, product candidates and other technologies, could be found to be infringed by our genetic medicine platform, product candidates and other technologies. In addition, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that our genetic medicine platform, product candidates and other technologies may infringe. Furthermore, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until a patent issues. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or technologies. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our genetic medicine platform, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Third parties have patents and may obtain patents in the future and may claim that the manufacture, use or sale of our genetic medicine platform, product candidates or other technologies infringes upon these patents. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our genetic medicine platform, product candidates or other technologies. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent or find that our product candidates or technology did not infringe any such claims. Further, even if we were successful in defending against any such claims, such claims could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. If we are found to infringe, misappropriate or otherwise violate a third-party's valid and enforceable patent rights, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay substantial license fees or royalties or both and the rights granted to us might be non-exclusive, which could result in our competitors and other third parties gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our genetic medicine platform, product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing, manufacturing or commercializing our infringing genetic medicine platform, product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize the genetic medicine platform, our product candidates or other technologies, which could harm our business significantly. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our owned or licensed patent portfolio may therefore have no deterrent effect.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could have an adverse effect on our ability to raise additional funds and attract collaborators and could impair our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. In many cases we rely on our employees' and contractors' representations and warranties that they will not engage in practices that could subject us to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing any product candidates we may develop or at all. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize any product candidates we may develop and our technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our scientific and management personnel.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third-party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. Disputes about the ownership of intellectual property that we own may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patent rights. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology and any product candidates we may develop. Such challenges may also result in our inability to develop, manufacture or commercialize our technology and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patent rights are threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology and product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make next generation immunotherapies for cancer or other diseases that are similar to ours but that are not covered by the claims of the patents that we own or have licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications or those that we license will not lead to issued patents;
- issued patents that we own or have licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a nonexclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may choose not to file a patent for certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

Our current and future trademark applications in the United States and in foreign jurisdictions may not be allowed or may subsequently be opposed. Once filed and registered, our registered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Risks Related to Acquisitions and Collaborations

We will need to grow the size of our organization, both organically and through acquisitions, and we may experience difficulties identifying and hiring the right employees and successfully managing this growth.

As of October 31, 2025, we had 82 employees. As our development and commercialization plans and strategies develop, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of technology research, product development and manufacturing, regulatory affairs and, if any product candidates are submitted for or receive marketing approval, sales, marketing and distribution. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical studies and clinical trials effectively;
- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors, licensors and other third parties;
- improving our operational, financial and management controls, reporting systems and procedures; and
- expanding our facilities.

Our future financial performance and our ability to commercialize our product candidates may depend, in part, on our ability to effectively manage any future growth and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, contractors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical

management and manufacturing. There can be no assurance that the services of independent organizations, advisors, contractors and consultants will continue to be available to us on a timely basis when needed or that we will be able to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by independent organizations, advisors, contractors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing independent organizations, advisors, contractors or consultants or find other competent resources on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding the roster of independent organizations, advisors and consultants on whom we rely on an outsourced basis, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Acquisitions, collaborations or other strategic partnerships may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may from time to time evaluate collaborations and strategic partnerships or potential acquisitions, including licensing or acquiring molecules, biologics, or gene therapies, etc., for use in our genetic medicine platform, intellectual property rights, technologies or businesses. For example, we may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. Collaboration, strategic partnerships or acquisitions entail numerous risks, including:

- increased operating expenses and cash requirements;
- reduced control over the development of certain of aspects of detalimogene, our genetic medicine platform or other product candidates;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our internal product development efforts and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status and their existing products or product candidates and marketing approvals;
- failure to recognize the synergies or other benefits intended for the acquisition, partnership or collaboration; and
- potential inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations and prospects.

We may make acquisitions to expand our business and as a result, our results of operations may be adversely affected.

We may choose to expand our current business through the acquisition of other businesses, products or technologies, or through strategic alliances. Acquisitions involve numerous risks, including the following:

- the possibility that we will pay more than the value derived from the acquisition which could result in future non-cash impairment charges, and incremental operating losses;
- difficulties in integration of the operations, technologies and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;
- the assumption of certain known and unknown liabilities of the acquired companies;
- difficulties in retaining key relationships with employees, customers, collaborators, vendors and suppliers of the acquired company;
- and in the case of acquisitions outside of the jurisdictions we currently operate in, the need to address the particular economic, currency, political, and regulatory risks associated with specific countries, particularly those related to our

collection of sensitive data, regulatory approvals, and tax management, which may result in significant additional costs or management overhead for our business.

Any of these factors could have a negative impact on our business, financial condition, results of operations and prospects.

Risks Related to Investment in our Securities

Because we are a Canadian company, shareholder protections differ from shareholder protections in the United States and elsewhere, and we are subject to a variety of additional risks that may negatively impact our operations.

We are organized and exist under the laws of British Columbia, Canada and, accordingly, are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction. We are subject to special considerations or risks associated with companies operating in Canada that may, at any time differ from the considerations and risks of companies operating in the United States, including any of the following:

- political regimes, rules and regulations or currency conversion or corporate withholding taxes on individuals;
- tariffs and trade barriers;
- regulations related to customs and import/export matters;
- longer payment cycles;
- tax issues, such as tax law changes and variations in tax laws as compared to the United States;
- requirements to maintain a company nexus with Canada or a particular province of Canada;
- currency fluctuations and exchange controls;
- challenges in collecting accounts receivable;
- cultural and language differences;
- employment regulations;
- crime, strikes, riots, civil disturbances, terrorist attacks and wars; and
- deterioration of political relations with the United States, which could result in uncertainty and/or changes in or to existing trade treaties.

In particular, we are subject to the risk of changes in economic conditions, social conditions and political conditions inherent in Canada, including changes in laws and policies that govern international investment, as well as changes in U.S. laws and regulations relating to international trade and investment, including the new trilateral trade agreement among the United States, Mexico and Canada called the United States-Mexico- Canada Agreement (the "USMCA"), which has been ratified by all three countries. The USMCA entered into force on July 1, 2020 and superseded the North American Free Trade Agreement. The USMCA is subject to review and renewal in 2026. There can be no assurance that any newly negotiated terms in the USMCA will not adversely affect our business or operations. It remains unclear what specific actions the current U.S. administration may take to resolve trade-related issues with Canada, Mexico and other countries. Although we believe that there have been no immediate effects on our operations with respect to the USMCA, we cannot predict future developments in the political climate involving the United States, Mexico and Canada and such developments may have a material adverse effect on our business, financial condition and results of operations.

The Articles and certain Canadian legislation contain provisions that may have the effect of delaying, preventing or making undesirable an acquisition of all or a significant portion of our shares or assets or preventing a change in control.

Certain provisions of our Articles and certain provisions under the BCBCA, together or separately, could discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which they might otherwise receive a premium for their common shares. These provisions include the establishment of a staggered board of directors, which divides the board into three groups, with directors in each group serving a three-year term. The existence of a staggered board can make it more difficult for shareholders to replace or remove incumbent members of our Board of Directors. As such, these provisions could also limit the price that investors might be willing to pay in the future for our common shares, thereby depressing the market price of our common shares. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board of Directors. Among other things, these provisions include the following:

- shareholders cannot amend our Articles unless such amendment is approved by shareholders holding at least 66 2/3% of the shares entitled to vote on such approval;
- our Board of Directors may, without shareholder approval, issue preferred shares in one or more series having any terms, conditions, rights, preferences and privileges as the board of directors may determine; and

- shareholders must give advance notice to nominate directors or to submit proposals for consideration at shareholders' meetings.

A non-Canadian must file an application for review with the Minister responsible for the Investment Canada Act and obtain approval of the Minister prior to acquiring control of a "Canadian business" within the meaning of the Investment Canada Act, where prescribed financial thresholds are exceeded. A reviewable acquisition may not proceed unless the Minister is satisfied that the investment is likely to be of net benefit to Canada. If the applicable financial thresholds were exceeded such that a net benefit to Canada review would be required, this could prevent or delay a change of control and may eliminate or limit strategic opportunities for shareholders to sell their common shares. Furthermore, limitations on the ability to acquire and hold our common shares may be imposed under the Competition Act (Canada). This legislation has a pre-merger notification regime and mandatory waiting period that applies to certain types of transactions that meet specified financial thresholds, and permits the Commissioner of Competition to review any acquisition, directly or indirectly, including through the acquisition of shares, of control over or of a significant interest in us.

The Articles designate specific courts in Canada and the United States as the exclusive forum for certain litigation that may be initiated by our shareholders without our prior written consent, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to the Articles, unless we consent in writing to the selection of an alternative forum, the courts of the Province of British Columbia and the appellate courts therefrom shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on our behalf; (b) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us; (c) any action or proceeding asserting a claim arising out of any provision of the BCBCA or the Articles (as either may be amended from time to time); or (d) any action or proceeding asserting a claim or otherwise related to our affairs (the "Canadian Forum Provision"). In addition, the Articles further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Delaware shall be the sole and exclusive forum for resolving any complaint filed in the United States asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act") or the Exchange Act (the "U.S. Forum Provision"). In addition, the Articles provide that any person or entity purchasing or otherwise acquiring any interest in our common shares is deemed to have notice of and consented to the Canadian Forum Provision and the U.S. Forum Provision; provided, however, that shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Canadian Forum Provision and the U.S. Forum Provision in the Articles may impose additional litigation costs on shareholders in pursuing any such claims. Additionally, the forum selection clauses in the Articles may limit our shareholders' ability to bring a claim in a judicial forum that they find favorable for disputes with our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts, including courts in Canada and other courts within the United States, will enforce our U.S. Forum Provision. If the U.S. Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The U.S. Forum Provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The courts of the Province of British Columbia and the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

Because we are a Canadian company, it may be difficult to serve legal process or enforce judgments against us.

We are incorporated and maintain operations in Canada. In addition, certain of our directors reside in the United States, while others reside outside of the United States. Accordingly, service of process upon us may be difficult to obtain within the United States. Furthermore, because substantially all of our assets are located outside the United States, any judgment obtained in the United States against us, including one predicated on the civil liability provisions of the U.S. federal securities laws, may not be collectible within the United States. Therefore, it may not be possible to enforce those actions against us.

In addition, it may be difficult to assert U.S. securities law claims in original actions instituted in Canada. Canadian courts may refuse to hear a claim based on an alleged violation of U.S. securities laws against us or these persons on the grounds that Canada is not the most appropriate forum in which to bring such a claim. Even if a Canadian court agrees to hear a claim, it may determine that Canadian law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Canadian law. Furthermore, it may not be possible to subject foreign persons or entities to the jurisdiction of the courts in Canada. Similarly, to the extent that our assets are located in Canada, investors may have difficulty collecting from us any judgments obtained in the U.S. courts and predicated on the civil liability provisions of U.S. securities provisions.

Our ability to use net operating loss carry-forwards and certain other tax attributes are limited.

In general terms, where control of a corporation is acquired or deemed to be acquired, which for our Company as a result of the Reverse Recapitalization, the corporation is subject to a "loss restriction event", and the corporation's non-capital loss carryforwards, other losses and certain other tax attributes are subject to limitation and possibly expiry after the loss restriction event. Similar rules apply for Canadian provincial purposes. Consequently, we may not be able to utilize a material portion of our non-capital loss carryforwards and certain other tax attributes in certain circumstances.

For U.S. tax purposes, net operating loss carryforwards allow companies to use past year net operating losses to offset against future years' profits, if any, to reduce future tax liabilities. Sections 382 and 383 of the Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow. Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of additional equity offerings or events over we will have little or no control, including purchases and sales of its equity by its five percent security holders, the emergence of new five percent security holders, redemptions of its securities or certain changes in the ownership of any of its five percent security holders.

We believe that we are and there is a significant risk that we may continue to be a passive foreign investment company (a "PFIC"), which could result in adverse U.S. federal income tax consequences to U.S. Holders of our Common Shares or Warrants.

In general and as relevant here, a non-U.S. corporation is a PFIC for U.S. federal income tax purposes for any taxable year in which (i) 50% or more of the value of its assets (generally determined on the basis of a quarterly average) consists of assets, including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, that produce, or are held for the production of, passive income, or (ii) 75% or more of its gross income, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, consists of passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets. Cash and cash equivalents are generally passive assets. The value of goodwill will generally be treated as an active or passive asset based on the nature of the income produced in the activity to which the goodwill is attributable.

Prior to the commercialization of our drug candidates, our income may be primarily passive. Accordingly, we believe we may have met the definition of PFIC for U.S. federal income tax purposes for the tax year ended October 31, 2024 and the tax year ended October 31, 2025 and there is a significant risk that we will be a PFIC for our current or any future taxable year. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below) owns Common Shares, the U.S. Holder generally will be subject to adverse U.S. federal income tax consequences, including increased tax liability on disposition gains and certain "excess distributions" and additional reporting requirements, unless the U.S. Holder makes (a) a qualified electing fund ("QEF") election or a mark-to-market election for the first taxable year for which we are or were a PFIC and in which such U.S. Holder held (or was deemed to hold) such Common Shares and maintain such election or (b) a QEF election along with an applicable purging election (collectively, the "PFIC Elections"). Under proposed Treasury regulations relating to PFICs which have a retroactive effective date, the PFIC rules may apply to rights to acquire shares of a PFIC as if they were shares, and thus could apply to dispositions (other than exercises) of Warrants. PFIC Elections may not be made with respect to Warrants. U.S. Holders of Common Shares or Warrants should consult their tax advisors regarding the application of the PFIC rules to us and the risks of owning equity securities, including warrants, in a company that may be a PFIC.

As a result of making and maintaining a timely and valid QEF election (if eligible to do so), a U.S. Holder of Common Shares must include in income such U.S. Holder's pro rata share of our net capital gains (as long-term capital gain) and other earnings and profits (as ordinary income), on a current basis, whether or not distributed. A U.S. Holder generally may make a separate election to defer the payment of taxes on undistributed income inclusions under the QEF rules, but if deferred, any such taxes will be subject to an interest charge. A subsequent distribution of such earnings and profits that were previously included in income should generally not be taxable as a dividend to such U.S. Holder. The tax basis of a U.S. Holder's shares in a PFIC with respect to which a QEF election has been made will be increased by amounts that are included in income, and decreased by amounts distributed but not taxed as dividends, under the above rules.

The QEF election is made on a shareholder-by-shareholder basis and, once made, can be revoked only with the consent of the IRS. A U.S. Holder generally makes a QEF election by attaching a completed IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund), including the information provided in a PFIC Annual Information Statement from us, to a timely filed U.S. federal income tax return for the tax year to which the election relates. In the event that we determine that we are a PFIC for U.S. federal income tax purposes for any taxable year, we will, upon request of a holder of Common Shares, provide a PFIC Annual Information Statement to such holder. Retroactive QEF elections generally may be made only by filing a protective statement with such federal income tax return and if certain other conditions are met or with the consent of the IRS. U.S.

Holders are urged to consult their tax advisors regarding the availability and tax consequences of a retroactive QEF election under their particular circumstances.

As an alternative to a QEF election, if a U.S. Holder owns shares in a company that is a PFIC and the shares are "regularly traded" on a "qualified exchange," such U.S. Holder could make a mark-to-market election that would result in tax treatment different from that under the interest charge rules described above. The Common Shares will be treated as regularly traded for any calendar year in which more than a de minimis quantity of the Common Shares are traded on a qualified exchange on at least 15 days during each calendar quarter. Nasdaq, where the Common Shares are listed, is a qualified exchange for this purpose.

Such electing U.S. Holder generally will include for each of its taxable years as ordinary income the excess, if any, of the fair market value of its Common Shares at the end of such year over its adjusted basis in its Common Shares. The U.S. Holder also will recognize an ordinary loss in respect of the excess, if any, of its adjusted basis of its Common Shares over the fair market value of its Common Shares at the end of its taxable year (but only to the extent of the net amount of previously included in income as a result of the mark-to-market election). The U.S. Holder's basis in its Common Shares will be adjusted to reflect any such income or loss amounts. Any gain recognized on a sale or other taxable disposition of its Common Shares will be treated as ordinary income, and any loss will be treated as an ordinary loss (but only to the extent of the net amount previously included in income as a result of the mark-to-market election, with any excess treated as a capital loss).

For purposes of this Risk Factor, a "U.S. Holder" is a beneficial holder of securities who or that, for U.S. federal income tax purposes is (i) an individual who is a United States citizen or resident of the United States; (ii) a corporation or other entity treated as a corporation for United States federal income tax purposes created in, or organized under the law of, the United States or any state or political subdivision thereof; (iii) an estate the income of which is includible in gross income for United States federal income tax purposes regardless of its source; or (iv) a trust (A) the administration of which is subject to the primary supervision of a United States court and which has one or more United States persons (within the meaning of the Code) who have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable Treasury regulations to be treated as a United States person.

Our Articles include provisions that may discourage takeover attempts, including a classified or "staggered" board.

Certain provisions in our articles (together with the articles of incorporation and notice of articles, the "Articles") may have the effect of deterring coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and by encouraging prospective acquirers to negotiate with our Board of Directors rather than to attempt a hostile takeover. These provisions include, among others:

- the existence of a classified or "staggered" board;
- the right of our Board of Directors to issue preferred stock and to determine the voting, dividend, and other rights of preferred stock without shareholder approval;
- the ability of our directors, and not shareholders, to fill vacancies on our Board in most circumstances and to determine the size of our Board of Directors;
- the requirement for two-thirds of the votes cast by shareholders on a special resolution in order to remove directors or amend certain provisions of the Articles; and
- the absence of cumulative rights in the election of directors.

While these provisions are not intended to make us immune from takeovers, they will apply even if the offer may be considered beneficial by some shareholders and may delay or prevent an acquisition that our Board of Directors determines is not in the best interests of us and our shareholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

Risks Related to Our Common Shares and Warrants and to Being a Public Company

Sales of Common Shares, or the perception of such sales, by us or the Selling Holders in the public market or otherwise could cause the market price for our Common Shares to decline and certain Selling Holders still may receive a significant rate of return.

On November 13, 2024, we filed (i) a registration statement on Form S-3 (File No. 333-283202) (the "resale registration statement") with the SEC to register the issuance of up to an aggregate of 8,511,968 Common Shares upon the exercise of a like number of Warrants as well as the resale from time to time by the selling securityholders named in the resale registration statement (the "Selling Holders") of (a) up to 46,977,183 of our Common Shares (which includes 6,289,198 Common Shares that may be issued upon exercise of the Warrants); and (b) up to 6,289,198 of our Warrants and (ii) a universal shelf registration statement on Form S-3 (File No. 333-283201) (the "shelf registration statement") with the SEC to register the issuance by us of up to $300 million of securities. The resale registration statement and the shelf registration statement each became effective November 21, 2024.

On November 14, 2025, we issued 12,558,823 of our Common Shares and 2,735,295 pre-funded warrants to purchase Common Shares under our shelf registration statement pursuant to an underwritten public offering, and on November 18, 2025 we issued an

additional 2,294,117 Common Shares pursuant to a greenshoe option granted to the underwriters in the offering, for an aggregate public offering price of approximately $149.5 million of securities, prior to deducting underwriting discounts and commissions.

The sale of Common Shares in the public market or otherwise, including sales pursuant to the resale registration statement or the shelf registration statement, or the perception that such sales could occur, could harm the prevailing market price of our Common Shares. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of Common Shares may cause the market price of our securities to drop significantly, even if our business is doing well.

We have agreed, at our expense, to prepare and file the resale registration statement with the SEC. The Common Shares and Warrants being offered for resale in the prospectus which forms a part of the resale registration statement, represent approximately 92.2% of our total outstanding Common Shares and approximately 73.9% of our outstanding Warrants, respectively, as of the date of such prospectus.

The resale, or expected or potential resale, of a substantial number of our Common Shares in the public market could adversely affect the market price for our Common Shares and make it more difficult for you to sell your Common Shares at times and prices that you feel are appropriate. Furthermore, we expect that, because there will be a large number of shares registered pursuant to the resale registration statement, Selling Holders will continue to offer the securities covered by the resale registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to a resale registration statement may continue for an extended period of time.

Certain existing securityholders acquired their securities in our Company at prices that may be below the current trading price of such securities, and may experience a positive rate of return based on such current trading price. Future investors in our Company may not experience a similar rate of return.

Certain securityholders in the Company, including certain of the Selling Holders, acquired Common Shares or Warrants at prices that may be below the current trading price of such securities and may experience a positive rate of return based on such current trading price. On December 17, 2025, the closing price of our Common Shares was $7.80 per share and the closing price for our Warrants was $2.40 per warrant. Selling Holders in some instances may earn a significant positive rate of return on their investment depending on the market price of our Common Shares and Warrants at the time that such Selling Holders choose to sell their securities. The Selling Holders acquired the securities offered for resale in exchange for non cash consideration or at effective purchase prices that may range from significantly below to above current trading prices. Investors who purchase our Common Shares and Warrants on the Nasdaq may not experience a similar rate of return on the securities they purchased due to differences in the purchase prices and the current trading price.

There is no assurance that Warrants will be and/or remain "in the money" prior to their expiration or that the holders of Warrants will elect to exercise any or all of their Warrants for cash; the Warrants may expire worthless.

The exercise price for our Warrants is $11.50 per Common Share. The Warrants will expire on October 31, 2028, the date that is five years after the completion of the Reverse Recapitalization (as defined herein).

The Warrants' cashless exercise period ended when the Company's registration statement on Form S-1 (File No. 333-275700) was declared effective on March 5, 2024. We will receive proceeds from Warrants only in the event that such Warrants are exercised for cash. We believe the likelihood that holders will exercise their Warrants will depend on the trading price of our Common Shares. If the market price for our Common Shares is less than the exercise price of Warrants, we believe the holders of Warrants will be unlikely to exercise them. If the market price for our Common Shares exceeds the exercise price of the Warrants, it is more likely that holders of the Warrants will exercise them.

There is no assurance that Warrants will be "in the money" prior to their expiration or that the holders of Warrants will elect to exercise any or all of their Warrants for cash. As such, the Warrants may expire worthless.

We will continue to incur increased costs as a result of operating as a public company, and the requirements for public companies may strain resources and divert management's attention.

Compliance with public company requirements places significant additional demands on management and will require them to enhance investor relations, legal, financial reporting and corporate communications functions. Our management is required to devote substantial time to maintaining and improving its internal controls over financial reporting and the requirements of being a public company. These additional efforts may strain resources and divert management's attention from other business concerns and affect its ability to accurately report its financial results and prevent fraud, which could adversely affect our business and profitability.

We may be unable to satisfy Nasdaq's continued listing requirements in the future, which could limit investors' ability to effect transactions in our securities and subject it to additional trading restrictions.

Our Common Shares and Warrants commenced trading on Nasdaq under the tickers "ENGN" and "ENGNW", respectively, on November 1, 2023. We are required to meet Nasdaq's continued listing requirements and may be unable to meet those requirements. Although our securities are listed on the Nasdaq as of the date of this Annual Report, we may be unable to maintain the listing of our securities in the future.

If we fail to meet the continued listing requirements and the Nasdaq delists our securities from its exchange, there could be significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our Common Shares are a "penny stock" which will require brokers trading in our Common Shares to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to obtain capital or pursue acquisitions by issuing additional equity or convertible securities.

We will continue to incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

As a publicly traded company, we will continue to incur significant legal, accounting and other expenses. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure for public companies, including the Dodd-Frank Act, the Sarbanes-Oxley Act, regulations related thereto and the rules and regulations of the SEC and Nasdaq, have increased the costs and the time that must be devoted to compliance matters. We expect these rules and regulations will increase our legal and financial costs and lead to a diversion of management time and attention from revenue-generating activities.

A market for our securities may not develop or be sustained, which would adversely affect the liquidity and price of our securities.

The price of our securities may fluctuate significantly due to the market's reaction to general market and economic conditions. An active trading market for our securities may never develop or, if it develops, it may not be sustained, which could have a material adverse effect on the liquidity and price of our securities.

The trading price of our Common Shares could be highly volatile, and purchasers of our Common Shares could incur substantial losses.

The price of our Common Shares is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their Common Shares at or above the price at which they paid. The market price for our Common Shares may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of detalimogene or any other product candidates we develop or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire, or license detalimogene or any future product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;

- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our Common Shares;
- an inability to obtain additional funding;
- sales of our Common Shares by us, our insiders or our shareholders;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;
- intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

We could be a target of securities class action and derivative lawsuits, which could result in substantial costs.

Our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their shares have from time to time been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any adverse determination in litigation could also subject us to significant liabilities.

If securities or industry analysts do not publish research about us at all or publish inaccurate or unfavorable research about us or our business, the market price and/or the trading volume of our Common Shares could decline.

The trading market for our Common Shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover us, then the market price for our Common Shares and Warrants could be adversely affected. If one or more of the analysts who cover us downgrade a recommendation with regard to our Common Shares, publish inaccurate or unfavorable research about us or our business, cease to cover us or fail to publish reports on it regularly, the market price and/or the trading volume of our Common Shares and Warrants could decline.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have implemented cybersecurity risk management procedures, in accordance with our risk profile and business size, that are designed to identify, assess, and mitigate risks from current and emerging cybersecurity threats. Our cybersecurity procedures, which are informed by the National Institute of Standards and Technology cybersecurity framework, are supported by a third-party managed services provider that assists us in managing our IT systems. We maintain cyber insurance coverage; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks, and other related breaches.

Our cybersecurity procedures are comprised of a variety of tools designed to protect our data and information technology systems, including but not limited to endpoint protection and network security measures, that are supported by our third-party service providers. We also have a process to require our employees to undergo cybersecurity awareness training. Further, we have implemented a process to review risks to our Company in connection with certain third-party providers and vendors, which involves assessments through vendor questionnaires, as appropriate.

To date, we have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party IT service providers and vendors have from time to time experienced threats that could affect our information or systems. For more information, see, “Risk Factors,” in this Annual Report.

Cybersecurity Governance

Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management. Our Vice President, IT reports to our Chief Financial Officer.

One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk. A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks.

Item 2. Properties.

As of October 31, 2025, we have leased approximately 10,620 sq. feet of laboratory and office space at 4868 Rue Levy Montreal, QC H4R 2P1, 6,450 sq. feet of office space at 200 Fifth Avenue, Waltham, Massachusetts 02451 and 26,355 sq. feet of office space at 99 High Street, Boston, Massachusetts, 02110.

We believe our current facilities are sufficient for our current needs. To meet future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings that arise in the regular course of our business. Our management believes that we are not currently involved in any legal proceedings that are likely to have a significant negative effect on our business. However, legal proceedings can negatively affect our business, financial condition, results, and future prospects, regardless of the outcome, due to costs associated with defense and settlement, as well as the diversion of management resources, among other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our Common Shares and Warrants commenced trading on the Nasdaq Global Market under the symbols "ENGN" and "ENGNW," respectively on November 1, 2023.

Shareholders

As of December 17, 2025, there were approximately 66,984,661 Common Shares issued and outstanding held of record by 45 holders, and approximately 8,511,968 Warrants held of record by 15 holders, each exercisable for one Common Share at a price of $11.50 per share. The actual number of holders of our Common Shares is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Additionally, we previously agreed to issue to the Lenders (as defined herein) Warrants to purchase up to 138,696 Common Shares, of which 62,413 have been issued as of December 17, 2025. See "*Notes to the Financial Statements-Note 8, Notes Payable*" for additional details. On November 14, 2025, we also issued pre-funded warrants to purchase 2,735,295 Common Shares (the "Pre-Funded Warrants") at an offering price of $8.4999 per Pre-Funded Warrant to a certain investor in an underwritten public offering. Each Pre-Funded Warrant has an initial exercise price per share of $0.0001, subject to certain adjustments. See "*Notes to the Financial Statements-Note 17, Subsequent Events*" for additional details.

Dividends

We have not paid any cash dividends on our Common Shares to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of the Board of Directors at such time.

Securities Authorized for Issuance Under Equity Compensation Plans

Equity Compensation Plan Information as of October 31, 2025

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights (a)	Weighted-average exercise price of outstanding options, warrants, and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders [1] [2]	5,717,948	$ 6.81	2,933,304
Equity compensation plans not approved by security holders [3]	3,315,350	$ 7.15	-
Total	9,033,298	$ 6.93	2,933,304

(1) On October 31, 2023, upon completion of the Business Combination, the enGene Holdings Inc. 2023 Incentive Equity Plan became effective, which authorized enGene to issue 2,607,943 Common Shares under the plan, plus 2,706,941 Common Shares that are subject to outstanding grants under the enGene Inc. employee share option and equity incentive plans. On May 15, 2024, the Company's shareholders approved the adoption of the Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, which authorizes enGene to issue 4,554,169 Common Shares under the plan, plus 2,706,941 Common Shares that are subject to outstanding grants

under the enGene Inc. employee share option and equity incentive plans. On January 2, 2025, 2,548,833 Common Shares were added to the Plan under the evergreen provision.

(2) As part of the Business Combination, the 2,706,941 Common Shares subject to outstanding grants under the enGene Inc. employee share option and equity incentive plans were modified to have the exercises price converted from the Canadian Dollar to the United States Dollar, at the exchange rate in effect on the date immediately prior to the close of the Business Combination.

(3) Consists of Common Shares issuable upon exercise of outstanding stock options granted pursuant to the Nasdaq inducement grant exception as a component of employment compensation for employees. The inducement grants were approved by our compensation committee and were made as an inducement material to employees entering into employment with us in accordance with Nasdaq Listing Rule 5635(c)(4).

Recent Sales of Unregistered Securities

We did not sell unregistered Common Shares or other equity securities during the quarter or fiscal year ended October 31, 2025.

Issuer Purchases of Equity Securities

We did not purchase any of our Common Shares or other equity securities during the quarter or fiscal year ended October 31, 2025.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Throughout this section, unless otherwise noted, "we", "our", "us", "enGene" and the "Company" refer to enGene Holdings Inc. and all of its subsidiaries following the consummation of the Reverse Recapitalization (as defined below). enGene Holdings Inc. is the publicly traded parent company resulting from the Reverse Recapitalization, in which shareholders of enGene Inc. and Forbion European Acquisition Company exchanged their shares for shares in enGene Holdings Inc.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements as of October 31, 2025 and 2024 and for the fiscal years ended October 31, 2025 and 2024, and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See the sections titled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in this Annual Report for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by these forward-looking statements.

We operate as a single operating segment focused on research, discovery, and clinical development of human genetic medicine products. Our fiscal year is the year ended October 31.

Overview

Business Overview

We are a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients suffering from bladder cancer. We are developing non-viral genetic medicines based on our novel and proprietary dually derivatized chitosan, or "DDX", gene delivery platform, which allows localized delivery of complex genetic cargos directly to mucosal tissues and other organs. Our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, is a therapy designed to generate a local immune reaction in proximity to tumors. We believe this enables the immune system to durably clear the tumor and develop memory to resist recurrence. Because this treatment is designed to work by delivering genetic cargo to the broader tumor tissue environment rather than tumor cells specifically, we believe it has the potential to be widely utilized across tumor types. Currently, we are developing detalimogene as a monotherapy to treat patients that have non-muscle invasive bladder cancer ("NMIBC") with carcinoma in situ ("CIS") that have been unresponsive to treatment with Bacillus Calmette-Guérin, or "BCG," or what is referred to as "BCG-unresponsive NMIBC with CIS." We are also exploring the clinical application of detalimogene to other forms of NMIBC, namely, in patients with papillary-only BCG-unresponsive NMIBC (i.e., NMIBC without CIS), as well as in patients with BCG-naïve NMIBC with CIS and in patients with BCG-exposed NMIBC with CIS (i.e., patients who have been treated with some BCG but who do not qualify as BCG-unresponsive in accordance with FDA and urology practice guidelines).

Detalimogene is currently being studied in a combined Phase 1/2 open-label trial, referred to as "LEGEND" (ClinicalTrials.gov identifier NCT04752722). The Phase 2 portion of LEGEND is comprised of three cohorts: Cohort 1 is a pivotal cohort studying detalimogene in patients with high-risk BCG-unresponsive NMIBC with CIS with or without concomitant papillary disease for which we have completed enrollment with 125 patients; Cohort 2 is evaluating detalimogene in patients with high-risk BCG-naïve NMIBC with CIS (Cohort 2a, with 30 enrolled patients as of November 11, 2025) and patients with high-risk BCG-exposed NMIBC with CIS (Cohort 2b, with 45 enrolled patients as of November 11, 2025); and Cohort 3 is evaluating detalimogene in patients with high-risk BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS, with 36 enrolled patients as of November 11, 2025). In addition, our preclinical research is focused on expanding the cancer indications that can be treated with detalimogene as well as discovering new opportunities to apply our DDX technology platform to treat other indications with high unmet medical needs.

Since our inception, we have devoted substantially all of our efforts to organizing and staffing our Company, business planning, raising capital, establishing our intellectual property portfolio, acquiring or discovering product candidates, research and development activities for our primary program, detalimogene voraplasmid, or detalimogene. We do not have any products approved for sale and have not generated any revenue from product sales. We operate as a single operating segment focused on research, discovery, and clinical development of detalimogene. Since our merger with Forbion European Acquisition Company ("FEAC") (the "Reverse Recapitalization"), we have financed the Company through a series of private investment in public equity ("PIPE") financings, debt arrangements, and issuance of warrants. In addition, in November 2025, we issued Common Shares and pre-funded warrants pursuant to an underwritten public offering, as further described in "*Notes to the Financial Statements-Note 17, Subsequent Events*".

We have never been profitable and have incurred net losses since inception. Our net losses were $117.3 million and $55.1 million for the years ended October 31, 2025 and 2024, respectively. As of October 31, 2025 and 2024, we had an accumulated deficit of $372.0 million and $254.7 million, respectively, and cash, cash equivalents and marketable securities of $202.3 million and $297.9 million, respectively. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance the ongoing LEGEND study of detalimogene, including the pivotal cohort of patients with BCG-unresponsive NMIBC, to completion; execute on our plan to file a Biologics License Application with the FDA in the second half of 2026; and pursue potential pipeline expansion via additional detalimogene development opportunities and other compounds. In addition, we expect to incur significant

expenses as we establish medical affairs, sales, marketing and distribution infrastructure and capabilities to support the potential commercial launch of detalimogene and significant additional commercialization-related expenses, if and when detalimogene is approved. As a result, we expect to need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, or other capital sources, which could include potential collaboration agreements, strategic alliances, or licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

As of October 31, 2025, we had $50.2 million in cash and cash equivalents and $152.1 million in marketable securities, mainly US Treasury Bonds. We believe that our existing cash and cash equivalents and marketable securities as of October 31, 2025 will be sufficient to fund our operating expenses, debt obligations, and capital expenditure requirements for at least the next 12 months from the issuance date of the consolidated financial statements included within this Annual Report. In addition, as discussed under "*Notes to the Financial Statements-Note 17, Subsequent Events*", we received aggregate net proceeds of approximately $140.1 million in November 2025 in connection with an underwritten public offering of our Common Shares and pre-funded warrants. While we have historically been successful in securing financing, raising additional funds is dependent on a number of factors outside of our control, and as such there is no assurance that we will be able to do so in the future. See *"Liquidity and Capital Resources"* below.

Components of Our Results of Operations

Revenue

We do not have any product candidates approved for sale, have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products or from other sources in the near future, if at all. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, if ever. If our development efforts for our current lead product candidate, detalimogene, or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales and payments from such collaboration or license agreements.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our clinical trials; CMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- personnel-related expenses including, salaries, benefits, share-based compensation, and other related costs for individuals involved in research and development activities; and
- costs associated with other research and development expenses including costs related to outside consultants, costs related to compliance with quality and regulatory requirements, payments made under third-party licensing agreements, and costs related to facilities, supplies, rent, insurance, certain legal fees.

We expense research and development costs as incurred. We recognize direct development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors or our estimate of the level of service that has been performed at each reporting date. Payments for these development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued expenses.

A significant portion of our research and development costs to date have been third-party costs, which we track on an individual product candidate basis after a clinical product candidate has been identified. Currently, our main clinical product candidate is detalimogene. Our indirect research and development costs are primarily personnel-related costs, facilities, and other costs. Employees and infrastructure are not directly tied to any one program and are deployed across our programs. As such, we do not track these costs on a specific program basis. We utilize third party contractors for our research and development activities and CMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities.

Research and development activities are central to our business model. Currently, the Company's sole laboratory facility is located in Montreal, Quebec, Canada, and as such, a portion of the Company's research and development and other operating expenses are incurred in Canada and denominated in the Canadian dollar. We expect that our research and development expenses will continue to increase for the foreseeable future as we progress our ongoing Phase 1/2 clinical trial for detalimogene, continue to discover and develop additional product candidates, expand our headcount and maintain, expand and enforce our intellectual property portfolio. If detalimogene or any future product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. There are numerous factors associated with the successful development and commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

The duration, costs, and timing of clinical studies and development of our product candidate will depend on a variety of factors, any of which could mean a significant change in the costs and timing associated with the development of our product candidate including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake;
- future clinical study results;
- uncertainties in clinical study enrollment rates;
- new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our drug substance and drug product;
- regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and
- the timing and receipt of any regulatory approvals.

Any changes in the outcome of any of these variables with respect to the development of detalimogene or any future product candidates in nonclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any clinical trials following the applicable regulatory authority's acceptance and clearance, we could be required to expend significant additional financial resources and time to complete clinical development than we currently expect. We may never obtain regulatory approval for any product candidates that we develop.

The successful development of detalimogene or any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development and commercialization of detalimogene and any other product candidates we may develop. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of detalimogene or any future product candidate, if approved. This is due to the numerous risks and uncertainties associated with product development.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, benefits, and share-based compensation expenses for personnel in executive and other administrative functions. Other significant general and administrative expenses include professional services, including legal, accounting and audit services, and other consulting fees, as well as facility costs not otherwise included in research and development expenses, insurance, and other operating costs.

We expect that our general and administrative expenses will continue to increase in the foreseeable future as our business expands to support our continued research and development activities, including our clinical trials. These increases will likely include increased costs related to the hiring of additional personnel and fees for outside consultants, among other expenses. In addition, if we obtain regulatory approval for our current product candidate or any product candidates we may develop in the future and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing, and distribution activities.

Other (Income) Expense, Net

Interest Expense

Interest expense consists of interest paid on our convertible notes and third-party debt, as well as non-cash interest expense for amortization of our debt discounts.

Interest Income

Interest income is associated with our interest-bearing cash and cash equivalents and marketable securities.

Other expense, net

Other expense, net primarily consists of foreign exchange gains and losses.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each period or for deductible temporary differences, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of October 31, 2025 and 2024, we have recorded a full valuation allowance against our deferred tax assets.

Results of Operations

Comparison of the Years Ended October 31, 2025 and 2024

The following table summarizes our results of operations for each of the periods presented (in thousands):

	Year Ended October 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 94,480	$ 38,315	$ 56,165
General and administrative	28,685	23,982	4,703
Total operating expenses	123,165	62,297	60,868
Loss from operations	123,165	62,297	60,868
Other (income) expenses, net:			
Interest income	(9,426)	(10,413)	987
Interest expense	2,994	2,798	196
Gain on extinguishment of debt	-	366	(366)
Other expenses, net	569	113	456
Total other income, net	(5,863)	(7,136)	1,273
Net loss before income tax	117,302	55,161	62,141
Provision for (recovery of) income tax	-	(19)	19
Net loss	$ 117,302	$ 55,142	$ 62,160

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands):

	Year Ended October 31,		
	2025	2024*	Change
Research and Development expenses:			
Chemistry, Manufacturing and Controls	$ 49,578	$ 11,994	$ 37,584
Clinical Operations	17,915	11,036	6,879
Personnel-related expenses, including stock-based compensation	19,935	10,687	9,248
Other research and development expenses	7,052	4,598	2,454
Total research and development expenses	$ 94,480	$ 38,315	$ 56,165

* Certain amounts reported in prior years have been reclassified to conform to the current year's presentation.

Research and development expenses increased by $56.2 million from $38.3 million for the year ended October 31, 2024 to $94.5 million for the year ended October 31, 2025. This increase was attributable to the following:

- a $37.6 million increase in detalimogene manufacturing activities is primarily attributable to the preparation for our planned Biologics License Application ("BLA") submission in the second half of 2026;
- a $9.2 million increase in personnel-related costs, including a $1.5 million increase in stock-based compensation, as the Company hired a number of key personnel to ramp up its clinical operations, quality, medical affairs and manufacturing functions to support our LEGEND study of detalimogene;

- a $6.9 million increase in clinical operations is a result of our increasing clinical trial activities including complete enrollment of the pivotal cohort of the Phase 2 LEGEND study of detalimogene in BCG-unresponsive NMIBC; and
- a $2.5 million increase in other research and development expenses is a result of regulatory and medical affairs professional service fees incurred in preparation for our planning BLA submission and research as the Company focuses on advancing the clinical and preclinical pipelines.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Year Ended October 31,		
	2025	2024*	Change
Personnel-related expenses, including stock-based compensation	$ 17,214	$ 12,031	$ 5,183
Other general and administrative expenses	11,471	11,951	(480)
Total general and administrative expenses	$ 28,685	$ 23,982	$ 4,703

* Certain amounts reported in prior years have been reclassified to conform to the current year's presentation.

General and administrative expenses increased by $4.7 million from $24.0 million for the year ended October 31, 2024 to $28.7 million for the year ended October 31, 2025. This increase was primarily attributable to the following:

- a $5.2 million increase in personnel-related expenses, including a $2.8 million increase in stock-based compensation, driven by the hiring of key general and administrative personnel; partially offset by
- a $0.5 million decrease in other general and administrative expenses primarily driven by decreased professional fees as work has transitioned to internal resources, partially offset by increased facilities expense.

Other (Income) Expense, Net

Other (income) expenses, decreased by approximately $1.3 million from income of $7.1 million for the year ended October 31, 2024 to income of $5.9 million for the year ended October 31, 2025 primarily due to a $1.0 million decrease in interest income earned in the current period, a $0.2 million increase in interest expense, $0.4 million gain on extinguishment of debt that was incurred during the prior year and $0.5 million increase in other expense primarily related to foreign currency fluctuations.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates or from other sources for several years, if at all. As of October 31, 2025, we had $50.2 million in cash and cash equivalents and $152.1 million in marketable securities, and we had an accumulated deficit of $372.0 million. Based on our current operating plans, we expect our cash, cash equivalents and marketable securities as of October 31, 2025 will be sufficient to fund the Company’s operating expenses and debt obligations requirements for at least the next 12 months from the issuance date of the consolidated financial statements included within this Annual Report.

From the Reverse Recapitalization through October 31, 2025, we have financed our operations primarily through proceeds received through PIPE and public financings and debt facility with Hercules. Those sources of liquidity include the $200.0 million from the February 2024 PIPE Financing, net of issuance costs of $12.4 million, and the $60.1 million from the October 2024 PIPE Financing, net of issuance costs of $3.8 million. Subsequent to October 31, 2025, we received gross proceeds of $149.5 million, net of issuance costs of $9.4 million, from the public offering of Common Shares and pre-funded warrants that closed in November 2025, as further described in “*Notes to the Financial Statements-Note 17, Subsequent Events*”.

The Company’s other sources of liquidity include $27.5 million that we may be eligible to drawdown further under our debt facility with Hercules, as well as the $100.0 million limit under our Open Market Sale Agreement with Jefferies LLC, which was entered into in December 2024. Our current operating plan is based on various assumptions. If we use our capital resources sooner than expected, we will evaluate reductions in expense or obtaining additional financing. This may include pursuing a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, research and development activities, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of many factors, including:

- the initiation, timing, costs, progress and results of our planned clinical trials of detalimogene and any other product candidates we develop;
- the scope, progress, results, and costs of our earlier-stage research programs, including the progress of preclinical development and possible clinical trials;
- the scope, progress, results and costs of our research programs and preclinical development of any future product candidates we may pursue;
- the cost of regulatory submissions and timing of regulatory approvals;
- the progress of the development efforts of parties with whom we may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we are obligated to make under our Nature Technology Corporation License Agreement or any future license agreements;
- the cash requirements of any future acquisitions or discovery of product candidates;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- the costs to acquire or in-license any products, product candidates or technologies;
- the costs associated with maintaining, expanding and protecting our intellectual property portfolio, including costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing detalimogene and any other product candidates we develop by third parties;
- the cost of establishing commercial launch capabilities in anticipation of a potential regulatory approval of detalimogene or any other product candidates we develop;
- the cost of commercialization activities if detalimogene or any future product candidates we develop are approved for sale, including marketing, sales and distribution costs;
- our efforts to add operational, financial and management information systems, enhance existing operational, financial and management information systems and hire additional personnel, including personnel to support development of our product candidates, commercial launch preparation and commercialization efforts and our other operations as a public company; and
- the costs of operating as a public company.

A change in the outcome of any of these or other variables with respect to the development of our lead candidates or any product or development candidate we may develop in the future could significantly change the costs and timing associated with our development plans. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or licensing arrangements. Adequate additional financing, if available, may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing shareholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such shareholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market

ourselves. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product development, there is no assurance that we will ever be profitable or generate positive cash flow from operating activities.

Cash Flows

Comparison of the years ended October 31, 2025 and 2024

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

	Year Ended October 31,	
	2025	2024
Net cash used in operating activities	$ (99,239)	$ (48,281)
Net cash used in investing activities	(25,138)	(125,953)
Net cash provided by financing activities	1,524	265,716
Effect of exchange rate changes on cash	1	1
Net (decrease) increase in cash and cash equivalents	$ (122,852)	$ 91,483

Net Cash Used in Operating Activities

Net cash used in operating activities for the fiscal year ended October 31, 2025 was $99.2 million and was primarily due to our net loss of $117.3 million, partially offset by adjustments for non-cash charges totaling $8.3 million. Further changes were driven by an increase of $0.6 million in investment tax credits receivable and a $10.3 million increase in other net working capital adjustments.

Net cash used in operating activities for the fiscal year ended October 31, 2024 was $48.3 million and was primarily due to our net loss of $55.1 million, partially offset by adjustments for non-cash charges totaling $6.8 million. Further changes were driven by the receipt of a $2.0 million refundable investment tax credit and a $1.9 million decrease in other net working capital adjustments.

Net Cash Used in Investing Activities

Net cash used in investing activities for each of the fiscal years ended October 31, 2025 and 2024 was $25.1 million and $126.0 million, respectively, primarily consisting of purchases, net of maturities, of marketable securities and purchases of property and equipment during each year.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the fiscal year ended October 31, 2025 was $1.5 million, primarily resulting from proceeds from exercise of stock options of $2.2 million, which were partially offset by $0.7 million in principal repayments of the Prior Term Loan (as defined herein).

Net cash provided by financing activities for the fiscal year ended October 31, 2024 was $265.7 million, primarily resulting from $260.1 million received from the 2024 PIPE Financings, which were partially offset by issuance costs of $12.4 million, $22.5 million received from the Term Loan (as defined herein), which was offset by $9.4 million in principal repayments of the Prior Term Loan, $6.1 million from exercise of common share warrants and stock options, offset by $0.6 million in debt issuance costs paid as part of the Term Loan, and $0.6 million of SPAC transaction costs paid to FEAC in connection with the Reverse Recapitalization.

Hercules Loan Agreement

On December 30, 2021, we entered into a Loan and Security Agreement (the "Prior Loan Agreement") with Hercules Capital, Inc. ("Hercules") for the issuance of a term loan facility with an aggregate principal amount of up to $20.0 million (the “Prior Term Loan”). On December 22, 2023 (the "Hercules Closing Date"), we entered into an amended and restated loan and security Agreement (the "Amended Loan Agreement”), with Hercules, as agent and lender, and the several banks and other financial institutions or entities from time to time parties thereto (the "Lenders"). The Amended Loan Agreement amended and restated in its entirety the Prior Loan Agreement. The Amended Loan Agreement provided for a term loan facility of up to $50.0 million available in multiple tranches (the “Term Loan”), as follows: (i) an initial term loan advance (the “Tranche 1 Advance”) that was made on the Tranche 1 Advance closing date of $22.5 million, approximately $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement, (ii) subject to the achievement of the specified Interim Milestone (the “Interim Milestone”), which includes no default or event of default, delivery of written notice to the Lenders that the Company has conducted an analysis of interim efficacy of data from the clinical evaluation of detalimogene in the Phase 2 clinical study, and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances in an aggregate principal amount of up to $7.5 million from the date of achievement of the Interim Milestone through the earlier of (x) 60 days following the achievement of the Interim Milestone and (y) March 31, 2025, and (iii) an uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time up to and including the Amortization Date (as defined below) that the Lenders make additional

term loan advances to the Company in an aggregate principal amount of up to $20.0 million. The Company is required to pay upon the earlier of January 1, 2028 (the “Maturity Date”) or payment in full of the Term Loan, an end of term fee equal to 5.50% of the aggregate principal amount of the Term Loan (the “End of Term Charge”). The Amended Loan Agreement also required us to pay on July 1, 2025 or, if earlier, the date we prepaid the Term Loan, $0.7 million representing the Prior Term Loan End of Term Charge (the "Prior Term Loan End of Term Charge" and "End of Term Charge", collectively the “End of Term Charges”).

We accounted for the Amended Loan Agreement as an extinguishment of the Prior Term Loan. As a result of the extinguishment, we recorded a loss of $0.4 million as a component within other income and expense in our consolidated statement of operations during the year ended October 31, 2024, which represented the difference between the reacquisition price of the debt, including fees, and the initial fair value of the warrants paid directly to Hercules, and the carrying value of the Prior Term Loan at the time of extinguishment.

On December 18, 2024, we entered into a First Amendment to Amended and Restated Loan and Security Agreement (the "First Amendment") with the Lenders. The First Amendment modified the Amended Loan Agreement to reallocate the $7.5 million previously available under Tranche 2 (as defined in the Amended Loan Agreement), which was not drawn by the Company upon achievement of Interim Milestone, to Tranche 3 (as defined in the Amended Loan Agreement). Pursuant to the First Amendment, the $7.5 million advance originally available upon achievement of the Interim Milestone was added to the uncommitted tranche subject to the Lenders' investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time that the Lenders make additional loan advances to the Company in an aggregate principal amount of up to $27.5 million. The First Amendment did not change the total term loan facility available to us of up to $50.0 million. The First Amendment further provided for certain administrative changes in accordance with the foregoing.

At our option, we may elect to prepay all, but not less than all, of the outstanding Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the Closing Date (as defined in the Amended Loan Agreement); (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date; and (iii) 1.0% of the principal amount outstanding if prepayment occurs at any time thereafter but prior to the Maturity Date.

As of October 31, 2025, we had borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of legal fees and End of Term Charges under the Term Loan. The remaining $27.5 million of the uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent described above remains undrawn and available to us. The Prior Term Loan End of Term Charge of $0.7 million has been paid as of October 31, 2025.

The Term Loan bears cash interest payable monthly at an annual rate equal to the greater of (a) the prime rate of interest as reported in the Wall Street Journal plus 0.75% (capped at 9.75%) and (b) 9.25%. The Term Loan also bears additional payment-in-kind interest at an annual rate of 1.15%, which is added to the outstanding principal balance of the Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement, as amended by the First Amendment, are repayable in monthly interest-only payments through the "Amortization Date", which is either: (x) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (y) if the Interim Milestone and certain clinical milestones are achieved and there has been no default, July 1, 2026. After the Amortization Date, the outstanding Term Loan and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date. Through October 31, 2025, we have achieved the Interim Milestone but have not yet achieved certain clinical milestones. Amounts payable on January 1, 2026 were classified as current liabilities on the consolidated balance sheet for the year ended October 31, 2025. The effective interest rate of the Term Loan was 11.63% as of October 31, 2025.

In connection with the Amended Loan Agreement, as amended by the First Amendment, we granted Hercules a security interest senior to any current and future debts and to any security interest in all of our right, title, and interest in, to and under all of our property and other assets, subject to limited exceptions including our intellectual property.

The Amended Loan Agreement, as amended by the First Amendment, contains negative covenants that, among other things and subject to certain exceptions, could restrict our ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. The Amended Loan Agreement, as amended by the First Amendment, also contains certain events of default and representations, warranties and non-financial covenants of the Company. The Company was in compliance with these financial covenants at October 31, 2025.

As of October 31, 2025 and 2024 the carrying value of the note payable consists of the following (in thousands):

	Year Ended October 31,	
	2025	2024
Note payable, including End of Term Charge	$ 24,231	$ 24,663
Debt discount, net of accretion	(1,088)	(1,673)
Accrued interest	183	182
Note payable, net of discount	$ 23,326	$ 23,172

As of October 31, 2025, we classified $8.0 million of the note payable as current. As of October 31, 2024, we classified $0.7 million of the note payable as current, which represents the back-end fee associated with the refinancing of the Prior Term Loan. During the years ended October 31, 2025 and 2024, we recognized $2.4 million and $2.2 million of interest expense related to the Amended Loan Agreement, respectively, and $0.6 million each year related to the amortization of the debt discount.

Estimated future principal payments due under the Term Loan, including the contractual End of Term Charges and payment-in-kind interest as of October 31, 2025 are as follows:

2026	8,417
2027	10,987
2028	5,161
Total principal payments, including End of Term Charge	$ 24,565

The Hercules Term Loan is our only outstanding debt instrument at October 31, 2025.

Contractual Obligations and Other Commitments

License Agreement with Nature Technology Corporation

On April 10, 2020, we entered into the License Agreement with NTC pursuant to which NTC granted us a worldwide non-exclusive, royalty-bearing and sublicensable license to certain patents and know-how relating to the Nanoplasmid™ vector backbone that is used in detalimogene voraplasmid to research, develop, make, use, import, sell and offer to sell, any gene and cell therapy products incorporating the Nanoplasmid™ vector backbone (excluding any such products in the field of dermatology). Unless terminated earlier, the License Agreement will continue until no valid claim of any licensed patent exists in any country. We can voluntarily terminate the License Agreement with prior notice to NTC.

We paid NTC an initial, upfront fee of $50 thousand which was recorded as research and development expense upon entering into the License Agreement. Beginning on the first anniversary of the effective date of the License Agreement and on each subsequent anniversary, we are required to pay NTC a $50 thousand annual maintenance fee until the first sale of a product for which a royalty is due. We are also required to make a payment to NTC of $50 thousand upon assigning the License Agreement to a third-party. The License Agreement provides for a one-time payment of $50 thousand for the first dose of a product covered by a valid claim of a licensed patent (a "Milestone Product") in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a Milestone Product by the U.S. Food and Drug Administration. The first milestone related to the first dose of a Milestone Product, was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a Milestone Product, has not yet been achieved as of the year ended October 31, 2025. We are also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by us, our affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the License Agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country. In the event that we or any of our affiliates or sublicensees manufactures any GMP lot of a licensed product, then we or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. Such manufacturing payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory.

For a more detailed description of this agreement, see "*Item 1. Business-Intellectual Property-Strategic License Agreement*" and "*Notes to the Financial Statements-Note 7, License Agreement and Clinical Research Organization*" included elsewhere in this Annual Report.

Lease Obligations

Our leases are comprised of all operating leases for Montreal, Canada, Boston, MA USA and Waltham, MA USA office space and Montreal, Canada lab space. Please refer to Note 13 to our consolidated financial statements included elsewhere in this Annual Report for expenses related to the lease obligations in the twelve months ended October 31, 2025, future payment requirements, and the guaranty obligations under the lease agreements.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, CMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including those incurred by subcontractors of our suppliers.

The Company did not have material capital expenditure commitments at October 31, 2025.

Critical Accounting Estimates for the years ended October 31, 2025 and 2024

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make judgments and estimates that affect the reported amounts of assets, liabilities and expenses, as well as related disclosures during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates.

While our accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Accrued and Prepaid Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued and prepaid third-party research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued and prepaid expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued and prepaid research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Share-Based Compensation

We measure all share-based awards granted to employees, officers, directors and non-employees based on the fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Our share-based payments related only to stock options issued to date. We account for forfeitures of our share-based awards as they occur. We have historically issued share-based awards with only service-based vesting conditions. In July 2023, we issued 1,046,764 stock options which have performance conditions tied to the closing of the Reverse Recapitalization and the

filing of an effective registration statement. For share-based awards with service-based vesting conditions, we record the expense using the straight-line method including when such awards have graded vesting. For performance-based awards, we record the expense when achievement of the performance condition is deemed probable using an accelerated attribution method, as if each vesting tranche was treated as an individual award.

For all stock options granted at fair value of the underlying Common Shares at the time of the grant with service-based vesting, the fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of our Common Shares (prior to the Reverse Recapitalization) expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. We determine the volatility for awards granted based on an analysis of reported data for a group of guideline companies that have issued options with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The expected option term for share-based awards with only service-based vesting was calculated based on the simplified method, which uses the midpoint between the vesting date and the contractual term, as we do not have sufficient historical data to develop an estimate based on participant behavior. The expected option term for performance-based awards has been determined considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, cash dividends on our Common Shares; therefore, the expected dividend yield is assumed to be zero.

Prior to the Reverse Recapitalization, because there was no public market for enGene Inc.'s common shares, its Board of Directors approved the fair value of its common share based on third-party valuations of its common shares. Initially, the enterprise equity value of enGene Inc. was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company's various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another. Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering, or sale of our Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, various objective and subjective factors were considered to determine the fair value of our Common Shares as of each grant date of stock options, including, among other factors:

- the prices at which we sold shares of preferred shares and the superior rights and preferences of the preferred shares relative to its Common Shares at the time of each grant,
- the estimated value of each security both outstanding and anticipated,
- the anticipated capital structure that will directly impact the value of the currently outstanding securities,
- our financial position, including cash on hand, and our historical and forecasted performance and operating results,
- the progress of our research and development programs,
- our stage of development and business strategy and the material risks related to our business and industry,
- the likelihood of achieving a liquidity event for the holders of our Common Shares, such as an initial public offering or a sale of our Company, given prevailing market conditions,
- external market conditions affecting the biotechnology industry sectors,
- local and global economic conditions, and
- the lack of an active public market for our Common Shares and redeemable convertible preferred shares.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if we had used different assumptions or estimates, or if there are changes to the unobservable inputs, the fair value of its Common Shares and share-based compensation expense could have been materially different.

Subsequent to the consummation of the Reverse Recapitalization, the fair value of the Common Shares used in the Black-Scholes option-pricing model to determine the fair value of the stock option is determined based on the quoted price of our Common Shares. Further, there were no performance conditions outstanding subsequent to the consummation of the Reverse Recapitalization.

Our share-based compensation expense is recorded in general and administrative and research and development expenses in the Company's consolidated statements of operations and comprehensive loss. We recorded share-based compensation expense of $9.6 million and $5.3 million for the fiscal years ended October 31, 2025 and 2024, respectively. See "*Notes to the Financial Statements-Note 10, Share-Based Compensation*" for additional information.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined by the JOBS Act. Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected to opt out of such extended transition period. In addition, for so long as we are an emerging growth company, we are permitted and intend to take advantage of exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting.

We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of FEAC's IPO, which occurred on December 14, 2021, (b) in which we have total annual revenue of at least $1.23 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds $700 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we have issued more than $1.00 billion in non-convertible debt securities during the prior three-year period. References herein to "emerging growth company" have the meaning associated with it in the JOBS Act.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common shares held by non-affiliates exceeds $250 million as of the prior April 30, or (2) our annual revenues exceed $100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds $700 million as of the prior April 30. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial reporting with that of other public companies difficult or impossible. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations including regarding executive compensation.

Recent Accounting Pronouncements

We have reviewed all recently issued accounting pronouncements and have determined that, other than as disclosed in Note 2 to our annual consolidated financial statements included elsewhere in this Annual Report and disclosed above, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 7A.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the reports of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report, and such information is incorporated by reference herein.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report, management, under the supervision of and with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer and principal accounting officer), carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) to determine whether such disclosure controls and procedures provide reasonable assurance that information to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and such information is accumulated and communicated to management, including our principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding disclosure. Based on our assessment, management concluded that, as of October 31, 2025, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with U.S. GAAP. Our management, under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of October 31, 2025, our internal control over financial reporting was effective.

This annual report does not include an attestation report of the Company's registered public accounting firm as the Company's status as an "emerging growth company" and a "non-accelerated filer" exempts it from such requirement, pursuant to established rules of the SEC.

Remediation Efforts to Address the Material Weakness

As previously reported, in connection with our preparation and the audit of our consolidated financial statements as of and for the years ended October 31, 2024 and 2023, we identified material weaknesses, as defined under the Exchange Act, in our internal control over financial reporting. The material weaknesses related to a lack of formal policies, procedures, and controls over financial reporting, a lack of sufficient accounting and financial reporting personnel with requisite knowledge of GAAP, general information technology controls that were not designed appropriately, and a lack of appropriate segregation of duties. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

Based on the remediation efforts described below, these material weaknesses have been tested and determined to be remediated as of October 31, 2025. Remediation efforts included the following:

- hiring finance and accounting personnel with adequate experience and U.S. GAAP knowledge, including a Chief Financial Officer;
- establishing adequate review and approval processes and procedures based on the roles and responsibilities of each accounting members;
- implementing a risk assessment over financial reporting controls;
- designing and implementing policies, procedures and controls around key business and financial reporting process and general information technology controls;
- enhancing software tools to ensure segregation of duties; and
- engaging a professional accounting services firm to assist with the documentation and assessment of our internal controls for compliance with the Sarbanes-Oxley Act.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, concluded that, as of October 31, 2025, our disclosure controls and procedures and internal control over financial reporting were effective at a reasonable assurance level. However, our management does not expect that effective disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the

fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

Other than the items discussed above with respect to the remediation of previously identified material weaknesses, there were no other changes in our internal control over financial reporting during the fourth quarter ended October 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report and will be incorporated by reference from our definitive proxy statement relating to our 2026 annual meeting of shareholders, pursuant to Regulation 14A of the Exchange Act, which we refer to as our 2026 Proxy Statement. We expect to file our 2026 Proxy Statement with the SEC within 120 days of October 31, 2025.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 of Form 10-K regarding executive compensation will be included in our 2026 Proxy Statement and, other than the information required by Item 402(v) of Regulation S-K, is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 of Form 10-K regarding executive compensation will be included in our 2026 Proxy Statement and, other than the information required by Item 402(v) of Regulation S-K, is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 of Form 10-K regarding security ownership of certain beneficial owners and management will be included in our 2026 Proxy Statement and is incorporated herein by reference.

The information required by Regulation S-K Item 201(d) is set forth herein under "*Part II, Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities-Securities Authorized for Issuance under Equity Compensation Plans*" and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 of Form 10-K regarding certain relationships and related transactions and director independence will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 of Form 10-K regarding principal accountant fees and services will be included in our 2026 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
2.1	Business Combination Agreement, dated May 16, 2023, by and among FEAC, enGene Inc. and enGene (incorporated by reference to Exhibit 2.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). †
3.1	Articles of enGene Holdings Inc. (incorporated by reference to Exhibit 3.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
4.1	Specimen Common Share Certificate of enGene (incorporated by reference to Exhibit 4.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
4.2	Specimen Warrant Certificate of enGene (incorporated by reference to Exhibit 4.3 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
4.3	Warrant Assignment, Assumption and Amendment Agreement, dated as of October 30, 2023, among FEAC, enGene Inc., enGene and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.3 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
4.4	Warrant Agreement, dated December 9, 2021, between FEAC and Continental Stock Transfer & Trust Company, as warrant agent (incorporated herein by reference to Exhibit 4.1 of FEAC's Current Report on Form 8-K filed with the SEC on December 14, 2021).
4.5	Form of Closing Date Warrant to Purchase Common Shares of enGene Holdings Inc., pursuant to the Amended and Restated Loan and Security Agreement dated December 22, 2023 (incorporated herein by reference to Exhibit 4.1 of enGene's Current Report on Form 8-K filed with the SEC on December 28, 2023).
4.6	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated herein by reference to Exhibit 4.6 to enGene's Annual Report on Form 10-K filed with the SEC on January 29, 2024).
4.7	Form of Indenture (incorporated by reference to Exhibit 4.1 to enGene's Form S-3 Registration Statement Registration No.: 333-283201 filed with the SEC on November 13, 2024).
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to enGene's Current Report on Form 8-K filed with the SEC on November 14, 2025).
10.1	Sponsor and Insiders Letter Agreement, dated May 16, 2023, by and among FEAC, the Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A., enGene Inc., enGene and the other parties named therein (incorporated by reference to Exhibit 10.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.2	Form of Subscription Agreement (incorporated by reference to Exhibit 10.2 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.3	Form of Subscription Agreement Side Letter Agreement (incorporated by reference to Exhibit 10.3 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.4	Form of enGene Lock-Up Agreement (incorporated by reference to Exhibit 10.4 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.5	Registration Rights Agreement, dated October 31, 2023, by and among enGene Holdings Inc., Forbion European Acquisition Corp. and each of the Holders identified therein (incorporated herein by reference to Exhibit 10.8 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.6	Private Placement Warrants Purchase Agreement, dated December 9, 2021, by and between FEAC and the Company and the Sponsor (incorporated by reference to Exhibit 10.4 to FEAC's Current Report on Form 8-K filed on December 14, 2021).
10.7	Non-Exclusive License Agreement, dated April 10, 2020, by and between enGene and Nature Technology Corporation (incorporated by reference to Exhibit 10.14 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +†
10.8	Master Service Agreement, dated November 11, 2019, by and between enGene and BioAgilytix Labs, LLC (incorporated by reference to Exhibit 10.15 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +†

10.9	Letter Agreement, dated May 16, 2023, by and among enGene, IQ, FEAC and enGene (incorporated by reference to Exhibit 10.16 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +†
10.10	Lease Agreement, dated December 29, 2022, by and between enGene and Are-Canada No. 5 Holdings, ULC (incorporated by reference to Exhibit 10.21 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.11	Waiver and Consent Letter, dated September 13, 2023, by and among FEAC, enGene Inc. and enGene Holdings Inc. (incorporated by reference to Exhibit 10.22 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.12	enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.20 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.13	Form of Nonqualified Stock Option Grant Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.21 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.14	Form of Incentive Stock Option Grant Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.22 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.15	Form of Restricted Stock Award Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.23 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.16	Form of Restricted Stock Unit Award Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.24 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.17	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.25 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.18	Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on May 15, 2024).
10.19	enGene Holdings Inc. 2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on June 10, 2025).
10.20(a)	Employment Agreement, dated July 22, 2024, by and between enGene USA, Inc. and Ronald H. W. Cooper. (incorporated herein by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on July 24, 2024).#
10.20(b)*	Amendment to Employment Agreement, dated October 2, 2025, by and between enGene USA, Inc. and Ronald H.W. Cooper.#
10.21	Inducement Grant Agreement, dated July 22, 2024, by and between enGene Holdings Inc. and Ronald H. W. Cooper (incorporated herein by reference to Exhibit 10.5 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).#
10.22(a)	Employment Agreement, dated December 13, 2023, by and between enGene USA, Inc. and Ryan Daws (incorporated herein by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on December 13, 2023).#
10.22(b)	Amended Employment Agreement, dated June 10, 2025, by and between enGene USA, Inc. and Ryan Daws (incorporated by reference to Exhibit 10.3 of enGene's Quarterly Report on Form 10-Q filed with the SEC on June 12, 2025).#
10.23	Employment Agreement, dated April 22, 2024, by and between enGene USA, Inc. and Lee Giguere (incorporated by reference to Exhibit 10.2 of enGene's Quarterly Report on Form 10-Q filed with the SEC on June 14, 2024).#
10.24	Amended and Restated Employment Agreement, dated October 16, 2024, by and between enGene USA, Inc. and Alexander Nichols (incorporated herein by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on October 21, 2024).#
10.25	Amended and Restated Employment Agreement, dated October 21, 2024, by and between enGene Inc. and Anthony T. Cheung (incorporated herein by reference to Exhibit 10.32 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024).#
10.26	Employment Agreement, dated October 21, 2024, by and between enGene USA, Inc. and Joan Connolly (incorporated herein by reference to Exhibit 10.33 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024)#
10.27	Employment Agreement, dated May 21, 2025, by and between enGene USA, Inc. and Amy Pott (incorporated by reference to Exhibit 10.2 of enGene's Quarterly Report on Form 10-Q filed with the SEC on June 12, 2025).#
10.28	Employment Agreement, dated July 8, 2025, by and between enGene USA, Inc. and Jill Buck (incorporated by reference to Exhibit 10.6 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 11, 2025).#
10.29	Employment Agreement, dated July 8, 2025, by and between enGene USA, Inc. and Matthew Boyd (incorporated by reference to Exhibit 10.7 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 11, 2025).#
10.30(a)	Employment Agreement, dated November 8, 2023, by and between EnGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.01 of enGene's Current Report on Form 8-K filed with the SEC on November 9, 2023).#
10.30(b)	Transition and Modification Agreement, dated February 13, 2024 by and between enGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on February 14, 2024).#

10.30(c)	Amendment to Transition and Modification Agreement, dated July 23, 2024 by and between enGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on July 24, 2024).#
10.31	Employment Agreement, dated July 22, 2024, by and between enGene USA, Inc. and Raj Pruthi (incorporated herein by reference to Exhibit 10.3 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).#
10.32*	Employment Agreement, dated September 15, 2025, by and between enGene USA, Inc. and Hussein Sweti
10.33	Amended and Restated Loan and Security Agreement, dated December 22, 2023, by and among enGene Holdings Inc., enGene Inc. and enGene USA, Inc., as borrower, Hercules Capital, Inc., as agent, and the lenders from time to time party thereto (incorporated by reference to Exhibit 10.1 to enGene's Current Report on Form 8-K filed with the SEC on December 28, 2023). †+
10.34	First Amendment to Amended and Restated Loan and Security Agreement, dated December 18, 2024 (incorporated herein by reference to Exhibit 10.36 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024). †+
10.35	Form of Subscription Agreement, dated February 13, 2024 (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on February 14, 2024).
10.36	Form of Subscription Agreement, dated October 24, 2024 (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on October 25, 2024).
10.37	Open Market Sale Agreement℠, dated December 20, 2024, by and between enGene Holdings Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.1 of enGene's Current Report on Form 8-K filed with the SEC on December 20, 2024).
10.38	99 High Street Office Lease, dated June 4, 2025, by and between 99 High Street Owner LLC and enGene USA, Inc. (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on June 9, 2025).
10.39	Lease Agreement Guaranty, dated June 4, 2025, by enGene Holdings Inc. in favor of 99 High Street Owner LLC (incorporated by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on June 9, 2025).
19.1	Insider Trading Policy (incorporated herein by reference to Exhibit 19.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024).
21.1	Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 21.1 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation (incorporated herein by reference to Exhibit 97.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024).
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
† Certain of the exhibits and schedules to these exhibits have been omitted in accordance with Regulation S-K Item 601(a)(5). The registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.
+ Portions of this exhibit are redacted in accordance with Regulation S-K Item 601(b)(10)(iv).
Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

enGene Holdings Inc.

Date: December 22, 2025

By: /s/ Ronald H. W. Cooper
Name: Ronald H. W. Cooper
Title: Chief Executive Officer and President

Pursuant to the requirements of the Securities Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ronald H. W. Cooper Ronald H. W. Cooper	Chief Executive Officer, President and Director *(Principal Executive Officer)*	December 22, 2025
/s/ Ryan Daws Ryan Daws	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	December 22, 2025
/s/ Philip Astley-Sparke Philip Astley-Sparke	Director	December 22, 2025
/s/ Michael Heffernan Michael Heffernan	Director	December 22, 2025
/s/ Gerald Brunk Gerald Brunk	Director	December 22, 2025
/s/ Dr. Richard Glickman Dr. Richard Glickman	Director	December 22, 2025
/s/ Dr. William Grossman Dr. William Grossman	Director	December 22, 2025
/s/ Paul Hastings Paul Hastings	Director	December 22, 2025
/s/ Wouter Joustra Wouter Joustra	Director	December 22, 2025
/s/ Lota Zoth Lota Zoth	Director	December 22, 2025

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors
enGene Holdings Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of enGene Holdings Inc. (the Company) as of October 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the consolidated financial stateme

nts). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.

Montreal, Canada
December 22, 2025

ENGENE HOLDINGS INC.
CONSOLIDATED BALANCE SHEETS
(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	October 31, 2025	October 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 50,152	$ 173,004
Marketable securities - short term	143,584	65,328
Restricted investments	79	72
Investment tax credits receivable	927	332
Prepaid and other current assets	6,649	8,626
Total current assets	201,391	247,362
Marketable securities - long term	8,522	59,527
Property and equipment, net	2,477	1,169
Operating lease right of use asset	7,716	1,741
Other assets	1,362	1,374
Total assets	$ 221,468	$ 311,173
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 6,688	$ 1,411
Accrued expenses and other current liabilities	15,275	12,128
Operating lease liabilities, current	2,014	423
Current portion of note payable	8,002	699
Total current liabilities	31,979	14,661
Note payable, net of current portion	15,324	22,473
Operating lease liabilities, net of current portion	6,455	1,427
Total liabilities	53,758	38,561
Shareholders' equity:		
Common shares, no par value; unlimited shares authorized, 52,018,658 and 50,976,676 shares issued and outstanding as of October 31, 2025 and October 31, 2024, respectively.	513,281	509,811
Additional paid-in capital	27,349	18,950
Accumulated other comprehensive loss	(888)	(1,419)
Accumulated deficit	(372,032)	(254,730)
Total shareholders' equity	167,710	272,612
Total liabilities and shareholders' equity	$ 221,468	$ 311,173

The accompanying notes are an integral part of these consolidated financial statements.

ENGENE HOLDINGS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	Year Ended October 31,	
	2025	2024
Operating expenses:		
Research and development	$ 94,480	$ 38,315
General and administrative	28,685	23,982
Total operating expenses	123,165	62,297
Loss from operations	123,165	62,297
Other (income) expenses, net:		
Interest income	(9,426)	(10,413)
Interest expense	2,994	2,798
Gain on extinguishment of debt	-	366
Other expenses (income), net	569	113
Total other income, net	(5,863)	(7,136)
Net loss before income taxes	117,302	55,161
Provision for (recovery of) income taxes	-	(19)
Net loss	$ 117,302	$ 55,142
Other comprehensive loss:		
Unrealized (gain) loss on available-for-sale investments	(531)	(403)
Total comprehensive loss	$ 116,771	$ 54,739
Net loss per share of common shares, basic and diluted	$ 2.29	$ 1.46
Weighted-average common shares outstanding, basic and diluted	51,119,479	37,782,346

The accompanying notes are an integral part of these consolidated financial statements.

ENGENE HOLDINGS INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	Common Shares		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at October 31, 2023	23,197,976	$ 259,373	$ 13,717	$ (1,016)	$ (199,588)	$ 72,486
Exercise of stock options	116,752	295	(182)	-	-	113
Share-based compensation expense	-	-	5,324	-	-	5,324
Issuance of common shares in connection with February PIPE Financing, net of issuance costs	20,000,000	187,614	-	-	-	187,614
Issuance of common share in connection with October PIPE Financing, net of issuance costs	6,758,311	56,318	-	-	-	56,318
Issuance of warrants in connection with Amended Term Loan	-	-	319	-	-	319
Issuance of common shares upon exercise of warrants	520,282	6,114	(131)	-	-	5,983
Issuance of common shares upon cashless exercise of warrants	383,355	97	(97)	-	-	-
Other comprehensive loss	-	-	-	(403)	-	(403)
Net loss	-	-	-	-	(55,142)	(55,142)
Balance at October 31, 2024	50,976,676	$ 509,811	$ 18,950	$ (1,419)	$ (254,730)	$ 272,612
Exercise of stock options	1,041,982	3,470	(1,247)	-	-	2,223
Share-based compensation expense	-	-	9,646	-	-	9,646
Other comprehensive income	-	-	-	531	-	531
Net loss	-	-	-	-	(117,302)	(117,302)
Balance at October 31, 2025	52,018,658	$ 513,281	$ 27,349	$ (888)	$ (372,032)	$ 167,710

The accompanying notes are an integral part of these consolidated financial statements.

ENGENE HOLDINGS INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	Year ended October 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (117,302)	$ (55,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	854	806
Gain on extinguishment of debt	-	366
Non-cash lease expense	378	163
Loss on the disposal of property and equipment	-	22
Net amortization of premiums (accretion of discounts) on marketable securities	(3,067)	(232)
Unrealized foreign currency losses (gains)	3	(6)
Share-based compensation expense	9,646	5,324
Depreciation of property and equipment	509	323
Changes in operating assets and liabilities:		
Investment tax credit receivable	(595)	2,011
Prepaid expenses and other assets	1,989	(7,566)
Accounts payable	4,942	474
Accrued expenses and other current liabilities	3,130	5,225
Lease liabilities	274	(49)
Net cash used in operating activities	(99,239)	(48,281)
Cash flows from investing activities		
Purchases of property and equipment	(1,485)	(925)
Purchases of marketable securities	(160,843)	(125,028)
Proceeds from maturities of marketable securities	137,190	-
Net cash used in investing activities	(25,138)	(125,953)
Cash flows from financing activities		
Payment of Reverse Recapitalization and PIPE Financing costs	-	(613)
Proceeds from the February 2024 PIPE Financing	-	260,149
Payments of issuance costs associated with the 2024 PIPE Financing	-	(12,386)
Proceeds from exercise of common share warrants	-	5,983
Proceeds from exercise of stock options	2,223	113
Repayments of term loan principal	(699)	(9,445)
Proceeds from issuance of term loan	-	22,500
Payments of debt issuance costs associated with the term loan	-	(585)
Net cash provided by financing activities	1,524	265,716
Effect of exchange rate changes on cash	1	1
Net (decrease) increase in cash and cash equivalents	(122,852)	91,483
Cash and cash equivalents at beginning of period	173,004	81,521
Cash and cash equivalents at end of period	$ 50,152	$ 173,004
Supplemental cash flow information:		
Cash paid for interest	$ 2,289	$ 1,925
Supplemental disclosure of non-cash investing and financing activities		
Reverse Recapitalization and PIPE financing transaction costs included within accrued expenses	-	$ 3,831
Warrant value issued as part of Amended Term Loan	-	319
Right of use assets obtained in exchange for lease liabilities	6,352	1,904
Property and equipment included in accrued expenses and accounts payable	332	-

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of Business

enGene Holdings Inc., together with its consolidated subsidiaries enGene Inc. and enGene USA, Inc. ("enGene" or the "Company") is a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients, and its head office is located in Montreal, Quebec, Canada. The Company is developing non-viral genetic medicines 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.

Merger with Forbion European Acquisition Corp.

Forbion European Acquisition Corporation ("FEAC") was a special purpose acquisition company ("SPAC") formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more business or entities. On October 31, 2023 (the "Closing Date"), the Company, FEAC, and enGene Inc., consummated the merger (the "Reverse Recapitalization") pursuant to a business combination agreement, dated as of May 16, 2023 (the "Merger Agreement"). As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its Common Shares and warrants on the Nasdaq Capital Market under the symbols "ENGN" and "ENGNW," respectively, commencing trading on November 1, 2023, with enGene Inc., a subsidiary of the Company, continuing the existing business operations.

Liquidity and Going Concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern,* the Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these consolidated financial statements are issued.

The Company's consolidated financial statements have been prepared assuming the Company will continue as a going concern, which presumes the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for developing non-viral genetic medicines and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future.

The Company has incurred a net loss of $117.3 million and negative cash flows from operating activities of $99.2 million for the year ended October 31, 2025, and, as of that date, has an accumulated deficit of $372.0 million. The Company has not yet commercialized any product candidates and does not expect to generate revenue from sales of any product candidates or from other sources for several years, if at all. The Company will need additional funding to support its continuing operations and pursue its development strategy. To date, the Company has not generated any revenues and has financed its liquidity needs primarily through PIPE financings, offering debt, and issuance of redeemable convertible preferred shares and warrants. In November 2025, the Company closed a public offering of its Common Shares and pre-funded warrants to purchase Common Shares which resulted in aggregate gross proceeds to the Company of approximately $149.5 million, before deducting the underwriting discounts and commissions and offering expenses of approximately $9.4 million.

The Company's ability to continue as a going concern depends on its ability to successfully develop and commercialize its products, achieve and maintain profitable operations, as well as the adherence to conditions of outstanding loans. As of the issuance date of these consolidated financial statements, the Company expects that its existing cash and cash equivalents as of October 31, 2025 will be sufficient to fund its operating expenses and debt obligations requirements for at least the next 12 months from the issuance date of these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates ("ASU's") of the Financial Accounting Standards Board ("FASB").

The consolidated financial statements are expressed in US dollars. The consolidated financial statements have been prepared on a historical cost basis, except for items that are required to be accounted for at fair value.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to the accrual of research and development expenses, share-based payments and the recoverability of investment tax credits receivable. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ from those estimates and such differences may be material to the consolidated financial statements.

Segment Information

The Company considered the Company's organizational structure and the information regularly reviewed and evaluated by the Company's chief operating decision maker ("CODM") when deciding how to allocate resources and assess performance. The Company has determined that its CODM is its Chief Executive Officer ("CEO"). The CODM reviews the financial information on a consolidated basis for purposes of evaluating financial performance and allocating resources. Based on this factor, the Company determined that it operates and manages its business as a single operating segment. As of October 31, 2025, the Company had $
7.2 million and $3.0 million in long-lived assets held in the United States and in Canada, respectively. As of October 31, 2024, the Company had $0.4 million and $2.5 million in long-lived assets held in the United States and in Canada, respectively.

Risk of Concentrations of Credit and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. Management believes that the Company is not currently exposed to significant credit risk as the Company's deposits were held in custody at third-party financial institutions.

The Company's investment policy limits investments to certain types of securities issued by the U.S. Government and its agencies, as well as institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Consolidated Balance Sheets.
As of October 31, 2025 and 2024, the Company had no off-balance sheet concentrations of credit risk.

The Company is dependent on third-party CMOs and CRO with whom it does business. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company's cash and cash equivalents include bank balances, demand deposits and

other short-term, highly liquid investments. The fair value of cash and cash equivalents approximate the amortized cost. The Company had $50.2 million of cash and cash equivalents as of October 31, 2025 and $173.0 million of cash and cash equivalents as of October 31, 2024. See Note 17, Subsequent Events, for additional discussion on the Company's cash position following the closing of an underwritten public offering in November 2025.

Marketable securities

The Company's marketable securities are maintained by investment managers and consist of money market funds, U.S. government agency securities and treasuries. If the remaining contractual maturity is within one year from the balance sheet date, the marketable securities are classified as current and otherwise, they are classified as non-current assets.

Investment in marketable securities is classified as available-for-sale and is reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity in other comprehensive loss. Premium or discounts from par value are amortized to investment income over the life of the underlying investment.

The Company periodically evaluates the need for an allowance for credit losses. The evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.

When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a credit loss expense within other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities.

Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaids and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its marketable securities.

Property and Equipment

Property and equipment are comprised mainly of research and development equipment, computer hardware and software, office furniture and equipment, and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if applicable.
Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Lab equipment	5 years
Computer equipment	3 years
Computer software	5 years
Office furniture	5 years
Leasehold improvements	Shorter of remaining lease term or useful life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.

The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected undiscounted cash flows are less than the carrying value of the assets, then the assets are considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows. To date, no such impairment losses have been recorded.

Leases

The Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use ("ROU") asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

Fair Value Measurements of Financial Instruments

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1-Quoted prices in active markets for identical assets or liabilities.
- Level 2-Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3-Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

At October 31, 2025, financial instruments measured at fair value on a recurring basis include marketable securities (see Note 4, Marketable Securities, and Note 3, Fair Value Measurements). The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Debt Issuance Costs

The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with the issuance of debt not accounted for using the fair value option as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the Company's consolidated balance sheets and amortized as interest expense on the Company's consolidated statements of operations and comprehensive loss using the effective interest method.

Research and Development Expenses

Research and development expenses are comprised primarily of costs incurred for our drug discovery efforts and development of our product candidates. These expenses include salaries, employee benefits, and share-based compensation expense for our research and development personnel, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside CROs and consultants to conduct research and development activities including costs of clinical trials and manufacturing, and the allocable portions of facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred.

Management estimates the Company's accrued research and development expenses as of each balance sheet date in the Company's financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations.

Share-Based Compensation

The Company has an incentive equity plan (the "2023 Incentive Equity Plan" or the "2023 Plan"), whereby employees render services as consideration for equity instruments. The 2023 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded enGene Inc.'s employee stock option plan (the "ESOP") and equity incentive plan (the "EIP") (collectively, the "Old Plans"). The 2023 Plan was amended and restated in May 2024 and is now the Company's Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan (the "2023 Plan"), which supersedes all prior plans. The Company measures all share-based awards granted to employees, officers, directors and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of its share-based awards as they occur. The Company issues share-based awards with service-based vesting conditions and awards with both performance and service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company records the expense using the straight-line method including when such awards have graded vesting. For share-based awards with both performance and service-based vesting conditions, the Company records the expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management's best estimate.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company's common shares, expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and

the Company's expected dividend yield. The Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies with similar characteristics including market capitalization, stage of development, therapeutic focus and certain financial measures. The expected volatility has been determined using an average of the historical volatility measures of this group of guideline companies. The expected option term was calculated based on the simplified method for awards with only service based vesting conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. For awards with both performance and service based vesting conditions, the expected term has been determined using management's best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common shares; therefore, the expected dividend yield is assumed to be zero.

Prior to the consummation of the Reverse Recapitalization, because there was no public market for the Company's common shares, the Board of Directors has determined the fair value of the Company's common shares based on third-party valuations of the Company's common shares. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company's various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another.

Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering ("IPO"), or sale of the Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, the Company's Board of Directors considered various objective and subjective factors to determine the fair value of the Company's common shares as of each grant date, including the prices at which enGene Inc. sold shares of redeemable convertible preferred shares and the superior rights and preferences of the redeemable convertible preferred shares relative to its common shares at the time of each grant, external market conditions, the progress of the Company's research and development programs, the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company's common shares and redeemable convertible preferred shares, among other factors.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if the Company had used different assumptions or estimates or if there are changes to the unobservable inputs, the fair value of its common shares and share-based compensation expense could have been materially different.

Subsequent to becoming a publicly traded Company upon the consummation of the Reverse Recapitalization, the fair value of common shares underlying equity awards is based on the market price of the Company's common stock at the date of the grant.

The Company's share-based compensation expense is recorded in general and administrative and research and development expenses in the Company's consolidated statements of operations and comprehensive loss.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax basis of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in shareholders' deficit that result from transactions and economic events other than those with shareholders.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common shares. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and warrants. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is generally the same as basic net loss per share attributable to common shareholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. See Note 11, Net Loss per Share, for further detail.

Deferred Transaction Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that were directly associated with PIPE or public financings as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs are recorded within equity as a reduction of the common share and warrants value within additional paid in capital. Costs are allocated to each equity instrument on a relative fair value basis for transactions that include both instruments.

Government Assistance Programs for Research and Development Expenditures

The Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation ("CCPC") on eligible scientific research and experimental development ("SR&ED") expenditures through September 2023, at which time the Company lost its status as a CCPC. In addition, effective for fiscal 2023, the Company's maximum refundable tax credits were reduced due to the Company's taxable capital, as defined in the *Income Tax Act* (Canada), which reduction in credits has been recorded in the fourth quarter. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on management's estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, the Company's SR&ED tax credits will be earned at a lower rate and some will no longer be refundable.

Amounts received or receivable resulting from government assistance programs, including investment tax credits for SR&ED, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible SR&ED expenditures pursuant to government assistance programs are received in cash. The amounts

receivable are recorded as reductions of research and development costs when the related costs have been incurred and there is reasonable assurance regarding collection of the claim. During the years ended October 31, 2025 and 2024, the Company recorded $0.6 million and $0.4 million, respectively, as a reduction of research and development expense associated with SR&ED investment tax credits.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, Segment Reporting (Topic 280: Improvements to Reportable Segment Disclosures) ("ASU 2023-07"), which requires public entities to disclose information about their reportable segments' significant expenses on an interim and annual basis. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The ASU is effective for annual periods beginning after December 15, 2023 and for interim periods within fiscal years beginning after December 15, 2024. The Company adopted this accounting standard during the year ended October 31, 2025 and there was no impact on the Company's reportable segments identified. Required disclosures have been included in Note 15 "Segment Reporting".

Recently Issued Accounting Pronouncements - Not Yet Adopted

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal Use Software (Subtopic 350-40) Targeted Improvements to the Accounting for Internal-Use Software*, which removes references to project stages and clarified when the Company is required to begin capitalizing eligible costs. The new guidance is effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years, with early adoption permitted. ASU 2025-06 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this updated standard on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income- Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, as further clarified by ASU 2025-01, *Income Statement - Reporting Comprehensive Income- Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*, issued in January, 2025, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. This ASU is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this updated standard on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740) - Improvements to* I*ncome Tax Disclosures*, which improves transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. ASU No 2023-09 is effective for the Company's annual financial statements for the year ending October 31, 2026. The Company is currently evaluating the impact of the guidance on the financial statements and related disclosures.

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*, which amends GAAP to reflect updates and simplifications to certain disclosure and presentation requirements referred to FASB by the SEC. The targeted amendments incorporate 14 of the 27 disclosures referred by the SEC into codification. Each amendment in ASU 2023-06 is effective on the date on which the SEC's removal of the related disclosure requirement from Regulation S-X or Regulation S-K becomes effective but will not be effective if the SEC has not removed the applicable disclosure requirements by June 30, 2027. Early adoption is prohibited. The Company is currently evaluating the impact of the amendments on its financial statements and related disclosures.

3. Fair Value Measurements

The following table presents the Company's fair value hierarchy for financial assets measured at fair value as of October 31, 2025:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

		October 31, 2025		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents				
Money market funds	$ 8,642	$ 8,642	$ -	$ -
U.S. government treasuries	21,623	$ 21,623	$ -	$ -
Government agency securities	3,249	$ -	$ 3,249	$ -
Short term marketable securities:				
U.S. government treasuries	125,467	$ 125,467	$ -	$ -
Government agency securities	18,117	$ -	$ 18,117	$ -
Long term marketable securities:				
U.S. government treasuries	8,522	$ 8,522	$ -	$ -
Total financial assets	$ 185,620	$ 164,254	$ 21,366	$ -

The following table presents the Company's fair value hierarchy for financial assets measured at fair value as of October 31, 2024:

		October 31, 2024		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents				
Money market funds	$ 121	$ 121	$ -	$ -
U.S. government treasuries	94,236	94,236	-	-
Government agency securities	9,955	-	9,955	-
Short term marketable securities:				
U.S. government treasuries	51,574	51,574	-	-
Government agency securities	13,754	-	13,754	-
Long term marketable securities:				
U.S. government treasuries	49,627	49,627	-	-
Government agency securities	9,900	-	9,900	-
Total financial assets	$ 229,167	$ 195,558	$ 33,609	$ -

As of October 31, 2025 and 2024, the Company classified its government agency marketable securities as Level 2 within the valuation hierarchy. The Company estimates the fair value of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly to estimate fair value. These inputs include market pricing based on real time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs.

During the years ended October 31, 2025 and 2024, there were no transfers or reclassifications between fair value measure levels of assets or liabilities. The carrying values of all other financial current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

4. Marketable securities

The Company invests in money market funds, U.S. Treasury and government agency debt securities; all marketable securities are classified as available-for-sale and carried at fair value, with unrealized changes in fair value reflected in the other comprehensive income (loss) in the consolidated statements of shareholders' equity.

As of October 31, 2025, the marketable securities consisted of the following:

	October 31, 2025			
Description	Amortized Cost	Unrealized Holdings Gains	Unrealized Holdings Losses	Aggregate Fair Value
Cash equivalents and short-term investments:				
Money market funds, included in cash and cash equivalents	$ 8,642	$ -	$ -	$ 8,642
US treasury	146,984	$ 131	$ (25)	$ 147,090
Government agency securities	21,368	$ 7	$ (9)	$ 21,366
Total cash equivalents and short-term investments	$ 176,994	$ 138	$ (34)	$ 177,098
Long-term investments:				
US treasury	8,498	$ 25	$ (1)	$ 8,522
Total long-term investments	$ 8,498	$ 25	$ (1)	$ 8,522
Total	185,492	163	(35)	185,620

As of October 31, 2025, all marketable securities held by the Company had remaining contractual maturities of one year or less, except for U.S. government securities that had maturities of one to two years.

As of October 31, 2025, the Company held 50 securities, 14 of which, with an aggregate fair value of $55.9 million, were in unrealized loss position. All investments in an unrealized loss position were in this position for less than 12 months. The Company does not intend to sell its investments before recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recorded as of October 31, 2025 because the decline in fair value below amortized cost is not related to credit losses. Securities are evaluated at the end of each reporting period. The unrealized losses on U.S. Treasury and Government agency securities range from 0-1% of their amortized cost.

As of October 31, 2024, the marketable securities consisted of the following:

	October 31, 2024			
Description	Amortized Cost	Unrealized Holdings Gains	Unrealized Holdings Losses	Aggregate Fair Value
Cash equivalents and short-term investments:				
Money market funds, included in cash and cash equivalents	$ 121	$ -	$ -	$ 121
US treasury	145,832	12	(30)	145,814
Government agency securities	23,714	3	(8)	23,709
Total cash equivalents and short-term investments	$ 169,667	$ 15	$ (38)	$ 169,644
Long-term investments:				
US treasury	49,931	-	(306)	49,625
Government agency securities	9,972	-	(74)	9,898
Total long-term investments	$ 59,903	$ -	$ (380)	$ 59,523
Total	$ 229,570	$ 15	$ (418)	$ 229,167

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

As of October 31, 2024, all marketable securities held by the Company had remaining contractual maturities of one year or less, except for certain government agency securities that had maturities of one to two years.

As of October 31, 2024, the Company held 31 securities, 21 of which were in an unrealized loss position. All investments in an unrealized loss position were in this position for less than 12 months. The Company does not intend to sell its investments before recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recorded as of October 31, 2024 because the decline in fair value below amortized cost is not related to credit losses. Securities are evaluated at the end of each reporting period. The unrealized losses on U.S. Treasury and Government agency securities range from 0-1% of their amortized cost.

Accrued interest receivable on the Company's available-for-sale debt securities totaled $1.3 million and $0.7 million as of October 31, 2025 and 2024, respectively, and was presented within prepaids and other current assets on the Company's consolidated balance sheets. No accrued interest receivable was written off during the twelve months ended October 31, 2025 or 2024.

There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the years ended October 31, 2025 or 2024.

5. Property and Equipment, Net

As of October 31, 2025 and 2024, property and equipment consisted of the following:

	October 31, 2025	October 31, 2024
Lab equipment	$ 3,134	$ 2,191
Computer equipment	169	62
Computer software	144	146
Office furniture	871	141
Leasehold improvements	262	239
Property and equipment	4,580	2,779
Less: Accumulated depreciation and amortization	2,103	1,610
Property and equipment, net	$ 2,477	$ 1,169

Depreciation and amortization expense related to property and equipment was $ 0.5 million and $0.3 million for the year ended October 31, 2025 and 2024, respectively.

6. Accrued Expenses and Other Current Liabilities

As of October 31, 2025 and 2024, accrued expenses and other current liabilities consisted of the following:

	October 31, 2025	October 31, 2024
Accrued research and development expenses	$ 9,397	$ 3,773
Employee compensation and related benefits	4,053	3,475
Professional fees	1,229	824
Accrued income taxes payable	19	-
Accrued financing costs	-	3,831
Other	577	225
Total accrued expenses and other current liabilities	$ 15,275	$ 12,128

7. License Agreement and Clinical Research Organization

License Agreement - Nature Technology Corporation

On April 10, 2020, the Company entered into a Non-Exclusive License Agreement (the “License Agreement”) with Nature Technology Corporation (“NTC”) whereby the Company licenses certain rights to Nanoplasmid™ technology from NTC for commercialization. Under the terms of the License Agreement, NTC granted to the Company and its affiliates a non-exclusive, royalty-bearing, sublicensable license to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, sell, offer to sell, and have sold or offered for sale any product in the defined license field. Unless terminated earlier, the NTC

license agreement will continue until no valid claim of any licensed patent exists in any country. The Company can voluntarily terminate the license agreement with prior notice to NTC.

The Company paid NTC an initial, upfront fee of $50 thousand which was recorded as research and development expense upon entering into the License Agreement. Beginning on the first anniversary of the effective date of the License Agreement and on each subsequent anniversary, the Company is required to pay NTC a $
50 thousand annual maintenance fee. The Company is also required to make a payment to NTC of $50 thousand upon assigning the License Agreement to a third party.

The License Agreement provides for a one-time payment of $50 thousand for the first dose of a milestone product, as defined in the License Agreement, in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a milestone product by the U.S. Food and Drug Administration. The first milestone related to the first dose of a milestone product, was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a milestone product, has not yet been achieved as of the year ended October 31, 2025. The Company is also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by the Company, its affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the license agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country.

In the event that the Company or any of its affiliates or sublicensees manufactures any Good Manufacturing Practice (“GMP”) lot of a product, then the Company or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. The payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory.

During each of the years ended October 31, 2025 and 2024, the Company incurred $50 thousand of expenses related to the annual maintenance fee under the License Agreement. During the year ended October 31, 2025, the Company incurred a fee of $235 thousand related to the manufacturing payment under the License Agreement. There were no fees related to the manufacturing payment incurred during the year ended October 31, 2024. All expenses related to License Agreement are recorded within research and development expenses.

8. Notes Payable

Amended Loan and Security Agreement and the First Amendment

On December 30, 2021, the Company entered into a Loan and Security Agreement (the "Prior Loan Agreement") with Hercules Capital, Inc. ("Hercules") for the issuance of a term loan facility with an aggregate principal amount of up to $20.0 million (the “Prior Term Loan”). On December 22, 2023 (the "Hercules Closing Date"), the Company entered into an amended and restated loan and security Agreement (the "Amended Loan Agreement”), with Hercules, as agent and lender, and the several banks and other financial institutions or entities from time to time parties thereto (the "Lenders"). The Amended Loan Agreement amended and restated in its entirety the Prior Loan Agreement. The Amended Loan Agreement provides for a term loan facility of up to $50.0 million available in multiple tranches (the “Term Loan”), as follows: (i) an initial term loan advance (the “Tranche 1 Advance”) that was made on the Tranche 1 Advance closing of $22.5 million, approximately $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement, (ii) subject to the achievement of the specified Interim Milestone (the “Interim Milestone”), which includes no default or event of default, delivery of written notice to the Lenders that the Company has conducted an analysis of interim efficacy of data from the clinical evaluation of detalimogene in the Phase 2 clinical study, and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances in an aggregate principal amount of up to $7.5 million from the date of achievement of the Interim Milestone through the earlier of (x) 60 days following the achievement of the Interim Milestone and (y) March 31, 2025, and (iii) an uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time up to and including the Amortization Date (as defined below) that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $20.0 million. The Company is required to pay upon the earlier of January 1, 2028 (the “Maturity Date”) or payment in full of the Term Loan, an end of term fee equal to 5.50% of the aggregate principal amount of the Term Loan (the “End of Term Charge”). The Company was also required to pay on July 1, 2025 or, if earlier, the date the Company prepays the Term Loan, $0.7 million representing the Prior Term Loan End of Term Charge (the "Prior Term Loan End of Term Charge" and "End of Term Charge", collectively the “End of Term Charges”).

The Company accounted for the Amended Loan Agreement as an extinguishment of the Prior Term Loan. As a result of the extinguishment, the Company recorded a loss of $0.4 million as a component within other income and expense in the Company's consolidated statement of operations during the year ended October 31, 2024, which represented the difference between the reacquisition price of the debt, including fees and the initial fair value of the warrants paid directly to the lender, and the carrying value of the Prior Term Loan at the time of extinguishment.

On December 18, 2024, the Company entered into a First Amendment to Amended and Restated Loan and Security Agreement (the "First Amendment") with the Lenders. The First Amendment modified the Amended Loan Agreement to reallocate the $7.5 million previously available under Tranche 2 (as defined in the Amended Loan Agreement), which was not drawn by the Company upon achievement of Interim Milestone, to Tranche 3 (as defined in the Amended Loan Agreement). Pursuant to the First Amendment, the $7.5 million advance originally available upon achievement of the Interim Milestone was added to the uncommitted tranche subject to the Lenders' investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time that the Lenders make additional loan advances to the Company in an aggregate principal amount of up to $27.5 million. The First Amendment did not change the total term loan facility available to the Company of up to $50.0 million. The First Amendment further provided for certain administrative changes in accordance with the foregoing.

At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the Closing Date (as defined in the Amended Loan Agreement); (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date; and (iii) 1.0% of the principal amount outstanding if prepayment occurs at any time thereafter but prior to the Maturity Date.

As of October 31, 2025, the Company had borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of legal fees and End of Term Charges under the Term Loan. The remaining $27.5 million of the uncommitted tranche subject to the Lenders' investment committee approval and satisfaction of certain other conditions precedent described above remains undrawn and available to the Company. The Prior Term Loan End of Term Charge of $0.7 million was paid during the year ended October 31, 2025.

The Term Loan bears cash interest payable monthly at an annual rate equal to the greater of (a) the prime rate of interest as reported in the Wall Street Journal plus 0.75% (capped at 9.75%) and (b) 9.25%. The Term Loan also bears additional payment-in-kind interest at an annual rate of 1.15%, which is added to the outstanding principal balance of the Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement, as amended by the First Amendment, are repayable in monthly interest-only payments through the "Amortization Date", which is either: (x) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (y) if the Interim Milestone and certain clinical milestones are achieved and there has been no default, July 1, 2026. After the Amortization Date, the outstanding Term Loan and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date. Through October 31, 2025, the Company has achieved the Interim Milestone but has not yet achieved certain clinical milestones. Amounts payable on January 1, 2026 were classified as current liabilities on the consolidated balance sheet for the year ended October 31, 2025. The effective interest rate of the Term Loan was 11.63% as of October 31, 2025 and October 31, 2024.

In connection with the Amended Loan Agreement, as amended by the First Amendment, the Company granted Hercules a security interest senior to any current and future debts and to any security interest in all of the Company’s right, title, and interest in, to and under all of the Company’s property and other assets, subject to limited exceptions including the Company’s intellectual property.

The Amended Loan Agreement, as amended by the First Amendment, contains negative covenants that, among other things and subject to certain exceptions, could restrict the Company's ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. The Amended Loan Agreement, as amended by the First Amendment, also contains certain events of default and representations, warranties and non-financial covenants of the Company. The Company is in compliance with the financial covenants at October 31, 2025 and October 31, 2024.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

Hercules Common Share Warrants

In connection with the Amended Loan Agreement, as amended by the First Amendment, the Company also agreed to issue to the Lenders in connection with each advance of Term Loans warrants to purchase that number of the Company's common shares, as shall be equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrants per share exercise price of $7.21 (which exercise price equals the ten-day volume weighted average price for the ten (10) trading days preceding the Hercules Closing Date and is subject to customary adjustments under the terms of the Warrants) (the "Hercules Common Share Warrants"). The Hercules Common Share Warrants are exercisable for a period of seven years from issuance.

Under the terms of the Amended Loan Agreement, as amended by the First Amendment, the maximum number of Hercules Common Share Warrants and underlying Common Shares of the Company that could be issued is 138,696 (i.e. 2% of the $50.0 million total commitment amount divided by the exercise price of $7.21 price specified in the Closing Date Warrant), assuming no adjustments are made under the terms of the Hercules Common Share Warrants and further assuming the full amount of Term Loans are drawn. On the Hercules Closing Date, the Company issued to the Lenders 62,413 Hercules Common Share Warrants in connection with the Tranche 1 Advance of the Term Loans (the "Closing Date Warrants"). The Closing Date Warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company's common shares as prescribed by ASC 815. Upon entering into the Amended Loan Agreement, $0.3 million of the total $22.5 million Tranche 1 Advance was allocated to the warrants, on a relative fair value basis, and recorded within additional paid in capital.

Subsequently issued Hercules Common Share Warrants shall be substantially in the form of the Closing Date Warrants.

As of October 31, 2025 and 2024, the carrying value of the Term Loan consists of the following:

	October 31, 2025	October 31, 2024
Note payable, including End of Term Charge	$ 24,231	$ 24,663
Debt discount, net of accretion	(1,088)	(1,673)
Accrued interest	183	182
Note payable, net of discount	$ 23,326	$ 23,172

As of October 31, 2025, the Company classified $8.0 million of the note payable as current. As of October 31, 2024, the Company classified $0.7 million of the note payable as current, which represented the back-end fee associated with the refinancing of the Prior Term Loan. During the years ended October 31, 2025 and 2024, the Company recognized $2.4 million and $2.2 million of interest expense related to the Amended Loan Agreement, respectively, and $0.6 million each year related to the amortization of the debt discount.

As of October 31, 2025, the estimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge, are as follows:

	Note Principal Payments
2026	$ 8,417
2027	10,987
2028	5,161
Total principal payments, including End of Term Charge	24,565

As of October 31, 2025, management believes that the carrying value of the Company's variable interest rate debt, excluding unamortized debt issuance costs, approximates fair value based on the consideration of the Company's credit risk and terms of the borrowing from Hercules.

9. Common Shares

The Company has an unlimited number of authorized shares of Common Shares, with no par value. As of October 31, 2025 and 2024 there were 52,018,658 and 50,976,676 common shares outstanding, respectively.

The holders of the Common Shares are entitled to one vote for each Common Share held on all matters submitted to a vote of shareholders. Common shareholders are entitled to receive dividends, as may be declared by the Board of Directors, if any, subject to the preferential dividend rights of preferred stock. Through October 31, 2025, no cash dividends had been declared or paid.

On February 13, 2024, the Company entered into subscription agreements (collectively, the "February 2024 Subscription Agreements") with the investors named therein, for the private placement (the "February 2024 PIPE Financing") of 20,000,000 common shares of the Company, at a price of $10.00 per share. The aggregate gross proceeds from the February 2024 PIPE Financing was $200 million, before deducting offering expenses of $12.4 million. The February 2024 PIPE Financing closed on February 20, 2024.

On October 24, 2024, the Company entered into subscription agreements (collectively, the "October 2024 Subscription Agreements") with the investors named therein, for the private placement (the "October 2024 PIPE Financing") of 6,758,311 common shares of the Company, at a price of $8.90 per share. The aggregate gross proceeds from the October 2024 PIPE Financing was $60.1 million, before deducting offering expenses of $3.8 million. The October 2024 PIPE Financing closed on October 29, 2024.

On December 20, 2024, the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to $100,000,000 of Common Shares. The Company will pay Jefferies a commission of up to 3.0% of the gross proceeds of Shares sold pursuant to the Sale Agreement, and has agreed to provide Jefferies with customary indemnification and contribution rights. The Company has also agreed to reimburse Jefferies for certain specified expenses. The Company is not obligated to sell any Shares under the Sale Agreement. The offering of the Shares pursuant to the Sale Agreement will terminate upon the termination of the Sale Agreement by Jefferies or the Company, as permitted therein. Through October 31, 2025, the Company sold no Common Shares under the Sale Agreement.

Warrants to Purchase Common Shares

As of October 31, 2025 and 2024, the Company had
8,511,968 warrants to purchase common shares outstanding.

Of the warrants to purchase Common Shares outstanding as of October 31, 2025, 8,449,555 have an exercise price of $11.50, and are exercisable through October 31, 2028. The Company may elect to call in the warrants for redemption if the share price of the Company equals or exceeds $18.00 for any twenty (20) trading days within the thirty (30) trading-day period ending on the third (3rd) trading day prior to the date on which notice of the redemption is given, subject to adjustments as provided in the terms of the warrant agreement.

The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company's common shares as prescribed by ASC 815.

The additional 62,413 of the warrants to purchase Common Shares outstanding as of October 31, 2025, were issued as part of the Amended Loan Agreement on December 22, 2023, have an exercise price of $7.21, are exercisable at any time beginning on December 22, 2023, and expire on December 22, 2030, or seven years from the issuance date. The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company's common shares as prescribed by ASC 815. Please refer to Note 10, Share-Based Compensation, below for the summary of the Common Shares reserved for the exercise of Common Share warrants, share options, and remaining shares reserved for future issuance under and outside the Company's Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan.

See Note 17, Subsequent Events, for a discussion of Common Shares and pre-funded warrants to purchase Common Shares issued by the Company pursuant to an underwritten public offering in November 2025.

10. Share-Based Compensation

Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan

The Company's Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan (the "2023 Plan") was adopted on May 15, 2024 and superseded all prior plans. The 2023 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board, (the "Committee"). The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value

of the Common Shares on the date of grant and the term of stock option may not be greater than ten years. Common Shares that are expired, terminated, surrendered or cancelled under the 2023 Plan without having been fully exercised will be available for future awards. The Plan authorizes the award of incentive stock options, or ISOs, non-qualified stock options, or NQSOs, Stock Units, Stock Appreciation Rights, or SARs, and other share-based awards including performance awards and share bonus awards. The Plan contains the evergreen provision (the "Evergreen Provision") pursuant to which on the first business day of each calendar year, the aggregate number of Common Shares that could be issued or transferred thereunder (the "Plan Share Reserve") and the number of Common Shares available for options intended to qualify as incentive stock options (the "ISO Sublimit") each increase by such number of Common Shares as equals 5% of the aggregate number of Common Shares outstanding on the final day of the immediately preceding calendar year (or such smaller number of shares as is determined by the compensation committee), and the ISO Sublimit by the lesser of 2,500,000 Common Shares and the increase in the Plan Share Reserve (or such smaller number of shares may be determined by the compensation committee of the Company's board of directors). On January 2, 2025 the Committee allowed the full 5% increase for 2025 under the Evergreen Provision.

As of October 31, 2025, inclusive of (i) the common shares subject to the outstanding grants under the prior plans, and (ii) 2,548,833 Common Shares added on January 2, 2025 under the Evergreen Provision, there were 8,651,209 of Common Shares reserved for issuance under the Plan and there are 2,933,304 shares remaining for issuance.

2025 Employee Stock Purchase Plan

On June 10, 2025, at its 2025 Annual General Meeting of shareholders, the shareholders of enGene Holdings Inc. approved the adoption of the 2025 Employee Stock Purchase Plan (the "ESPP"), pursuant to which 2,000,000 common shares of the Company, no par value, were reserved for issuance. The price of common shares purchased under the ESPP is equal to 85% of the lower of the fair market value of the common shares on the first trading day of the offering period or the relevant purchase date and is subject to change by a Plan Administrator prior to each purchase period. As of October 31, 2025, there were no shares issued and 2,000,000 shares remained available for issuance.

Inducement Grants

The Company may grant inducement equity award consisting of a non-qualified stock option to purchase Common Shares to newly hired employees as an inducement material to the employee's entering into employment with the Company, in accordance with NASDAQ Listing Rule 5635(c)(4), which, if made, are granted outside of the 2023 Plan. During year ended October 31, 2025, the Company issued options to purchase an aggregate of 1,709,550 Common Shares to certain new hire employees at a weighted-average exercise price of $5.59 per share. The options awarded have an exercise price equal to the closing stock price of the Company on the date of the grant and vest over four years, with 25% of the underlying shares vesting on the one-year anniversary of the grant date and the remainder vesting in equal amounts monthly for three years thereafter, subject continued service as an employee. The options have a term of 10 years from the date of the grant. During the year ended October 31, 2024, the Company issued options to purchase an aggregate of 1,643,000 Common Shares to certain new hire employees at a weighted-average exercise price of $8.69 per share.

As of October 31, 2025, 493,851 of the inducement grant stock options have vested, 37,200 have been forfeited and none have expired, and, other than forfeited options, all options remain outstanding.

As of October 31, 2025, and 2024, the Company has reserved the following Common Shares for the exercise of Common Share warrants, share options, and remaining shares reserved for future issuance under the 2023 Plan and options granted outside of the 2023 Plan as part of the inducement grants:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	October 31, 2025	October 31, 2024
Warrants to purchase common shares	8,511,968	8,511,968
Incentive options to purchase common shares awarded pursuant to the 2023 Plan	5,717,948	4,391,512
Inducement grant stock options awarded outside of the 2023 Plan	3,315,350	1,643,000
Remaining shares reserved for future issuance under the 2023 Plan	2,933,304	2,752,889
Remaining shares reserved for future issuance under ESPP	2,000,000	-
Total	22,478,570	17,299,369

Stock Options

The assumptions that the Company used to determine the grant-date fair value of stock options during the years ended October 31, 2025 and 2024, were as follows:

	Year ended October 31,	
	2025	2024
Expected term (in years)	5.5-6.08	5.51 - 6.08
Expected volatility	78.78-83.53%	78.24 - 82.33%
Risk-free interest rate	3.84-4.49%	1.78 - 4.66%
Expected dividend yield	-	-
Fair value of common shares and exercise price of options (USD)	$ 3.31-7.39	$ 4.73 - 12.60

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted-Average Exercise Price (USD)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of October 31, 2024	6,034,512	$ 6.88	7.4	$ 17,809
Granted	4,926,875	6.41		
Exercised	(1,041,982)	2.13		
Forfeited or expired	(886,107)	9.86		
Outstanding as of October 31, 2025	9,033,298	$ 6.93	8.5	$ 10,979
Options vested and exercisable as of October 31, 2025	2,935,183	$ 6.07	7.0	$ 6,497
Options unvested as of October 31, 2025	6,098,115	$ 7.35	$ 9.2	$ 4,482

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's common share as of each reporting date.

The weighted-average grant-date fair value per share of share options granted during the years ended October 31, 2025 and 2024 was $4.62 and $7.30, respectively.

Modification of Employment Agreements

On February 13, 2024, the Company entered into a Transition and Modified Employment Agreement (the "Transition Agreement") with the Company's former Chief Executive Officer, Jason Hanson, which amends and modifies the CEO's Employment Agreement

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

dated November 8, 2023 (the "Amended Employment Agreement"). Under the terms of the Amended Employment Agreement Mr. Hanson will be entitled to:

(i) twelve months of continued health insurance benefits;

(ii) payment of a 2024 target annual bonus in the amount of $390,000, less applicable taxes and withholdings;

(iii) acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination; and

(iv) extension of the period to exercise his vested equity awards to three years following the later of date of termination of his employment or the date of termination of the Consulting Period (as defined below), but in no event shall the post-termination exercise period of the CEO's vested equity awards extend beyond the respective applicable term thereof.

The Transition Agreement further provided that, in the event Mr. Hanson were to resign upon the appointment by the Company of a new chief executive officer, Mr. Hanson would be immediately engaged in a consulting role to provide transition services as a Senior Strategic Advisor to the Company for a period of at least six months following the effective date of resignation (the "Consulting Period") in exchange for a monthly fee of $25,000 for the initial six-month Consulting Period, and $500 per hour thereafter, provided that Mr. Hanson need not devote more than fifteen (15) hours per week to providing such transition services.

Under the Transition Agreement, the 1,216,266 stock option awards issued to Mr. Hanson were modified to allow for an extended exercise period as described above. The modification resulted in an incremental share-based compensation expense of $1.0 million which was recorded upon the effective date of the Transition Agreement.

Mr. Hanson resigned effective as of July 19, 2024 in connection with the Company's appointment of a new chief executive officer. On July 20, 2024, enGene appointed Ronald H. W. Cooper as Chief Executive Officer of the Company and as director of the Company's Board of Directors.

Additionally, in 2024, the Company entered into a Severance Agreement with each of three former employees, including the former Chief Medical Officer and the former Chief Scientific Officer. Under the terms of Severance Agreement, the employees are entitled to twelve months of continued pay and health insurance benefits; a payment of a 2024 target annual bonus prorated through the last day of employment, acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination and an extended expiry period, which resulted in a stock-based compensation modification. Under the terms of the agreements, 231,684 stock option awards were modified to allow for an extended exercise period as described above. As of October 31, 2024, the Company recognized incremental stock-based compensation expense of $0.3 million related to the severance agreements.

Share-based Compensation Expense

Share-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss was as follows:

	Year Ended October 31,	
	2025	2024
Research and development	$ 3,282	$ 1,794
General and administrative	6,364	3,530
Total share-based compensation expense	$ 9,646	$ 5,324

As of October 31, 2025, there was $
30.7 million of unrecognized compensation, which is expected to be recognized over a weighted-average period of 3.0 years.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

11. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented, retrospectively restated to reflect the exchange of shares upon the close of the reverse recapitalization:

	Year Ended October 31,	
	2025	2024
Numerator:		
Net loss attributable to common shareholders, basic and diluted	$ 117,302	$ 55,142
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	51,119,479	37,782,346
Net loss per common share, basic and diluted	$ 2.29	$ 1.46

The Company excluded the following shares from the computation of diluted net loss per share attributable to common shareholders during the year ended October 31, 2025, and 2024 because including them would have had an anti-dilutive effect:

	Year Ended October 31,	
	2025	2024
Warrants to purchase common shares	8,511,968	8,511,968
Options to purchase common shares	9,033,298	6,034,512
Total	17,545,266	14,546,480

12. Income Taxes

Loss before provision for income taxes consisted of the following:

	Year ended October 31,	
	2025	2024
Domestic (Canada)	$ (103,727)	$ (53,460)
Foreign (US)	(13,575)	(1,701)
Loss before income taxes	$ (117,302)	$ (55,161)

The components of the provision for (recovery of) income taxes is as follows:

	Year ended October 31,	
	2025	2024
Current expense (benefit):		
Domestic (Canada)	$ -	$ -
Foreign (US)	-	(19)
Total current expense (benefit)	-	(19)
Deferred expense (benefit)		
Domestic (Canada)	-	-
Foreign (US)	-	-
Total deferred tax expense (benefit)	-	-
Total income tax expense (benefit)	$ -	$ (19)

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended October 31,	
	2025	2024
Income at Canadian statutory rate	26.50%	26.50%
State taxes, net of federal benefit	0.66%	0.18%
Permanent differences	) (0.29%	) (2.77%
Tax credits	0.60%	1.07%
Foreign rate differential	) (0.64%	) (0.17%
Valuation allowance	) (26.82%	) (25.02%
Other	) (0.01%	0.24%
	) (0.00%	0.03%

The net deferred income tax balances related to the following:

	October 31,	
	2025	2024
Deferred tax assets:		
R&D expenditures	10,021	8,172
Net operating loss (NOL) carryforwards	61,127	31,661
Capital loss carryforwards	285	97
Investment tax credits, net	2,688	1,934
Property and equipment	270	704
Financing costs	4,000	5,452
Accruals	924	747
Operating lease liability	2,270	404
Note payable	15	197
Stock-based compensation	894	
Other	-	1
Total deferred tax assets	82,494	49,369
Deferred tax liabilities:		
Operating lease-right of use asset	(2,068)	(377)
Total deferred tax liabilities	(2,068)	(377)
Valuation allowance	(80,426)	(48,992)
Net deferred tax assets (liability)	-	-

The calculation of the Company’s tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the provinces and states in which the Company operates or does business. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjusts these liabilities when the Company’s judgment changes as a result of evaluating new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of October 31, 2025 and 2024,
no uncertain tax positions have been recorded in the consolidated financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. As of October 31, 2025 and 2024, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

As of October 31, 2025, the Company has Canadian Federal NOL carryforwards of $220.5 million, that expire between 2026 and 2045 and Canadian provincial NOL carryforwards of $214.3 million, that expire between 2028 and 2045. These losses are available to offset future taxable income in Canada and Quebec. As of October 31, 2025, the Company has a U.S. Federal NOL carryforward of $11.7 million, that may be carried forward indefinitely, and a U.S. state NOL carryforward of $10.0 million, which are available to offset against future taxable income in the U.S and Massachusetts. The U.S. State tax loss carryforward will expire between 2041 and 2045. The Company has not recognized the tax benefit of these losses.

As of October 31, 2025, the Company also has non-refundable Canadian investment tax credits of $3.7 million that expire between 2026 and 2045. These credits may be utilized to reduce Canadian federal income taxes payable. The Company has not recognized the tax benefits related to these non-refundable investment tax credits.

As of October 31, 2025, the Company also has capital losses of $2.2 million which are available to be used indefinitely against future capital gains.

As of October 31, 2025, the Company had Scientific Research and Experimental Development ("SR&ED") expenditures of approximately $36.7 million for Canadian federal and $39.2 million for Québec provincial purposes, which have not been deducted. These expenditures are available to reduce future taxable income and have an unlimited carryforward period. SR&ED expenditures are subject to verification by the tax authorities and, accordingly, the amounts may vary.

13. Leases

The Company's leases are comprised of all operating leases for office and lab space.

On December 29, 2022, the Company signed a new lease for approximately 10,620 square feet of new laboratory and office space at 4868 Rue Levy, Montreal, QC. The term of the lease is for 10 years, beginning on the commencement date, and requires an annual initial base rent of $36.50 CAD per square foot, which is subject to annual increases of 2%. The lease commenced in November 2023. Upon commencement the Company recognized an initial lease liability and corresponding right of use asset of $1.4 million.

On January 1, 2024, enGene USA entered into a lease agreement, in which the Company is sub-leasing approximately 6,450 square feet of office space located at 200 Fifth Avenue, Waltham, MA. The Company will make an aggregate amount of base rental payments of $0.5 million under the initial term of the lease, which is set to expire on December 30, 2026 and does not have an option to renew. Upon commencement, the Company recognized an initial lease liability and corresponding right of use asset of $0.4 million.

On June 4, 2025, enGene USA, Inc entered into a lease agreement, pursuant to which the Company agreed to lease approximately 26,335 square feet of office space located at 99 High Street, Boston, Massachusetts. The Company is expected to make an aggregate amount of base rental payments of $10.6 million, under the initial term of the lease, which is set to expire in November 2030. In connection with the lease, enGene Holdings Inc. has delivered a guaranty, dated June 4, 2025, pursuant to which the Company guaranteed enGene USA's payment and performance. The lease commenced in June 2025 and upon commencement, the Company recognized an initial lease liability of $6.4 million and corresponding right of use asset of $6.5 million.

During the year ended October 31, 2025 and 2024, the components of operating lease cost were as follows, and are reflected in general and administrative expenses and research and development expenses, as determined by the underlying activities:

	Year Ended October 31,	
	2025	2024
Lease Cost:		
Operating lease cost	$ 1,266	$ 444
Variable operating lease cost	-	24
Total operating lease cost	$ 1,266	$ 468

The following table summarizes the cash paid for amounts included in the measurement of the Company's operating lease liabilities for the year ended October 31, 2025, and 2024:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	Year Ended October 31,	
	2025	2024
Cash paid for amounts included in the measurement of operating lease liabilities	$ 620	$ 365

Maturities of the Company's operating lease liabilities as of October 31, 2025 are as follows:

2026	$ 2,191
2027	2,391
2028	2,409
2029	2,457
2030	2,502
Thereafter	1,081
Total	13,031
Less: Interest	(4,562)
Total lease liability	$ 8,469

As of October 31, 2025, the Company had operating lease liabilities of $8.5 million recorded on the balance sheet. As of October 31, 2024, the Company had operating lease liabilities of $1.8 million recorded on the balance sheet.

14. Commitments and Contingencies

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of October 31, 2025 and 2024, there were no material claims outstanding.

Purchase and Other Obligations

The Company enters into contracts in the normal course of business with CROs, CMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including those incurred by subcontractors of our suppliers.

15. Segment Reporting

The Company operates and manages its business as one operating segment and one reportable segment, which is focused on developing genetic medicines to improve the lives of patients suffering from bladder cancer. The CODM manages the Company’s operations on a consolidated basis, assesses performance for the operating segment and decides how to allocate resources based on consolidated net loss, which is reported on the consolidated statements of operations.

The CODM uses consolidated net loss to evaluate the Company’s spend, deploy resources across research and development activities and monitor budget versus actual results. The monitoring of budgeted versus actual results is used in assessing the performance of the operating segment and in establishing resource allocation across the organization.

Factors used in determining the reportable segment include the nature of the Company's operating activities, the organizational and reporting structure and the type of information reviewed by the CODM to allocate resources and evaluate financial performance. The accounting policies of the segment are the same as those described in Note 2, Summary of Significant Accounting Policies. The measure of segment assets used in determining how to manage and allocate resources is reported within the Company's consolidated balance sheets as cash and cash equivalents and marketable securities.

The following table summarizes significant segment expenses, other segment items and the measure of segment net loss of the Company's reportable segment for the years ended October 31, 2025 and 2024:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	Year Ended October 31,	
	2025	2024
Research and development expenses:		
Chemistry, Manufacturing and Controls[1]	$ 49,578	$ 11,994
Clinical operations[2]	17,915	11,036
Other research and development expenses[3]	7,052	4,598
Personnel-related expenses, excluding stock-based compensation	16,653	8,893
Stock based compensation	3,282	1,794
Total research and development expenses	$ 94,480	$ 38,315
General and administrative expenses:		
Personnel-related expenses, excluding stock-based compensation	10,850	8,501
Stock based compensation	6,364	3,530
Other general and administrative expenses[4]	11,471	11,951
Total general and administrative expenses	28,685	23,982
Other segment items[5]	(5,863)	(7,155)
Net loss	$ 117,302	$ 55,142

(1) External expenses associated with clinical manufacturing of the Company's lead compound, detalimogene.
(2) External and internal expenses associated with clinical operations related to research and development of the Company's lead compound, detalimogene.
(3) Represents research and development expenses associated with preclinical, medical affairs, regulatory, quality, program management and facility related costs.
(4) Represents general and administrative costs associated with external legal fees, facilities, professional fees, and other overhead costs.
(5) For the year ended October 31, 2025, other segment items consist of $9.4 million of interest income, $3.0 of interest expense, and $0.6 million of other expense, net. For the year ended October 31, 2024, other segment items consists of $10.4 million of interest income, $2.8 million of interest expense, $0.4 million gain on extinguishment of debt, and $0.1 million other expense, net. Interest income consists of interest income earned on cash equivalents and marketable securities. Interest expense consists of interest expense on our term loan. Other (income) expense, net primarily consists of realized and unrealized gains and losses.

16. Related Party Transactions

During the year ended October 31, 2025 the Company did not have transactions with shareholders that hold more than 10% of the total outstanding shares of the Company. During the year ended October 31, 2024, the Company had the following transactions with shareholders that hold more than 10% of the total outstanding shares of the Company:

On February 20, 2024, the Company completed the February 2024 PIPE Financing, which provided for the private placement of 20,000,000 Common Shares, at a price of $10.00 per share and included both new and existing investors. One of the Company's directors, Mr. Gerald Brunk, is a managing director of Lumira Ventures ("Lumira"), and certain entities affiliated with Lumira were party to the 2024 Subscription Agreements, purchasing an aggregate of 800,000 Common Shares for a total price of $8.0 million in the February 2024 PIPE Financing.

On October 29, 2024, the Company completed the October 2024 PIPE Financing, which provided for the private placement of 6,758,311 Common Shares at a price of $8.90 per share and included both new and existing investors. One of the Company's current directors and one former director, Messrs. Wouter Joustra and Jasper Bos, respectively, are general partners of FEAC, and an entity affiliated with FEAC was party to one of the October 2024 Subscription Agreements, purchasing an aggregate of

561,797 Common Shares for a total price of approximately $5.0 million in the October 2024 PIPE Financing.

17. Subsequent Events

The Company has evaluated subsequent events through the date these financial statements were issued. Except as noted below, the Company concluded that no subsequent events have occurred that require disclosure.

Public Offering of Common Shares and Pre-Funded Warrants

On November 12, 2025, the Company entered into an underwriting agreement with Jefferies LLC, Leerink Partners LLC and Wells Fargo Securities, LLC, as representatives of the several underwriters named therein (collectively, the "Underwriters") relating to the issuance and sale by the Company, in an underwritten public offering, of 12,558,823 Common Shares at an offering price of $8.50 per Common Share and pre-funded warrants to purchase 2,735,295 Common Shares at an offering price of $8.4999 per pre-funded warrant,

in each case before underwriting discounts and commissions. The offering closed on November 14, 2025. The aggregate gross proceeds from the offering were approximately $130.0 million, before deducting the underwriting discounts and commissions and offering expenses of approximately $8.2 million.

The Company also granted to the Underwriters a 30-day option to purchase up to 2,294,117 additional Common Shares at the public offering price, less underwriting discounts and commissions (the "Option"), which the Underwriters exercised in full pursuant to a Notice of Exercise dated November 14, 2025. The aggregate gross proceeds from the Option exercise were approximately $19.5 million, before deducting the underwriting discounts and commissions and offering expenses of approximately $1.2 million. The offering closed on November 18, 2025, with respect to the Option.

The pre-funded warrants have an exercise price of $0.0001 and do not expire. A holder (together with its affiliates and other attribution parties) may not exercise any portion of a pre-funded warrant to the extent that immediately prior to or after giving effect to such exercise the holder would own more than 9.99% of the Company's outstanding Common Shares immediately after exercise, which percentage may be changed at the holder's election to a lower or higher percentage not in excess of 19.99% (if exceeding such percentage would result in a change of control under Nasdaq Listing Rule 5635(b) or any successor rule) upon 61 days' notice to the Company, subject to the terms of the pre-funded warrants.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended October 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-41854

enGene Holdings Inc.

(Exact name of Registrant as specified in its Charter)

British Columbia, Canada	**N/A**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4868 Rue Levy, Suite 220	**H4R 2P1**
Saint-Laurent, QC, Canada	**(Zip Code)**
(Address of principal executive offices)	

Registrant's telephone number, including area code: (514) 332-4888

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares	ENGN	The Nasdaq Stock Market LLC
Warrants, each exercisable for one Common Share, at an exercise price of $11.50 per share	ENGNW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the common equity held by non-affiliates of the Registrant, based on the closing price of the Common Shares on The Nasdaq Stock Market LLC on April 30, 2025 was $154,176,366.

The number of the registrant's Common Shares outstanding as of February 17, 2026 was 66,989,466.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Auditor Firm Id: 85 Auditor Name: KPMG LLP Auditor Location: Montreal, Canada

EXPLANATORY NOTE

enGene Holdings Inc. is filing this Amendment No. 1 (the "Amendment No. 1") to the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2025 (the "Original Form 10-K"), as filed with the Securities and Exchange Commission (the "SEC") on December 22, 2025, only for the purpose of including the Part III information required under the instructions to Form 10-K and the general rules and regulations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Part III information was previously omitted from the Original Form 10-K in reliance on General Instruction G(3) to Form 10-K, which permits the omitted information to be incorporated in the Original Form 10-K by reference from our definitive proxy statement if such statement is filed no later than 120 days after our fiscal year-end.

This Amendment No. 1 amends and restates only Part III, Items 10, 11, 12, 13, and 14, and Part IV, Item 15 of the Original Form 10-K. In addition, this Amendment No. 1 deletes the reference on the cover of the Original Form 10-K to the incorporation by reference of portions of our proxy statement into Part III of the Original Form 10-K. No other Items of the Original Form 10-K have been amended or revised herein, and all such other Items shall be as set forth in the Original Form 10-K.

In addition, pursuant to SEC rules, Item 15 of Part IV of the Original Form 10-K is hereby amended solely to include, as Exhibits 31.3 and 31.4, new certifications of our principal executive officer and principal financial officer pursuant to Rule 13a-14(a) and Rule 12b-15 under the Exchange Act. Because no financial statements are included in this Amendment No. 1 and this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4, and 5 of such certifications have been omitted. We are not including new certifications required by Rule 13a-14(b) under the Exchange Act as no financial statements are included in this Amendment No. 1.

In addition, no other information has been updated for any subsequent events occurring after December 22, 2025, the date of the filing of the Original Form 10-K. Accordingly, this Amendment No. 1 should be read in conjunction with the Original Form 10-K and our other filings made with the SEC subsequent to the filing of the Original Form 10-K.

Unless the context otherwise requires, references in this Amendment No. 1 to "enGene," "enGene Holdings," the "Company," "we," "our," or "us" mean enGene Holdings Inc. and its subsidiaries.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Amendment No. 1 may constitute "forward-looking statements" within the meaning of U.S. securities laws 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," "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 in this Amendment No. 1 may include, for example, statements about:

- our financial performance, including financial projections and business metrics and any underlying assumptions thereunder;
- our success in recruiting and retaining, or changes required in, officers, key personnel or directors;
- our ability to effectively manage the transition of executive-level roles to new leaders, and to attract and retain key executives and employees;
- our ability to implement and maintain effective internal controls.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. Certain assumptions made in preparing the forward-looking statements include:

- we are able to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials and acquire technologies complementary to, or necessary for, detalimogene or any other programs;
- we are able to enroll, in a timely manner, a sufficient number of patients in each cohort of the Phase 2 LEGEND trial to assess the efficacy and safety of detalimogene including the cohorts with the BCG-naïve patient population, the BCG-exposed patient population and the BCG-unresponsive, papillary-only Ta/T1 disease;
- we are able to file our planned Biologics License Application in second half of 2026 with the FDA for approval to market detalimogene in the United States as a monotherapy to treat BCG-unresponsive NMIBC with CIS;
- detalimogene's product profile can be integrated seamlessly into community urology clinics where the vast majority of NMIBC patients are treated;
- we are able to retain commercial rights to detalimogene in the United States and commercialize detalimogene independently, while selectively partnering outside of the United States;
- we are able to execute the "pipeline-in-a-product" development strategy for detalimogene; and
- we are able to utilize the DDX gene delivery platform to develop effective, new product candidates for the delivery of genetic medicines to mucosal tissues.

You should not place undue reliance on these forward-looking statements which speak only as of the date hereof. The forward-looking statements contained in this Amendment No. 1 are based primarily on current expectations and projections about future events and trends that may affect our business, financial condition and operating results. The following uncertainties and factors, among other things (including those described in "*Risk Factors*" in the Original 10-K), could affect future performance and actual results to differ materially and adversely from those expressed in, anticipated or implied by forward-looking statements:

- risks applicable to our business, including the heavy dependence on the success of detalimogene and the extensive regulation of all aspects of our business, competition from other existing or newly developed products and treatments;
- risks associated with the protection of intellectual property, our ability to raise additional capital to fund our product development activity, and our ability to maintain key relationships and to attract and retain talented personnel;
- the possibility that we may be adversely affected by changes in domestic and foreign laws and regulations, including but not limited to resultant changes in business, market, financial, political, legal or geopolitical conditions, including tariffs, economic sanctions and economic slowdowns or recessions, or prolonged government shutdowns or defunding;
- the risk that any regulatory approvals are not obtained, are delayed or are subject to unanticipated conditions that could adversely affect our business; or
- other risks and uncertainties set forth in the section entitled "*Risk Factors*" in the Original 10-K.

In addition, statements that "we believe" and similar statements reflect beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Amendment No. 1. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Amendment No. 1 relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Amendment No. 1 to reflect events or circumstances after the date of this Amendment No. 1 or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors and Management

The following table sets forth, as of February 17, 2026, certain information regarding our directors and executive officers who are responsible for overseeing the management of our business.

Name	Age	Position
Executive Officers		
Ronald H.W. Cooper	62	Chief Executive Officer, President and Director
Matthew Boyd	52	Chief Regulatory Officer
Jill Buck	51	Chief Development Officer
Dr. Anthony T. Cheung	55	Chief Scientific Officer
Joan Connolly	56	Chief Technology Officer
Ryan Daws	52	Chief Financial Officer
Lee G. Giguere	45	Chief Legal Officer and Corporate Secretary
Dr. Alexander Nichols	40	Chief Strategy and Operations Officer
Amy Pott	49	Chief Global Commercialization Officer
Dr. Hussein Sweiti	39	Chief Medical Officer and Head of Research and Development
Non-Executive Directors		
Philip Astley-Sparke	54	Director
Gerald Brunk	57	Director
Dr. Richard Glickman	67	Chairman
Dr. William Grossman	56	Director
Paul Hastings	66	Director
Michael Heffernan	61	Director
Wouter Joustra	37	Director
Lota Zoth	66	Director

Executive Officers

Ronald H.W. Cooper has served as Chief Executive Officer and as a director of enGene since July 22, 2024 and as President since October 21, 2024. Prior to joining enGene, Mr. Cooper most recently served as the President and Chief Executive Officer and as a member of the board of directors of Albireo Pharma, Inc., a position he held from November 2016 until that company's acquisition by Ipsen in March 2023. He also previously served as president and chief executive officer of Albireo Limited from July 2015 until November 2016 and as a director of Albireo Limited from September 2015 until Albireo Limited was dissolved in August 2021. Earlier in his career, Mr. Cooper spent nearly 30 years at Bristol-Myers Squibb ("BMS") in roles of increasing responsibility in sales, marketing and general management, most recently serving as President, Europe. While at BMS, he played a leadership role in several successful product launches. Mr. Cooper currently serves as the Chairman of the board of directors of C4 Therapeutics, Inc. (NASDAQ: CCCC). He previously served as a member of the board of directors of Generation Bio Co. (NASDAQ: GBIO) from March 2021 to February 2026. He is a graduate of St. Francis Xavier University. The Company's board of directors, or Board, believes Mr. Cooper is qualified to serve as a director due to his extensive experience in the pharmaceutical and biotechnology industries, including in leadership and management roles, and his knowledge of our business as Chief Executive Officer.

Matthew Boyd has served as Chief Regulatory Officer of enGene since July 8, 2025. He previously served as enGene's Senior Vice President, Regulatory Affairs from September 2024 to July 8, 2025. Prior to enGene, Mr. Boyd was Vice President, Head of Regulatory Affairs and Quality Assurance at Zambon USA Ltd. ("Zambon") from May 2024 to September 2024. Prior to Zambon, from January 2020 to July 2023, Mr. Boyd was a Vice President, Regulatory Affairs at Albireo Pharma, Inc. From 2014 to 2020, Mr. Boyd held senior positions in Regulatory and Medical Affairs at Sobi, Inc. Prior to Sobi, Mr. Boyd held senior positions in Commercial and Regulatory at EMD Serono, Inc. from 2009 to 2014. Mr. Boyd holds a B.S. from the Philadelphia College of Pharmacy and an MBA from the Kelley School of Business, Indiana University.

Jill Buck has served as Chief Development Officer of enGene since July 8, 2025. She previously served as enGene's Senior Vice President, Clinical Development Operations from September 2024 to July 8, 2025. Prior to enGene, Ms. Buck was Head, Clinical Development Operations, Rare Diseases at Ipsen S.A. ("Ipsen") from March 2023 to September 2024. Before joining Ipsen, Ms. Buck was Vice President of Clinical Operations at Albireo Pharma, Inc. from October 2022 until that company's acquisition by Ipsen in

March 2023. From 2006 to 2021, Ms. Buck held several senior roles in clinical development and operations at Ziopharm Oncology, Inc. and Synageva BioPharma Corp. She holds a B.A. in English and Communications from Boston College.

Dr. Anthony T. Cheung co-founded our Company and has served enGene and enGene Inc. in various capacities since the company's inception. Dr. Cheung currently serves as Chief Scientific Officer, a role he has held since October 21, 2024, and previously served as Chief Technology Officer of enGene from August 7, 2023 to October 21, 2024, and served in that same capacity for enGene Inc. since July 2018. From February 2013 to July 2018, Dr. Cheung served as the President and Chief Executive Officer of enGene Inc. From May 2011 to February 2013, Dr. Cheung served as Interim Chief Executive Officer. From March 2004 to May 2011, Dr. Cheung served as the Chief Scientific Officer of enGene Inc. From November 1999 to February 2015, Dr. Cheung served as the Corporate Secretary of enGene Inc., and from November 1999 to March 2004, Dr. Cheung served as its President and Chief Executive Officer. Dr. Cheung has co-authored numerous book chapters, review articles and peer-reviewed journals, and is named inventor on numerous patents, in the areas of gene therapy and polymer chemistry. Dr. Cheung holds a B.Sc. from University of British Columbia and a Ph.D. in Physiology from the Tulane University School of Medicine.

Joan Connolly has served as Chief Technology Officer of enGene since October 21, 2024. Previously, Ms. Connolly served as Chief Technology Officer of Albireo Pharma, Inc. from April 2021 to April 2023, where she oversaw drug substance and product development, clinical supply distribution, commercial supply chain and quality. Prior to Albireo, she served as Senior Vice President, Technical Operations at Stemline Therapeutics, Inc. from 2013 to 2021. Prior to Stemline Therapeutics, she held senior roles at ImClone Systems Inc., and Bristol-Myers Squibb. Ms. Connolly holds a B.Sc. in Engineering Chemistry from Queen's University.

Ryan Daws has served as Chief Financial Officer and Head of Business Development of enGene since November 27, 2023. Mr. Daws joined the Company from Obsidian Therapeutics, Inc., where he was Chief Financial Officer and Head of Business Development from July 2019 to November 2023. Prior to that, from June 2017 to March 2019, he served as a Managing Director in the Healthcare Investment Banking Group at Robert W. Baird & Co. with a focus on life sciences companies. Prior to Baird, Mr. Daws was the Chief Financial Officer and Head of Business Development of Concert Pharmaceuticals, Inc. from January 2014 to June 2017, and a life-science-focused investment banker at Stifel, Nicolaus and Company from September 2010 to June 2013. Mr. Daws has a B.Sc. in Finance and an International MBA, both from the University of South Carolina.

Lee G. Giguere has served as Chief Legal Officer and Corporate Secretary of enGene since January 29, 2024. Prior to joining enGene, Mr. Giguere served as Chief Legal Officer of Obsidian Therapeutics, Inc. from November 2021 to January 2024. From September 2019 to November 2021, Mr. Giguere served as Vice President, General Counsel of Chiasma, Inc. (NASDAQ: CHMA). Prior to Chiasma, Mr. Giguere served as Deputy General Counsel and Assistant Secretary from July 2018 to September 2019 and Associate General Counsel and Assistant Secretary from September 2016 to July 2018 at Karyopharm Therapeutics Inc. (NASDAQ: KPTI). From November 2013 to September 2016, Mr. Giguere served as Senior Securities and Governance Counsel at Boston Scientific Corporation (NYSE: BSX). Mr. Giguere began his professional career in the business law department of Goodwin Procter LLP, where he concentrated his practice on representing public companies in connection with securities law and corporate governance matters and corporate finance transactions. Mr. Giguere holds a J.D. from Northeastern University School of Law and a B.Sc. in Finance from Northeastern University.

Dr. Alexander Nichols has served as Chief Strategy and Operations Officer of enGene since October 21, 2024. He previously served as enGene's President and Chief Operating Officer from November 1, 2023 to October 21, 2024, and served in that same capacity for enGene Inc. since December 2022. Prior to joining enGene Inc., Dr. Nichols served as President, CEO, and co-founder of Mythic Therapeutics, Inc., a clinical-stage product-platform company developing a pipeline of antibody-drug conjugates ("ADCs"). In this role, Dr. Nichols co-invented the company's technology platform and lead program, raised more than $130 million across several financing rounds and helped grow the company into an emerging ADC innovator. From November 2014 to September 2016, Dr. Nichols worked as an associate at Flagship Pioneering Inc., where he was part of the co-founding team of Cogen Therapeutics (now Repertoire Immune Medicines). Dr. Nichols holds a B.A. in Biochemistry from Oberlin College and Ph.D. in Biophysics from Harvard University.

Amy Pott has served as Chief Global Commercialization Officer of enGene since May 27, 2025. Ms. Pott joined enGene from Astellas Pharma US, Inc. ("Astellas"), where she served as Senior Vice President, Strategic Brand Marketing, Ophthalmics and Rare Diseases from April 2024 to May 2025 and as Head of Commercial, Gene Therapies from January 2021 to April 2024. Prior to Astellas, she was President, North America from April 2019 to October 2020 at Swedish Orphan Biovitrum AB. Prior to Astellas, she was Global Vice President ("GVP") US Franchise Head for Internal Medicine and Oncology from October 2017 to March 2019 and GVP, US Commercial Operations, from July 2016 to October 2017 at Shire Pharmaceuticals LLC ("Shire"). Before joining Shire, Amy was Vice President, Strategy, Planning and Analytics at Baxalta, Inc. She holds a M.S. in European Studies from the London School of Economics and a B.A. in History from the University of Bristol.

Dr. Hussein Sweiti has served as Chief Medical Officer of enGene since September 29, 2025 and also as Head of Research and Development since February 6, 2026. Prior to joining enGene, Dr. Sweiti served as Global Medical Head, Oncology Clinical Development at Johnson & Johnson since August 2024, where he led end-to-end clinical strategy and execution for the company's

bladder cancer portfolio and was closely involved in U.S. FDA interactions that culminated in an FDA approval for NMIBC in 2025. Prior to this role, Dr. Sweiti held several positions of increasing responsibility at Johnson & Johnson, including Executive Medical Director - Oncology Clinical Research & Development from 2022 to 2024, Medical Director - Oncology Clinical Research & Development from 2019 to 2022, and Country Medical Manager - Oncology Medical Affairs from 2018 to 2019. Before joining Johnson & Johnson, Dr. Sweiti completed a surgical oncology residency and fellowship in Germany from 2010 to 2017. He holds board certification in surgical oncology, ESMO certification in medical oncology and is the author or co-author of over 70 peer-reviewed publications. Dr. Sweiti earned his M.D. from the University of Heidelberg and a M.S. in Public Health from the University of Düsseldorf.

Non-Employee Directors

Philip Astley-Sparke has served as a member of enGene's Board since July 8, 2025. Mr. Astley-Sparke is a co-founder of Replimune Group, Inc. (NASDAQ:REPL) and a member of its board of directors since 2015, and has served as its Executive Chairman since April 2024. Previously, Mr. Astley-Sparke served as Replimune Group, Inc.'s Chief Executive Officer from January 2020 to April 2024 and its Executive Chairman from its formation in 2015 to January 2020. From 2016 until June 2021, Mr. Astley-Sparke served as Chairman of uniQure N.V., a Nasdaq-listed gene therapy company. From 2013 to 2015, Mr. Astley-Sparke served as uniQure N.V.'s President of U.S. operations, where he established its U.S. infrastructure. Mr. Astley-Sparke served as Vice President and General Manager at Amgen, Inc. until December 2011, following Amgen Inc.'s acquisition of BioVex Group, Inc. in March 2011. Mr. Astley-Sparke was previously President and Chief Executive Officer of BioVex Group, Inc. Prior to BioVex Group, Inc., Mr. Astley-Sparke was a healthcare investment banker at Chase H&Q and qualified as a Chartered Accountant with Arthur Andersen LLP. Mr. Astley-Sparke has been a Venture Partner at Forbion Capital Partners, a venture capital fund, since May 2012. Since 2025, Mr. Astley-Sparke has served as Chairman of Synox Therapeutics Ltd., and he previously served as Chairman of the board of directors of Oxyrane Limited, a biotechnology company, from 2012 to 2020. Mr. Astley-Sparke served on the board of Forbion European Acquisition Corp. from 2021 until the completion of the business combination of enGene Holdings Inc. in October 2023. Mr. Astley-Sparke received a B.Sc. in Cellular and Molecular Pathology from Bristol University. The Board believes Mr. Astley-Sparke is qualified to serve as a director due to his extensive experience in the life science industry and his extensive financial and leadership experience.

Gerald Brunk has served as a member of enGene's Board since August 8, 2023 and as a member of the board of enGene Inc. since October 2017. Mr. Brunk is a co-founder and Managing Director at Lumira Ventures, a healthcare venture capital firm. Prior to beginning his venture capital career in 2002, Mr. Brunk was an entrepreneur and co-founder of several venture-capital funded healthcare companies and served as an Engagement Manager in the healthcare practice of The Boston Consulting Group from July 1994 to May 1999. Earlier, Mr. Brunk was a member of the investment banking group of Credit Suisse First Boston in New York from June 1990 to June 1992. Mr. Brunk received an MBA from Stanford University Graduate School of Business and a B.A. from the University of Virginia. The Board believes Mr. Brunk is qualified to serve as a director due to his experience in the biotechnology industry and the venture capital industry.

Dr. Richard M. Glickman has served as a member of enGene's Board since April 24, 2023 and chairman of the Board since May 14, 2024. Prior to that appointment, he served as chair of the board of enGene Inc. since January 2015, and as a member of that board since October 2011. Dr. Glickman was a co-founder of Aurinia Pharma Corp. where he served as its Chairman and CEO until 2019. He was also the founding Chairman of the Board of Essa Pharma Inc. until October 2025. He is currently a director and Chairman of the compensation committee, and a member of the nominating and corporate governance committee of Eupraxia Pharmaceuticals Inc. (TSX: EPRX; NASDAQ: EPRX), a clinical-stage biotechnology company. Previously, Dr. Glickman was a co-founder of Apsreva Pharmaceuticals where he served as its Chairman and CEO from 2001 to 2006. Dr Glickman is the recipient of numerous awards including the Ernst and Young Entrepreneur of the Year and Canada's Top 40 under 40. Dr. Glickman holds a B.Sc. in Microbiology and Immunology from McGill University. The Board believes Dr. Glickman is qualified to serve as a director due to his extensive experience in the life science industry, including his broad leadership experience.

Dr. William Grossman has served as a member of enGene's Board since July 8, 2025. Dr. Grossman currently serves as Co-Founder and Head of Research & Development of Oncko, Inc., a pharmaceutical drug development company, since November 2024. He is also the Founder of Grossman Biotech & Pharma Consulting, LLC, a consulting firm which offers fractional CMO services to biotechnology and venture capital/private equity organizations, since February 2019. Previously, he served as Senior Vice President and Oncology Therapeutic Area Head of Clinical Development at Gilead Sciences, Inc. (NASDAQ: GILD), a biopharmaceutical company, from August 2021 to August 2024. Prior to that, he held Chief Medical Officer roles at Arcus Biosciences from April 2019 to August 2021 and Bellicum Pharmaceuticals, Inc. from February 2018 to April 2019. He has held additional leadership roles at Merck, Baxter, Biothera, AbbVie and Genentech/Roche between 2008 and 2018. He also served at the Children's Hospital of Wisconsin/Medical College of Wisconsin as Founder and Medical Director of the Clinical Immunodiagnostic and Research Laboratory, Professor for Microbiology and Genetics and Director of the Bone Marrow Transplant Division for the Immunodeficiency Transplant Program from 2004 to 2008. Dr. Grossman has served as a member of the board of directors of Day One Biopharmaceuticals, Inc. (NASDAQ:DAWN) since January 2024. 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 the Divisions of Pediatrics and Medicine

at Washington University School of Medicine. The Board believes Dr. Grossman is qualified to serve as a director due to his medical training and extensive leadership experience in the biotechnology industry.

Paul Hastings has served as a member of the Board since May 15, 2024. He has served as the Chief Executive Officer and a member of the board of directors of Nkarta, Inc. (NASDAQ: NKTX) since February 2018. Prior to that, Mr. Hastings served as President, Chief Executive Officer, and Director of the publicly traded, clinical-stage biopharmaceutical company OncoMed Pharmaceuticals, Inc. from January 2006 until January 2018. In August 2013, he was elected chairman of the board of directors of OncoMed and served in that role until January 2018. Prior to joining OncoMed, Mr. Hastings was President, Chief Executive Officer, and Director of QLT, Inc., a publicly traded biotechnology company dedicated to the development and commercialization of innovative ocular products, from February 2002 to September 2006. From 2000 to 2002, Mr. Hastings served as President, Chief Executive Officer, and Director of Axys Pharmaceuticals, Inc., which was acquired by Celera Corporation in 2001. Mr. Hastings was also previously the President of Chiron Biopharmaceuticals, a division of Chiron Corporation, President and Chief Executive Officer of LXR Biotechnology, and he held a variety of management positions of increasing responsibility at Genzyme Corporation, including President of Genzyme Therapeutics Europe and President of Worldwide Therapeutics. Mr. Hastings currently serves as the Chair of the board of directors of Specific Biologics, a biopharmaceutical company. Previously he was the chairman of the board of directors of Pacira Biosciences, Inc. (NASDAQ: PCRX), a publicly traded biotechnology company, a member of the board of directors of Relypsa, a publicly traded biotechnology company acquired by Galencia AG, chairman of the board of directors of Proteolix, Inc., a privately held biopharmaceutical company acquired by Onyx Pharmaceuticals, Inc., a member of the board of directors of ViaCell, Inc., a publicly traded biotechnology company sold to Perkin Elmer, and a member of the board of directors of ViaCyte, Inc., a privately held regenerative medicine company acquired by Vertex Pharmaceuticals, Inc. Mr. Hastings has served on the board of directors of the Biotechnology Innovation Organization ("BIO") for more than two decades, chairing the board from 2021 to 2023 after twice serving as BIO vice chair. Mr. Hastings received a B.Sc. in pharmacy from the University of Rhode Island. The Board believes Mr. Hastings is qualified to serve as a director due to his extensive experience in the pharmaceutical and biotechnology industries, including his leadership and management experience.

Michael Heffernan has served as a member of enGene's Board since July 8, 2025. Mr. Heffernan is a seasoned biopharmaceutical executive and entrepreneur with over 30 years of experience in the industry. Mr. Heffernan is the Founder of Collegium Pharmaceutical (NASDAQ: COLL), or Collegium, and served as the Chairman and a member of its board of directors until May 2025. Mr. Heffernan served as Interim President and Chief Executive Officer of Collegium from May 2024 until November 2024 and as the President, Chief Executive Officer and a director of Collegium from October 2003 until June 2018. Mr. Heffernan co-founded Avenge Bio, an oncology-focused biotechnology company, where he has served as Chairman since 2019 and served as Chief Executive Officer from January 2022 until May 2024. Mr. Heffernan has built and led multiple companies through numerous financings and successful exits. He has also held leadership positions at Onset Dermatologics, Clinical Studies Ltd., and Eli Lilly and Company. Mr. Heffernan currently serves on the boards of directors of Biohaven Ltd. (NYSE: BHVN) (2020 to present), Trevi Therapeutics (NASDAQ: TRVI) (2017 to present), and Avalo Therapeutics (NASDAQ:AVTX) (2025 to present). Mr. Heffernan previously served on the board of directors of Synlogic, Inc. (NASDAQ:SYBX) from December 2020 to February 2025, and Akebia Therapeutics, Inc. (NASDAQ:AKBA) from December 2018 until June 2022. Mr. Heffernan is a current member of the boards of several privately held companies. He holds a Bachelor of Science in Pharmacy from the University of Connecticut and is a registered pharmacist. The Board believes Mr. Heffernan is qualified to serve as a director due to his extensive experience in building and leading biopharmaceutical companies and driving shareholder value combined with his leadership skills and board experience.

Wouter Joustra has served as a member of the Board since May 15, 2024. He is a General Partner at Forbion, a leading European life sciences venture capital firm. At Forbion, Mr. Joustra is responsible for deal origination, general portfolio management and divestment strategies, and focuses on Forbion's Growth Opportunities Funds, which concentrates on investing in late-stage life sciences companies. Prior to joining Forbion in 2019, Mr. Joustra previously was a Senior Trader, as well as Executive Board member of the Life Sciences franchise at Kempen, a European boutique investment bank. In this role, Mr. Joustra managed Kempen's trading portfolio, and was involved in deal structuring and equity capital markets transactions, as well as larger block trades. Mr. Joustra also served as a member of the board of directors of Gyroscope Therapeutics until the closing of its acquisition by Novartis in February 2022 for up to $1.5 billion, the board of directors of VectivBio (NASDAQ: VECT) from December 2022 until the closing of its $1.2 billion acquisition by Ironwood Pharmaceuticals in December 2023, the board of directors of Aiolos Bio until the closing of its acquisition by GSK plc in February 2024 for up to $1.4 billion and the board of Forbion European Acquisition Corp. until the completion of the business combination of enGene Holdings Inc. in October 2023. Currently Mr. Joustra serves on the board of directors of VectorY Therapeutics, Beacon Therapeutics, Navigator Medicines, Verdiva Bio and NewAmsterdam Pharma N.V. (NASDAQ: NAMS). Mr. Joustra holds an M.Sc. in Business Administration and a B.Sc. in International Business and Management from the University of Groningen. The Board believes Mr. Joustra is qualified to serve as a director due to his experience in the biotechnology industry and the venture capital industry.

Lota Zoth has served as a member of the Board since December 18, 2023. Ms. Zoth is a Certified Public Accountant and has also served as a member of the board of directors and chair of the audit committee of Inovio Pharmaceuticals, Inc. (Nasdaq: INO), a biotechnology company, since January 2018 and August 2018, respectively. Ms. Zoth previously served as a member of the board of directors and chair of the audit committee of 89BIO, Inc. (Nasdaq: ETNB), a clinical-stage biopharmaceutical company, from June 2020 to October 2025 and a member of the board of directors and chair of the audit committee of Lumos Pharma, Inc. (Nasdaq: LUMO)

(previously, NewLink Genetics Corporation), a biopharmaceutical company, from November 2012 to December 2024. Ms. Zoth also served as member of the board of directors and chair of the audit committee of Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company, from November 2016, as chair of the board of directors from September 2019 to January 2022 and as lead director since January 2022, until stepping down from the Zymeworks Inc. board in December 2023. In addition, she previously served as a member of the board of Spark Therapeutics, Inc., a gene therapy platform company, from January 2016 to December 2019, Circassia Pharmaceuticals, plc (LON: CIR), a specialty biopharmaceutical company, from February 2015 to February 2019, Orexigen Therapeutics, Inc., a biopharmaceutical company, from April 2012 to May 2019, Aeras, a non-profit product development organization, from November 2011 to October 2018, Hyperion Therapeutics, Inc., a commercial-stage biopharmaceutical company, from February 2008 to May 2015 and Ikaria, Inc., a commercial stage biopharmaceutical company, from January 2008 to February 2014. Prior to her retirement, Ms. Zoth most recently served as Senior Vice President and Chief Financial Officer of MedImmune, Inc., a biotechnology company, from April 2004 to July 2007 and as Vice President, Controller & Chief Accounting Officer from August 2002 to April 2004. Ms. Zoth received her B.B.A. from Texas Tech University. The Board believes Ms. Zoth is qualified to serve as a director because of her experience as a senior executive and member of the board of other life science companies.

Role of Board in Risk Oversight

One of the key functions of the Board is informed oversight of the Company's risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through the Board's various standing committees that address risks inherent in their respective areas of oversight. Specifically, the audit committee of the Board is responsible for overseeing the management of risks associated with the Company's financial reporting, accounting, and auditing matters, and the compensation committee of the Board oversees the management of risks associated with the Company's compensation policies and programs.

Board Composition and Election of Directors

Board Composition

Our board of directors currently consists of nine (9) directors: (i) Ronald H.W. Cooper, the Chief Executive Officer and President of enGene, (ii) Philip Astley-Sparke, (iii) Gerald Brunk, (iv) Dr. Richard Glickman, (v) Dr. William Grossman, (vi) Paul Hastings, (vii) Michael Heffernan, (viii) Wouter Joustra and (ix) Lota Zoth. Under the *Business Corporations Act* (British Columbia) ("BCBCA"), a director may be removed with or without cause by a resolution passed by a special majority of the votes cast by shareholders present in person or by proxy at a meeting and who are entitled to vote.

Staggered Board Provisions

Our articles of incorporation and notice of articles (together, the "Articles") provide for a staggered board of directors consisting of three groups of directors with directors serving staggered three-year terms.

At every annual general meeting and in every unanimous shareholder resolution in lieu thereof, all of the directors whose terms expire cease to hold office immediately before the election or appointment of directors, but are eligible for re-election or re-appointment. The shareholders entitled to vote at the annual general meeting for the election of directors may elect, or in a unanimous resolution appoint, the number of directors required to fill any vacancies created. The directors will hold office for the applicable terms contemplated in the staggered board provisions. Upon the resignation of a director, the remaining directors may fill the casual vacancy resulting from such resignation for the remainder of the unexpired term.

The terms of office for each of our directors are as follows:

1. Philip Astley-Sparke, Ronald Cooper, William Grossman and Michael Heffernan have terms expiring at the annual general meeting to be held in 2026;
2. Paul Hastings, Wouter Joustra and Lota Zoth have terms expiring at the annual general meeting to be held in 2027; and
3. Gerald Brunk and Richard Glickman have terms expiring at the annual general meeting to be held in 2028.

Upon the expiry of the initial terms described above, directors will be elected pursuant to Article 14.2 of the Articles to hold office for three-year terms expiring on the third annual general meeting following their election.

Replacement or Removal of Directors

Under the BCBCA and the Articles, a director may be removed with or without cause by a special resolution passed by a special majority (being two-thirds) of the votes cast by shareholders present in person or by proxy at a duly convened meeting and who are entitled to vote.

To the extent directors are elected or appointed to fill casual vacancies or vacancies arising from the removal of directors, in both instances whether by shareholders or directors, the directors shall hold office until the remainder of the unexpired portion of the term of the departed director that was replaced.

Under the Articles, the number of directors of enGene must be set at a minimum of three (3). The directors will be authorized to determine the actual number of directors to be elected from time to time.

Director Term Limits and Other Mechanisms of Board Renewal

enGene's Board has not adopted director term limits or other automatic mechanisms of board renewal. Rather than adopting formal term limits, mandatory age-related retirement policies and other mechanisms of board renewal, the nominating and corporate governance committee of the Board has developed a skills and competencies matrix for enGene's Board as a whole and for individual directors. The nominating and corporate governance committee has developed and oversees a process for the assessment of the Board, each committee and each director regarding their or its effectiveness and contribution, and report evaluation results to the Board on a regular basis.

enGene does not have a formal policy nor measurable objectives (such as a target) regarding board diversity or for the representation of women on their board of directors, management team or executive officers. enGene expects that its priority in the selection of enGene's Board members will be to identify members who will further the interests of its shareholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, and knowledge of enGene's business and understanding of the competitive landscape.

Independence of the Members of the Board of Directors

Director Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under National Instrument 58-101 - *Disclosure of Corporate Governance Practices* ("NI 58-101") implemented by the Canadian Securities Administrators, a director is considered to be independent if that person is independent within the meaning of National Instrument 52-110 - *Audit Committees* ("NI 52-110"). Pursuant to NI 52-110, an independent director is a director who is free from any direct or indirect relationship which could, in the view of enGene's Board of Directors, be reasonably expected to interfere with a director's independent judgment.

enGene's Board has determined that (i) each of Philip Astley-Sparke, Gerald Brunk, Richard Glickman, William Grossman, Paul Hastings, Michael Heffernan, Wouter Joustra and Lota Zoth is an independent director under applicable Nasdaq rules and pursuant to NI 52-110 and (ii) each of Philip Astley-Sparke, Gerald Brunk, Richard Glickman, William Grossman, Paul Hastings, Michael Heffernan and Lota Zoth are independent under the heightened independence standards of NI 52-110, the SEC and Nasdaq rules for audit committee independence.

The independent directors of enGene's Board hold regularly scheduled meetings at which non-independent directors and members of management are not in attendance.

Mandate of the Board of Directors

enGene's Board is responsible for the stewardship of the Company and providing oversight as to the management of enGene and its affairs, including providing guidance and strategic oversight to management. enGene's Board has adopted a formal mandate that includes the following:

(1) appointing enGene's Chief Executive Officer;

(2) developing the corporate goals and objectives that enGene's Chief Executive Officer is responsible for meeting and reviewing the performance of enGene's Chief Executive Officer against such corporate goals and objectives;

(3) taking steps to satisfy itself as to the integrity of enGene's Chief Executive Officer and other executive officers and that enGene's Chief Executive Officer and other executive officers create a culture of integrity throughout the organization;

(4) reviewing and approving enGene's Code of Conduct (as defined herein) and reviewing and monitoring compliance with the Code of Conduct and enGene's enterprise risk management processes;

(5) adopting a strategic planning process to establish objectives and goals for enGene's business and reviewing, approving, and modifying, as appropriate, the strategies proposed by management to achieve such objectives and goals; and

(6) reviewing and approving material transactions not in the ordinary course of business.

Meetings of Directors

enGene's board of directors may meet together for the conduct of business, adjourn and otherwise regulate their meetings as they think fit, and meetings of the directors held at regular intervals may be held at the place, at the time and on the notice, if any, as the directors may from time to time determine. The independent members of enGene's board of directors will also meet, as required, without the non-independent directors and members of management before or after each regularly scheduled board meeting.

A director who has a material interest in a matter before the Board or any committee on which they serve is required to disclose such interest as soon as the director becomes aware of it. In situations where a director has a material interest in a matter to be considered by the Board or any committee on which they serve, such director may be required to absent themselves from the meeting while discussions and voting with respect to the matter are taking place. Directors will also be required to comply with the relevant provisions of the BCBCA regarding conflicts of interest.

The frequency of meetings of the Board and the nature of agenda items may change from year to year depending upon the Company's activities, however the Board generally meets at least quarterly, and at each meeting there is a review of enGene's business. The Board facilitates its exercise of independent supervision over the Company's management by holding regular meetings of the Board where the directors discuss significant corporate activities and plans, both with and without members of the Company's management being in attendance.

Board Committees

The standing committees of the Board consist of an audit committee, a compensation committee, a nominating and corporate governance committee and a research and development committee. The Board may from time to time establish other committees.

Our chief executive officer and other executive officers will regularly report to the non-executive directors and the audit, the compensation, the nominating and corporate governance and the research and development committees to ensure effective and efficient oversight of our activities and to assist in proper risk management and the ongoing evaluation of management controls. We believe that the leadership structure of the board of directors provides appropriate risk oversight of our activities.

Audit Committee

enGene has established an audit committee comprised of independent directors as required by applicable SEC, Nasdaq rules and NI 52-110. At least one member of the audit committee will qualify as an "audit committee financial expert", as such term is defined the rules and regulations established by the SEC, and all members of the audit committee are "financially literate", as such term is defined in NI 52-110 (except as may be permitted by NI 52-110). The principal purpose of enGene's audit committee is to assist the Board in its oversight of:

(1) the quality and integrity of enGene's financial statements and related information;

(2) the independence, qualifications, appointment and performance of enGene's external auditor;

(3) enGene's disclosure controls and procedures, internal control over financial reporting and management's responsibility for assessing and reporting on the effectiveness of such controls;

(4) enGene's compliance with applicable legal and regulatory requirements; and

(5) enGene's enterprise risk management processes.

The Board has established a written charter setting forth the purpose, composition, authority and responsibility of the audit committee, consistent with the rules of the Nasdaq, the SEC and NI 52-110.

enGene's audit committee has access to all of the Company's books, records, facilities and personnel and may request any information about enGene as it may deem appropriate. It also has the authority in its sole discretion and at enGene's expense, to retain and set the compensation of outside legal, accounting or other advisors as necessary to assist in the performance of its duties and responsibilities.

The audit committee currently consists of Lota Zoth (Chair), Philip Astley-Sparke and Michael Heffernan. The Board has determined that Ms. Zoth qualifies as an audit committee financial expert.

Compensation Committee

Under SEC and the Nasdaq rules, there are heightened independence standards for members of the compensation committee. enGene's compensation committee members meet this heightened standard and are also independent for purposes of NI 58-101. The functions of the compensation committee include:

(1) reviewing and making recommendations with respect to compensation policy and programs and determining and recommending option grants under enGene's incentive stock plan;

(2) reviewing and recommending to enGene's Board the manner in which executive compensation should be tied to corporate goals and objectives;

(3) reviewing and approving annually the corporate goals and objectives applicable to the compensation of the Chief Executive Officer, evaluating at least annually the Chief Executive Officer's performance in light of those goals and objectives and determining and approving the Chief Executive Officer's compensation level based on this evaluation;

(4) making recommendations to enGene's Board regarding the compensation of all other executive officers;

(5) reviewing and making recommendations to enGene's Board regarding incentive compensation plans and equity-based plans;

(6) authority to oversee enGene's non-executive incentive compensation plans and equity-based plans, including the discharge of any duties imposed on the compensation committee by any of those plans; and

(7) reviewing director compensation for service on enGene's Board and board committees at least once a year and to recommending any changes to the Board.

The Board has established a written charter that sets forth the purpose, composition, authority and responsibility of the compensation committee consistent with the rules of the Nasdaq, the SEC and the guidance of the Canadian Securities Administrators.

The compensation committee currently consists of Gerald Brunk (Chair), Paul Hastings, Michael Heffernan and Wouter Joustra.

Nominating and Corporate Governance Committee

The members of the nominating and governance committee are independent for purposes of NI 58-101.

enGene's Board has established a written charter that sets forth the purpose, composition, authority and responsibility of enGene's nominating and corporate governance committee. The nominating and corporate governance committee's purpose is to assist the Board in:

(1) identifying individuals qualified to become members of enGene's Board;

(2) selecting or recommending that enGene's Board select director nominees for the next annual meeting of shareholders and determining the composition of the Board and its committees;

(3) developing and overseeing a process to assess enGene's Board, the Chair of the board, the committees of the board, the chairs of the committees, individual directors and management; and

(4) developing and implementing enGene's corporate governance guidelines.

In identifying new candidates for enGene's Board, the nominating and corporate governance committee will consider what competencies and skills the Board, as a whole, should possess and assess what competencies and skills each existing director possesses, considering enGene's Board as a group, and the personality and other qualities of each director, as these may ultimately determine the boardroom dynamic.

It is the responsibility of the nominating and corporate governance committee to regularly evaluate the overall efficiency of enGene's Board and its Chair and all board committees and their chairs. As part of its mandate, the nominating and corporate governance committee will conduct the process for the assessment of enGene's Board, each committee and each director regarding their or its effectiveness and contribution, and report evaluation results to the Board on a regular basis.

The nominating and corporate governance committee currently consists of Richard Glickman (Chair), Philip Astley-Sparke, Paul Hastings and Lota Zoth.

Research and Development Committee

enGene's Board has established a written charter that sets forth the purpose, composition, authority and responsibility of enGene's research and development committee. The research and development committee's purpose is to assist the Board by:

(1) reviewing and providing advice for enGene's research and development programs;

(2) providing input and advice on enGene's preclinical studies, clinical trials and clinical development;

(3) reviewing and advising the Board regarding the strategic direction of enGene's research and development activities, including long-term objectives;

(4) monitoring significant emerging trends and issues in relevant science and technology and considering their potential impact on the Company's research and development programs; and

(5) providing advice to management and the Board on the allocation, deployment, and utilization of resources in support of enGene's research and development activities.

The research and development committee currently consists of William Grossman (Chair), Gerald Brunk and Richard Glickman.

Code of Business Conduct and Ethics

enGene has established a code of business conduct and ethics (the "Code of Conduct") applicable to all of enGene's directors, officers and employees, including its Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which will be a "code of ethics" as defined in Item 406(b) of Regulation S-K promulgated by the SEC and which will be a "code" under NI 58-101. The Code of Conduct sets out the fundamental values and standards of behavior that are expected from enGene's directors, officers, employees, consultants and contractors with respect to all aspects of its business. The objective of the Code of Conduct is to provide written standards designed to promote integrity and deter wrongdoing.

The full text of the Code of Conduct is posted on enGene's website at www.engene.com. The written Code of Conduct is filed with the Canadian securities regulatory authorities on SEDAR+ at www.sedarplus.ca. Information contained on, or that can be accessed through, enGene's website does not constitute a part of this Amendment No. 1 and is not incorporated by reference herein. If enGene makes any amendment to the Code of Conduct or grants any waivers, including any implicit waiver, from a provision of the code of ethics included within the Code of Conduct, enGene will disclose the nature of such amendment or waiver on its website to the extent required by the rules and regulations of the SEC and the Canadian Securities Administrators. enGene intends to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or a waiver from, a provision of its code of ethics that applies to its principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, by posting such information on enGene's internet website.

Monitoring Compliance with the Code of Conduct

enGene's nominating and corporate governance committee is responsible for reviewing and evaluating the Code of Conduct at least annually and recommending any necessary or appropriate changes to the Board for consideration. Additionally, the nominating and corporate governance committee assists enGene's Board with the monitoring of compliance with the Code of Conduct, and will be responsible for considering any waivers of the Code of Conduct (other than waivers applicable to members of the nominating and corporate governance committee, which shall be considered by the audit committee, or waivers applicable to enGene's directors or executive officers, which shall be subject to review by the Board as a whole).

Insider Trading Policy

We are committed to promoting high standards of ethical business conduct and compliance with applicable laws, rules and regulations. As part of this commitment, we have adopted and maintain our Insider Trading Policy which we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us. Our Insider Trading Policy was filed as Exhibit 19 to the Original Form 10-K filed with the SEC on December 22, 2025. Our Insider Trading Policy governs the purchase, sale and/or other disposition of our securities and applies to all directors, officers, and employees of enGene and its subsidiaries as well as consultants that we may designate from time to time. Pursuant to the Company's Insider Trading Policy, every Company insider is prohibited from speculative or indirect trading in Company securities - such as short sales, trading in puts, calls or options - or similar rights or obligations to buy or sell Company securities, or the purchase of Company securities with the intention of quickly reselling them. In addition, Company insiders may not buy Company securities on margin, and are prohibited from purchasing financial instruments designed to hedge or offset a decrease in the market value of Company securities. Insiders are strongly discouraged from using Company securities as collateral for loans or in margin accounts. In addition, our policy prohibits Company insiders from purchasing or selling our securities while in possession of material, non-public information, or otherwise using such information for their personal benefit or to make recommendations or express opinions to another person regarding trading our securities. In addition, we maintain a quarterly black-out window and will impose special blackout periods during which applicable individuals may not trade.

Company insiders are permitted to enter into trading plans that are intended to comply with the requirements of Exchange Act Rule 10b5-1 and comparable Canadian securities law requirements so they may make predetermined trades of our securities.

Corporate Governance Guidelines

The Rule 5600 Series of the Nasdaq Listing Rules generally requires that a listed company's constituting documents provide for a quorum for any meeting of the holders of the company's Common Shares that is greater than 33-1/3% of the outstanding shares of the company's Common Shares that provide voting rights. enGene's Articles provide that a quorum of shareholders is the holders of at least 33-1/3% of the shares entitled to vote at the meeting, present in person or represented by proxy, and at least two persons entitled to vote at the meeting, present in person or represented by proxy.

Except as stated above, enGene complies with the rules generally applicable to U.S. domestic companies listed on the Nasdaq.

The Canadian Securities Administrators has issued corporate governance guidelines pursuant to National Policy 58-201 - *Corporate Governance Guidelines* (the "Corporate Governance Guidelines"), together with certain related disclosure requirements pursuant to NI 58-101. The Corporate Governance Guidelines are recommended as guidelines for issuers to consider in developing their own corporate governance practices. enGene recognizes that good corporate governance plays an important role in its overall success and in enhancing shareholder value and, accordingly, enGene has adopted certain corporate governance policies and practices which reflect its consideration of the recommended Corporate Governance Guidelines.

The disclosure herein describes enGene's approach to corporate governance in relation to the Corporate Governance Guidelines.

Delinquent Section 16(a) Reports

Under Section 16(a) of the Exchange Act, directors, executive officers and beneficial owners of 10% or more of our common shares (collectively, "reporting persons"), are required to report to the SEC on a timely basis the initiation of their status as a reporting person and any changes with respect to their beneficial ownership of our common shares. Based solely on our review of copies of reports filed pursuant to Section 16(a), or written representations from reporting persons, we believe that during the fiscal year ended October 31, 2025, all Section 16(a) filing requirements applicable to the reporting persons were timely met, with the exception of one late Form 4 filing by Matthew Boyd caused by a delay in obtaining his EDGAR filer codes.

Item 11. Executive Compensation.

Executive Compensation Overview

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

The compensation provided to our named executive officers for the fiscal years ended October 31, 2025 and 2024 ("fiscal 2025" and "fiscal 2024," respectively) is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow this section.

For fiscal 2025, the "named executive officers" and their positions were as follows:

(1) Ronald H.W. Cooper, our Chief Executive Officer and President;

(2) Ryan Daws, our Chief Financial Officer; and

(3) Hussein Sweiti, our Chief Medical Officer.

Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the fiscal years ended October 31, 2025 and 2024.

Name and Principal Position[1]	Fiscal Year	Salary ($)[2]	Bonus($) [3]	Option Awards ($)[4]	Nonequity Incentive Plan Compensation[5]	All Other Compensation ($)[6]	Total ($)
Ronald H.W. Cooper	2025	700,000	-	4,544,760	483,000	30,529	5,758,289
Chief Executive Officer and President	2024	196,951	-	7,985,375	246,960	4,526	8,433,812
Ryan Daws	2025	473,000	-	1,497,097	222,640	23,389	2,216,126
Chief Financial Officer							
Hussein Sweiti	2025	43,750	212,195	2,894,340	-	1,617	3,151,902
Chief Medical Officer							

1. Mr. Daws and Dr. Sweiti were not named executive officers during fiscal 2024. Mr. Cooper began employment with the Company on July 22, 2024. Dr. Sweiti began employment with the Company on September 29, 2025.
2. The fiscal 2024 base salary for Mr. Cooper and the fiscal 2025 base salary for Dr. Sweiti represent their prorated base salaries. Mr. Cooper began employment with the Company on July 22, 2024. Dr. Sweiti began employment with the Company on September 29, 2025.
3. The fiscal 2025 bonus for Dr. Sweiti represents a $150,000 sign-on bonus paid in connection with the commencement of his employment and a $50,000 one-time cash bonus that was payable in February 2026 in lieu of any annual cash incentive compensation for 2025 in accordance with his employment agreement. See "- Employment Arrangements with our Named Executive Officers - Dr. Hussein Sweiti." In addition, in January 2026, enGene's compensation committee awarded Dr. Sweiti a discretionary bonus of $12,195 in light of his contributions to the performance of the Company against the pre-established corporate goals during 2025.
4. The amount reported represents the aggregate grant date fair value of the stock options awarded to Messrs. Cooper and Daws and Dr. Sweiti during fiscal 2025 and to Mr. Cooper during fiscal 2024, calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option reported in this column are set forth in Note 10 to our consolidated financial statements as of and for the years ended October 31, 2025 and 2024 in the Original Form 10-K. The amount reported in this column reflects the grant date accounting cost for these stock option awards and does not correspond to the actual economic value that may be received by Messrs. Cooper and Daws and Dr. Sweiti upon the vesting of their stock options or any sale of the shares, which depends on the market value of our Common Shares on a date in the future.

5. The amounts in the "Nonequity incentive plan compensation" column represent annual cash incentive compensation amounts awarded to the named executive officers by enGene's compensation committee, as detailed in "- Cash Incentive Compensation" below.
6. For fiscal 2025, "all other compensation" includes the following: (a) 401(k) employer matching contributions in the amounts of $23,473, $18,772 and $1,588 for Mr. Cooper, Mr. Daws and Dr. Sweiti, respectively, (b) life insurance premiums in the amounts of $2,574, $897 and $29 for Mr. Cooper, Mr. Daws and Dr. Sweiti, respectively, and (c) supplemental disability insurance premiums in the amounts of $4,482, $3,720 and $0 for Mr. Cooper, Mr. Daws and Dr. Sweiti, respectively. For fiscal 2024, "all other compensation" for Mr. Cooper includes the following: (a) 401(k) employer matching contributions in the amount of $2,632, (b) life insurance premiums in the amount of $213, and (c) supplemental disability insurance premiums in the amount of $1,681.

Narrative to Summary Compensation Table

Base Salaries

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. For the fiscal year ended October 31, 2025, the annualized base salary for each of Mr. Cooper, Mr. Daws and Dr. Sweiti, was $700,000, $484,000, and $525,000, respectively.

Cash Incentive Compensation

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations. Cash bonuses are earned by our executives based on the achievement of overall company performance criteria over the course of each calendar year (not fiscal year). Accordingly, amounts for each of the Company's named executive officers in the "Nonequity incentive plan compensation" column for fiscal 2025 and fiscal 2024 were awarded as a result of the achievement of certain performance measures over calendar years 2025 and 2024. The company performance criteria for calendar years 2025 and 2024 included operational goals in the areas of the clinical development of detalimogene voraplasmid, or detalimogene, the manufacturing of detalimogene, potential indications for detalimogene, preparations for a potential biologics license application submission, financial discipline and building awareness. For 2025, the compensation committee determined that overall corporate performance was achieved based on an assessment of the pre-established corporate goals and determined to grant cash incentive compensation awards to our named executive officers (other than Dr. Sweiti) for 2025 in the amounts of $483,000 and $222,640 to Mr. Cooper and Mr. Daws, respectively. For Dr. Sweiti, his employment agreement provides that in lieu of any annual cash incentive compensation for 2025, he is entitled to a one-time cash bonus of $50,000, to be paid in the second regular payroll cycle in February 2026, subject to his continued employment in good standing through the payment date. See "- Employment Arrangements with our Named Executive Officers - Dr. Hussein Sweiti." However, as a result of the performance of the company against the pre-established corporate goals during 2025, in January 2026, the compensation committee determined to grant a discretionary bonus award to Dr. Sweiti in the amount of $12,195.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our shareholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. We have used stock options to compensate our executive officers in the form of initial grants in connection with the executive officer's appointment to his or her position, which are typically negotiated in connection with their hiring, and generally on an annual basis thereafter. In connection with the hiring of Dr. Sweiti in September 2025, we awarded him a stock option for Common Shares in the amount of 600,000. In connection with our annual compensation process, in January 2025, we awarded stock options for Common Shares in the amounts of 850,000 and 280,000 to Messrs. Cooper and Daws, respectively. The new hire stock options we grant to executives have a 10-year term and vest over four years, with 25% of the underlying shares vesting on the one-year anniversary of the grant date or employment commencement date, as applicable, and the remainder vesting in equal amounts monthly for three years thereafter, subject to the executive officer's continued service as an employee of, or other service provider to, the Company through the applicable vesting dates. The stock options we grant to executives on an annual basis have a 10-year term and vest in equal amounts monthly over four years, subject to the executive officer's continued service as an employee of, or other service provider to, the Company through the applicable vesting dates.

Employment Arrangements with our Named Executive Officers

Ronald H.W. Cooper

On July 22, 2024, in connection with Mr. Cooper's appointment as Chief Executive Officer, enGene USA, Inc., an indirect, wholly-owned subsidiary of the Company ("enGene USA"), Mr. Cooper entered into an employment agreement, which we subsequently amended on October 2, 2025 (as amended, the "Cooper Employment Agreement"). The Cooper Employment Agreement has no fixed

term and is terminable at will. Mr. Cooper is entitled under the Cooper Employment Agreement to an annual base salary of $700,000, an annual 60% bonus opportunity, and to participate in enGene USA's employee benefit plans. In addition, the Cooper Employment Agreement provided for the grant to Mr. Cooper of an inducement equity award consisting of a non-qualified stock option to purchase 1,250,000 Common Shares. The Company granted the stock option to Mr. Cooper on July 22, 2024 at an exercise price per share of $8.81. The agreement to grant the stock option was an inducement material to Mr. Cooper's entering into employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4). While the stock option was granted outside of the Company's Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, it has terms and conditions consistent with those set forth under the plan.

Pursuant to the Cooper Employment Agreement, (a) upon the termination of Mr. Cooper's employment by enGene USA without Cause (as defined in the Cooper Employment Agreement) or by Mr. Cooper for Good Reason (as defined in the Cooper Employment Agreement), Mr. Cooper is entitled to receive post-termination severance benefits from enGene USA consisting of (i) twelve months' base salary, (ii) twelve months of continued health insurance benefits, (iii) a prorated portion of his annual bonus, (iv) acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination, and (v) acceleration and vesting of any then unvested equity awards that are subject to performance-based vesting; and (b) upon the termination of Mr. Cooper by enGene USA without Cause or by Mr. Cooper for Good Reason during a change in control period, which includes the ninety days prior to and twelve months following a change in control, Mr. Cooper is entitled to receive post-termination severance benefits from enGene USA consisting of (i) eighteen months' base salary, (ii) an amount equal to 1.5 times his annual bonus opportunity at the target level, (iii) eighteen months of post-termination health insurance benefits; and (iv) acceleration and vesting of all then unvested equity awards, regardless of any restriction with respect to time, performance or other restrictions.

In addition, pursuant to the Cooper Employment Agreement, Mr. Cooper has agreed to standard restrictive covenant obligations, including a noncompete and nonsolicit obligation which run while employed and for twelve months thereafter, or eighteen months, if such termination occurs during a change in control period.

As an employee of the Company, Mr. Cooper will not receive any separate compensation for his service on the Board.

Ryan Daws

On December 13, 2023, enGene USA and the Company's Chief Financial Officer, Ryan Daws, entered into an employment agreement, which was amended and restated on June 10, 2025 (as amended and restated, the "Daws Employment Agreement"). The Daws Employment Agreement has no fixed term and is terminable at will. Mr. Daws is entitled to, under the Daws Employment Agreement, an annual base salary of $484,000, an annual 40% bonus opportunity, and eligibility to participate in enGene USA's employee benefit plans.

Pursuant to the Daws Employment Agreement, (a) upon the termination of Mr. Daws's employment by enGene USA without Cause (as defined in the Daws Employment Agreement) or by Mr. Daws for Good Reason (as defined in the Daws Employment Agreement), Mr. Daws is entitled to receive post-termination severance benefits from enGene USA consisting of (i) twelve months' base salary, (ii) twelve months of continued health insurance benefits, (iii) a prorated portion of his annual bonus, if such termination occurs six months or more into the applicable performance period for such annual bonus, and (iv) acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination; and (b) upon the termination of Mr. Daws by enGene USA without Cause or by Mr. Daws for Good Reason during a change in control period, which includes the ninety days prior to and twelve months following a change in control, Mr. Daws is entitled to receive post-termination severance benefits from enGene USA consisting of (i) twelve months' base salary, (ii) an amount equal to his annual bonus opportunity at the target level, (iii) twelve months of post-termination health insurance benefits; and (iv) acceleration and vesting of all then unvested time-based equity awards.

In addition, pursuant to the Daws Employment Agreement, Mr. Daws has agreed to standard restrictive covenant obligations, including a noncompete and nonsolicit obligation which run while employed and for twelve months thereafter.

Dr. Hussein Sweiti

On September 15, 2025, enGene USA and the Company's Chief Medical Officer, Dr. Hussein Sweiti, entered into an employment agreement (the "Sweiti Employment Agreement") to be effective as of September 29, 2025. The Sweiti Employment Agreement has no fixed term and is terminable at will. Dr. Sweiti is entitled to, under the Sweiti Employment Agreement, an annual base salary of $525,000, an annual 40% bonus opportunity, and eligibility to participate in enGene USA's employee benefit plans. Dr. Sweiti is also entitled to a cash signing bonus in the amount of $150,000, which was paid in the first regular payroll period following Dr. Sweiti's commencement of employment, and which shall be deemed earned upon completion of one full year of active employment with the Company. In addition, in lieu of any annual cash incentive compensation for 2025, Dr. Sweiti is entitled to a one-time cash bonus of $50,000, to be paid in the second regular payroll cycle in February 2026, subject to his continued employment in good standing through the payment date. In addition, the Sweiti Employment Agreement provided for the grant to Dr. Sweiti of an inducement equity award consisting of a non-qualified stock option to purchase 600,000 Common Shares. The Company granted the stock option to Dr. Sweiti on September 30, 2025 at an exercise price per share of $6.83. The agreement to grant the stock option was an inducement material to Dr. Sweiti's entering into employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4). While the stock option

was granted outside of the Company's Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, it has terms and conditions consistent with those set forth under the plan.

Pursuant to the Sweiti Employment Agreement, (a) upon the termination of Dr. Sweiti's employment by enGene USA without Cause (as defined in the Sweiti Employment Agreement) or by Dr. Sweiti for Good Reason (as defined in the Sweiti Employment Agreement), Dr. Sweiti is entitled to receive post-termination severance benefits from enGene USA consisting of (i) twelve months' base salary, (ii) twelve months of continued health insurance benefits, (iii) a prorated portion of his annual bonus, if such termination occurs six months or more into the applicable performance period for such annual bonus, and (iv) acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination; and (b) upon the termination of Dr. Sweiti by enGene USA without Cause or by Dr. Sweiti for Good Reason during a change in control period, which includes the ninety days prior to and twelve months following a change in control, Dr. Sweiti is entitled to receive post-termination severance benefits from enGene USA consisting of (i) twelve months' base salary, (ii) an amount equal to his annual bonus opportunity at the target level, (iii) twelve months of post-termination health insurance benefits; and (iv) acceleration and vesting of all then unvested time-based equity awards.

In addition, pursuant to the Sweiti Employment Agreement, Dr. Sweiti has agreed to standard restrictive covenant obligations, including a noncompete and nonsolicit obligation which run while employed and for twelve months thereafter.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of October 31, 2025.

Name	Grant Date	Number Of Securities Underlying Unexercised Options (#) Exercisable		Number Of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)[1]	Option Expiration Date
Ronald H.W. Cooper	7/22/2024	390,625	(1)	859,375	8.81	7/22/2034
	1/29/2025	159,375	(2)	690,625	7.39	1/29/2035
Ryan Daws	11/30/2023	111,166	(3)	120,834	7.66	11/30/2033
	1/29/2025	52,500	(2)	227,500	7.39	1/29/2035
Hussein Sweiti	9/30/2025	-	(4)	600,000	6.83	9/30/2035

1. This option vests at 25% on July 22, 2025 with the remaining portion to vest in approximately equal amounts monthly over the remaining three years, subject to Mr. Cooper's continued service.
2. This option vests in approximately equal amounts monthly for 48 months following the grant date, subject to the executive's continued service.
3. This option vests at 25% on November 30, 2024 with the remaining portion to vest in approximately equal amounts monthly over the remaining three years, subject to Mr. Daws's continued service.
4. This option vests at 25% on September 29, 2026 with the remaining portion to vest in approximately equal amounts monthly over the remaining three years, subject to Dr. Hussein's continued service.

Employee Benefit and Equity Compensation Plans

Summary of the Equity Plans

For the fiscal years ended October 31, 2024 and 2025, executive compensation was under the enGene Holdings Inc. Amended and Restated 2023 Incentive Equity Plan (the "Incentive Equity Plan"). The following is a summary of the Incentive Equity Plan.

Type of Awards

The Incentive Equity Plan provides for the issuance of stock options (including non-statutory stock options and incentive stock options), stock appreciation rights ("SARs"), restricted shares, restricted share units and other share-based awards to employees, non-employee directors, and certain consultants and advisors of enGene or its subsidiaries.

Administration

The Incentive Equity Plan is administered by the compensation committee of the Board or another committee appointed by the Board to administer the Incentive Equity Plan (the "Committee"); provided that any grants to members of the Board must be authorized by a majority of the Board (counting all the Board members for purposes of a quorum, but only non-interested Board members for purposes of such majority approval). The Committee (if other than the full Board) must consist of directors who are "non-employee

directors" as defined under Rule 16b-3 promulgated under the Exchange Act and "independent directors," as determined in accordance with the independence standards established by the stock exchange on which the Common Shares is at the time primarily traded. The Committee may delegate authority under the Incentive Equity Plan to one or more subcommittees as it deems appropriate. Subject to compliance with applicable law and stock exchange requirements, so long as the Chief Executive Officer is also a director on the Board, the Committee may delegate all or part of its authority to the Chief Executive Officer (or if there is none then appointed, the President), as it deems appropriate, with respect to grants to employees or consultants who are not executive officers under Section 16 of the Exchange Act.

Shares Subject to the Incentive Equity Plan

As of February 17, 2026, the number of Common Shares subject to the Incentive Equity Plan was 11,922,732, inclusive of 2,888,237 Common Shares enGene is authorized to issue under the plan, plus 8,761,570 Common Shares that are subject to outstanding grants and outstanding restricted stock units of 272,925 Common Shares. The Incentive Equity Plan contains an evergreen provision, pursuant to which, commencing with the first business day of each calendar year, the aggregate number of Common Shares that may be issued or transferred under the Incentive Equity Plan will be increased by a number of Common Shares equal to the lesser of (x) 5% of the issued and outstanding Common Shares, or (y) such lesser number of shares as may be determined by the Committee.

If any options or SARs granted under the Incentive Equity Plan (including options or SARs granted under the prior enGene Inc. Plans) expire or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any share awards, share units, or other share-based awards granted under the Incentive Equity Plan (including options or SARs granted under the prior enGene Inc. Plans) are forfeited, terminated, or otherwise not paid in full, the Common Shares subject to such awards will again be available for purposes of the Incentive Equity Plan. If Common Shares are surrendered in payment of the exercise price of an option, the number of Common Shares available for issuance under the Incentive Equity Plan will be reduced only by the net number of shares actually issued by the Company upon such exercise and not by the gross number of shares as to which such option is exercised. Upon the exercise of any SAR under the Incentive Equity Plan, the number of Common Shares available for issuance will be reduced only by the net number of shares actually issued by the Company upon such exercise.

If Common Shares are withheld by the Company in satisfaction of the withholding taxes incurred in connection with the issuance, vesting or exercise of any grant or the issuance of Common Shares under the Incentive Equity Plan, the number of Common Shares available for issuance will be reduced by the net number of shares issued, vested, or exercised under such grant, calculated in each instance after payment of such share withholding. If any awards are paid in cash, and not in Common Shares, any Common Shares subject to such awards will also be available for future awards. If the Company repurchases its Common Shares on the open market with the proceeds from the exercise price the Company receives from options, the repurchased shares will not be available for issuance under the Incentive Equity Plan.

Individual Limits for Non-Employee Directors

The maximum aggregate grant date value of Common Shares granted to any non-employee director in any one calendar year, taken together with any cash fees earned by such non-employee director for services rendered during the calendar year, shall not exceed $500,000 in total value; provided, however, that with respect to the year during which a non-employee director is first appointed or elected to the Board, the maximum aggregate grant date value of Common Shares granted to such non-employee director, taken together with any cash fees earned by such non-employee director for services rendered during such period, shall not exceed $750,000 in total value during the initial annual period.

Adjustments

In connection with stock splits, stock dividends, recapitalizations, and certain other events affecting Common Shares, the Committee will make adjustments as it deems appropriate in: the maximum number of Common Shares reserved for issuance as grants; the maximum amount of awards that may be granted to any individual non-employee director in any year; the number and kind of shares covered by outstanding grants; the number and kind of shares that may be issued under the Incentive Equity Plan; the price per share or market value of any outstanding grants; the exercise price of options; the base amount of SARs; and the performance goals or other terms and conditions as the Committee deems appropriate.

Eligibility and Vesting

All of the employees and non-employee directors of enGene are eligible to receive grants under the Incentive Equity Plan. In addition, consultants who perform certain services for enGene may receive grants under the Incentive Equity Plan. The Committee will (i) select the employees, non-employee directors, and consultants to receive grants and (ii) determine the number of Common Shares subject to a particular grant and the vesting and exercisability terms of awards granted under the Incentive Equity Plan.

Options

Under the Incentive Equity Plan, the Committee will determine the exercise price of the options granted and may grant options to purchase Common Shares in such amounts as it determines. The Committee may grant options that are intended to qualify as incentive stock options under Section 422 of the Code, or non-qualified stock options, which are not intended to so qualify. Incentive stock options may only be granted to employees. Anyone eligible to participate in the Incentive Equity Plan may receive a grant of non-qualified stock options. The exercise price of a stock option granted under the Incentive Equity Plan cannot be less than the fair market value of a Common Share on the date the option is granted. If an incentive stock option is granted to a 10% shareholder of the total combined voting power of all classes of enGene securities, the exercise price cannot be less than 110% of the fair market value of a Common Share on the date the option is granted.

The exercise price for any option is generally payable in cash. In certain circumstances as permitted by the Committee, the exercise price may be paid: by the surrender of Common Shares with an aggregate fair market value, on the date the option is exercised, equal to the exercise price; by payment through a broker in accordance with procedures established by the Federal Reserve Board; solely with respect to non-qualified stock options, by Common Shares subject to the exercisable option that have a fair market value on the date of exercise equal to the aggregate exercise price; or by such other method as the Committee approves.

The term of an option cannot exceed 10 years from the date of grant, except that if an incentive stock option is granted to a 10% shareholder of the total combined voting power of all class of enGene securities, the term cannot exceed five years from the date of grant. In the event that on the last day of the term of a non-qualified stock option, the exercise is prohibited by applicable law, including a prohibition on purchases or sales of Common Shares under the enGene insider trading policy, or pursuant to any restrictions on transfer imposed by the Committee, the term of the non-qualified option will be extended for a period of 30 days following the end of the legal prohibition, or until the expiration of such restrictions on transfer, unless the Committee determines otherwise.

Except as provided in the grant instrument, an option may only be exercised while a participant is employed by or providing service to us. The Committee will determine in the grant instrument under what circumstances and during what time periods a participant may exercise an option after termination of employment.

Share Awards

Under the Incentive Equity Plan, the Committee may grant share awards. A share award is an award of Common Shares that may be subject to restrictions as the Committee determines. The restrictions, if any, may lapse over a specified period of employment or based on the satisfaction of pre-established criteria, in installments or otherwise, as the Committee may determine, including, but not limited to, restrictions based on the achievement of performance goals. Except to the extent restricted under the grant instrument relating to the share award, a participant will have all of the rights of a shareholder as to those shares, including the right to vote and the right to receive dividends or distributions on the shares. Dividends with respect to share awards that vest based on performance shall vest if and to the extent that the underlying share award vests, as determined by the Committee. All unvested share awards are forfeited if the participant's employment or service is terminated for any reason, unless the Committee determines otherwise.

Share Units

Under the Incentive Equity Plan, the Committee may grant share units to anyone eligible to participate in the Incentive Equity Plan. Share units represent hypothetical Common Shares. Share units become payable on terms and conditions determined by the Committee, including specified performance goals, and will be payable in cash, Common Shares, or a combination thereof, as determined by the Committee. All unvested share units are forfeited if the participant's employment or service is terminated for any reason, unless the Committee determines otherwise.

Stock Appreciation Rights

Under the Incentive Equity Plan, the Committee may grant SARs, which may be granted separately or in tandem with any option. SARs granted in tandem with a non-qualified stock option may be granted either at the time the non-qualified stock option is granted or any time thereafter while the option remains outstanding. SARs granted in tandem with an incentive stock option may be granted only at the time the grant of the incentive stock option is made. The Committee will establish the base amount of the SAR at the time the SAR is granted, which will be equal to or greater than the fair market value of a Common Share as of the date of grant.

If a SAR is granted in tandem with an option, the number of SARs that are exercisable during a specified period will not exceed the number of Common Shares that the participant may purchase upon exercising the related option during such period. Upon exercising the related option, the related SARs will terminate, and upon the exercise of a SAR, the related option will terminate to the extent of an equal number of Common Shares. Generally, SARs may only be exercised while the participant is employed by, or providing services to, us. When a participant exercises a SAR, the participant will receive the excess of the fair market value of the underlying Common Shares over the base amount of the SAR. The appreciation of a SAR will be paid in Common Shares, cash, or both.

The term of a SAR cannot exceed 10 years from the date of grant. In the event that on the last day of the term of a SAR, the exercise is prohibited by applicable law, including a prohibition on purchases or sales of Common Shares under our Insider Trading Policy, or pursuant to any restrictions on transfer imposed by the Committee, the term of the SAR will be extended for a period of 30 days following the end of the legal prohibition, or until the expiration of such restrictions on transfer, unless the Committee determines otherwise.

Other Share-Based Awards

Under the Incentive Equity Plan, the Committee may grant other types of awards that are based on, or measured by, Common Shares, and granted to anyone eligible to participate in the Incentive Equity Plan. The Committee will determine the terms and conditions of such awards. Other share-based awards may be payable in cash, Common Shares or a combination of the two, as determined by the Committee.

Dividend Equivalents

Under the Incentive Equity Plan, the Committee may grant dividend equivalents in connection with grants of share units or other share-based awards made under the Incentive Equity Plan. Dividend equivalents entitle the participant to receive amounts equal to ordinary dividends that are paid on the shares underlying a grant while the grant is outstanding. The Committee will determine whether dividend equivalents will be paid currently or accrued as contingent cash obligations. Dividend equivalents may be paid in cash or Common Shares. The Committee will determine the terms and conditions of the dividend equivalent grants, including whether the grants are payable upon the achievement of specific performance goals. Dividend equivalents with respect to share units or other share-based awards that vest based on performance shall vest and be paid only if and to the extent that the underlying share units or other share-based awards vest and are paid as determined by the Committee.

Change of Control

If the Company experiences a change of control where the Company is not the surviving company (or survives only as a subsidiary of another company), unless the Committee determines otherwise, all outstanding grants that are not exercised or paid at the time of the change of control will be assumed, or replaced with grants (with respect to cash, securities or a combination thereof) that have comparable terms, by the surviving company (or a parent or subsidiary of the surviving company).

If there is a change of control and all outstanding grants are not assumed, or replaced with grants that have comparable terms, by the surviving company, the Committee may (but is not obligated to) make adjustments to the terms and conditions of outstanding grants, including, without limitation, taking any of the following actions (or combination thereof) without the consent of any participant:

(1) determine that outstanding options and SARs will accelerate and become fully exercisable and the restrictions and conditions on outstanding share awards, share units, and dividend equivalents immediately lapse;

(2) pay participants, in an amount and form determined by the Committee, in settlement of outstanding share units or dividend equivalents;

(3) require that participants surrender their outstanding stock options and SARs in exchange for a payment by us, in cash or Common Shares, equal to the difference between the exercise price and the fair market value of the underlying Common Shares; provided, however, if the per share fair market value of Common Shares does not exceed the per share stock option exercise price or SARs base amount, as applicable, enGene will not be required to make any payment to the participant upon surrender of the stock option or SAR and shall have the right to cancel any such option or SAR for no consideration; or

(4) after giving participants an opportunity to exercise all of their outstanding stock options and SARs, terminate any unexercised stock options and SARs on the date determined by the Committee.

In general terms, a change of control under the Incentive Equity Plan occurs if:

(1) a person, entity or affiliated group, with certain exceptions, acquires more than 50% of the then-outstanding voting securities;

(2) the Company merges into, or consummates an amalgamation or arrangement with, another entity unless the holders of voting shares immediately prior to such transaction have at least 50% of the combined voting power of the securities in the combined entity or its parent;

(3) the Company merges into, or consummates an amalgamation or arrangement with, another entity and the members of the Board prior to such transaction would not constitute a majority of the board of the combined entity or its parent;

(4) the Company sells or disposes of all or substantially all of the assets of the Company;

(5) the Company consummates a complete liquidation or dissolution; or

(6) a majority of the members of the Board are replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the incumbent directors.

Deferrals

The Committee may permit or require participants to defer receipt of the payment of cash or the delivery of Common Shares that would otherwise be due to the participant in connection with a grant under the Incentive Equity Plan. The Committee will establish the rules and procedures applicable to any such deferrals, consistent with the requirements of Section 409A of the Code.

Withholding

All grants under the Incentive Equity Plan are subject to applicable U.S. federal (including taxes under FICA), state, and local, foreign or other tax withholding requirements. The Company may require participants or other persons receiving grants or exercising grants to pay an amount sufficient to satisfy such tax withholding requirements with respect to such grants, or the Company may deduct from other wages and compensation paid by the Company the amount of any withholding taxes due with respect to such grant.

The Committee may permit or require that tax withholding obligation with respect to grants paid in Common Shares be paid by having shares withheld up to an amount that does not exceed the participant's minimum applicable withholding tax rate for U.S. federal (including FICA), state, and local tax liabilities, or as otherwise determined by the Committee. In addition, the Committee may, in its discretion, and subject to such rules as the Committee may adopt, allow participants to elect to have such share withholding applied to all or a portion of the tax withholding obligation arising in connection with any particular grant.

Transferability

Except as permitted by the Committee with respect to non-qualified stock options, only a participant may exercise rights under a grant during the participant's lifetime. Upon death, the personal representative or other person entitled to succeed to the rights of the participant may exercise such rights. A participant cannot transfer those rights except by will or by the laws of descent and distribution or, with respect to grants other than incentive stock options, pursuant to a domestic relations order. The Committee may provide in a grant instrument that a participant may transfer non-qualified stock options for no consideration to a permitted assign in compliance with applicable securities laws.

Amendment; Termination

The Board may amend or terminate the Incentive Equity Plan at any time, except that the Company's shareholders must approve an amendment if such approval is required in order to comply with the Code, applicable laws or applicable stock exchange requirements. Unless terminated sooner by the Board or extended with shareholder approval, the Incentive Equity Plan will terminate on the day immediately preceding the tenth anniversary of the effective date of the Incentive Equity Plan.

Shareholder Approval

Except in connection with certain corporate transactions, including stock dividends, stock splits, a recapitalization, a change in control, a reorganization, a merger, an amalgamation, a consolidation, and a spin-off, shareholder approval is required (i) to reduce the exercise price or base price of outstanding stock options or SARs, (ii) to cancel outstanding stock options or SARs in exchange for the same type of grant with a lower exercise price or base price, and (iii) to cancel outstanding stock options or SARs that have an exercise price or base price above the current price of a Common Share, in exchange for cash or other securities, each as applicable.

Clawback

All grants under the Incentive Equity Plan (including any proceeds, gains or other economic benefit actually or constructively received upon receipt of any grant or receipt or resale of any Common Shares underlying the grant) will be subject to any applicable policies implemented by the Board, which may be adopted in the future and be amended from time to time, including any clawback or recoupment policies and share trading policies. Additionally, on November 22, 2023, the Board adopted a Clawback Policy consistent with Nasdaq Listing Rule 5608, which requires the Company to recoup incentive-based compensation from current and former executive officers in the event of an accounting restatement, subject to certain exceptions as provided by the Listing Rule.

Performance Measures

Under the Incentive Equity Plan, the grant, vesting, exercisability or payment of certain awards, or the receipt of Common Shares subject to certain awards, may be made subject to the satisfaction of performance measures. The performance goals applicable to a

particular award will be determined by the Committee at the time of grant. One or more of the following business criteria for the Company may be used by the Committee in establishing performance measures under the Incentive Equity Plan: cash flow; free cash flow; earnings (including gross margin, earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation, amortization and charges for share-based compensation, earnings before interest, taxes, depreciation and amortization, adjusted earnings before interest, taxes, depreciation and amortization and net earnings); earnings per share; growth in earnings or earnings per share; book value growth; share price; return on equity or average shareholder equity; total shareholder return or growth in total shareholder return either directly or in relation to a comparative group; return on capital; return on assets or net assets; revenue, growth in revenue or return on sales; sales; expense reduction or expense control; expense to revenue ratio; income, net income or adjusted net income; operating income, net operating income, adjusted operating income or net operating income after tax; operating profit or net operating profit; operating margin; gross profit margin; return on operating revenue or return on operating profit; regulatory filings; regulatory approvals, litigation and regulatory resolution goals; other operational, regulatory or departmental objectives; budget comparisons; growth in shareholder value relative to established indexes, or another peer group or peer group index; development and implementation of strategic plans and/or organizational restructuring goals; development and implementation of risk and crisis management programs; improvement in workforce diversity; compliance requirements and compliance relief; safety goals; productivity goals; workforce management and succession planning goals; economic value added (including typical adjustments consistently applied from generally accepted accounting principles required to determine economic value added performance measures); measures of customer satisfaction, employee satisfaction or staff development; development or marketing collaborations, formations of joint ventures or partnerships or the completion of other similar transactions intended to enhance the enGene's revenue or profitability or enhance its customer base; merger and acquisitions; and other similar criteria as determined by the Committee. Performance goals may be established on an absolute or relative basis and may be established on a corporate-wide basis or with respect to one or more business units, divisions, subsidiaries or business segments. Relative performance may be measured against a group of peer companies, a financial market index or other objective and quantifiable indices.

Retirement Plans

We maintain a US tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a US tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The retirement plan is intended to qualify under Section 401(a) of the Code. We contribute 3% of an individual's eligible compensation to the 401(k) Plan irrespective of employee contribution.

We maintain a Canadian tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a Canadian tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. We contribute 1.5% to the Registered Retirement Savings Plan (RRSP) irrespective of employee contribution.

Director Compensation

We compensate non-employee members of our Board for their service using a combination of cash and equity compensation. Directors who are also employees do not receive any compensation for service on the Board in addition to compensation payable for their service as our employees. The non-employee members of our Board are also reimbursed for travel, lodging, and other reasonable expenses incurred in attending Board or committee meetings. See the "Summary Compensation Table" above for a discussion of our Chief Executive Officer's compensation and awards granted in the fiscal year ended October 31, 2025.

During the fiscal year ended October 31, 2025, we compensated our non-employee directors pursuant to the non-employee compensation policy established by our Board, upon the recommendation of our compensation committee:

Compensation Type	Amount
Annual Cash Fee	
Board of Directors	
Independent Chairman or Lead Independent Director	$ 75,000
All non-employee directors	$ 40,000
Audit Committee	
Chair	$ 20,000
Non-chair members	$ 10,000
Compensation Committee	
Chair	$ 18,000
Non-chair members	$ 9,000
Nominating and Corporate Governance Committee	
Chair	$ 10,000
Non-chair members	$ 5,000
Research and Development Committee	
Chair	$ 18,000
Non-chair members	$ 9,000
Initial Stock Option Award[(1)]	45,000 shares
Annual Stock Option Award[(2)]	22,500 shares

(1) This one-time option award is granted following the initial election or appointment of a new director to our Board. The option vests with respect to one-third of the shares on each of the first, second and third anniversaries of the grant date, subject to the director's continued service. Equity awards to our non-employee directors are subject to the individual limits set forth in the Incentive Equity Plan. See "Employee Benefit and Equity Compensation Plans - Summary of the Equity Plans - Individual Limits for Non-Employee Directors" for more information.

(2) This option award is granted after each annual meeting of our shareholders, provided that the non-employee director has served on the Board for at least four months preceding the date of the applicable annual meeting, and vests in full on the first anniversary of the grant date, subject to the director's continued service. Equity awards to our non-employee directors are subject to the individual limits set forth in the Incentive Equity Plan. See "Employee Benefit and Equity Compensation Plans - Summary of the Equity Plans - Individual Limits for Non-Employee Directors" for more information.

The stock options granted to our non-employee directors for service on our Board or its committees have an exercise price equal to the fair market value of the Common Shares on the date of grant, expire ten years after the date of grant, and are subject to the director's continued service on our Board.

The following table sets forth information concerning the compensation for our non-employee directors during the fiscal year ended October 31, 2025.

Name[(1)]	Fees earned or paid in cash[(2)]	Option Awards[(3)]	Total
Philip Astley-Sparke[(4)]	$13,723	$122,233	$135,956
Jasper Bos[(5)]	$30,783	$52,772	$83,555
Gerald Brunk[(6)]	$68,879	$52,722	$121,601
Dr. Richard Glickman[(7)]	$95,879	$52,772	$148,651
Dr. William Grossman[(8)]	$15,989	$122,233	$138,222
Paul Hastings[(9)]	$54,000	$52,772	$106,772
Michael Heffernan[(10)]	$14,041	$122,233	$136,274
Wouter Joustra[(11)]	$49,000	$52,772	$101,772
Lota Zoth[(12)]	$65,000	$52,772	$117,772

(1) Mr. Cooper served as a director during the fiscal year ended October 31, 2025 concurrently with his service as the Company's Chief Executive Officer and President, but did not receive any separate compensation for his services as a director and, consequently, is not included in this table. The compensation paid to Mr. Cooper during the fiscal year ended October 31, 2025 is presented in the "Summary Compensation

Table" above.

(2) Amounts represent cash compensation for services rendered by each member of our Board for their services on our Board or a committee thereof.

(3) The amounts reported in the "Option awards" columns above represent the aggregate grant date fair value of the stock options granted during the fiscal year ended October 31, 2025 as computed in accordance with FASB ASC Topic 718, not including any estimates of forfeitures related to service-based vesting conditions. See Note 10 of "Notes to Consolidated Financial Statements" in the Original Form 10-K for a discussion of assumptions made by the Company in determining the aggregate grant date fair value of our option awards. Messrs. Bos, Brunk, Hastings and Joustra, Dr. Glickman and Ms. Zoth were each awarded an annual stock option to purchase 22,500 Common Shares on June 16, 2025. Messrs. Astley-Sparke and Heffernan and Dr. Grossman were each awarded an initial stock option to purchase 45,000 Common Shares on July 8, 2025. Upon Mr. Bos's departure from the Board on July 7, 2025, his option award was forfeited.

(4) As of October 31, 2025, Mr. Astley-Sparke held options to purchase 45,000 of our Common Shares of which none were vested on such date.

(5) Jasper Bos served as a director until July 7, 2025. As of October 31, 2025, Mr. Bos held no options to purchase our Common Shares.

(6) As of October 31, 2025, Mr. Brunk held options to purchase 42,500 of our Common Shares of which 20,000 were vested on such date.

(7) As of October 31, 2025, Dr. Glickman held options to purchase 108,261 of our Common Shares of which 85,761 were vested on such date.

(8) As of October 31, 2025, Dr. Grossman held options to purchase 45,000 of our Common Shares of which none were vested on such date.

(9) As of October 31, 2025, Mr. Hastings held options to purchase 62,500 of our Common Shares of which 13,333 were vested on such date.

(10) As of October 31, 2025, Mr. Heffernan held options to purchase 45,000 of our Common Shares of which none were vested on such date.

(11) As of October 31, 2025, Mr. Joustra held options to purchase 62,500 of our Common Shares of which 13,333 were vested on such date.

(12) As of October 31, 2025, Ms. Zoth held options to purchase 82,500 of our Common Shares of which 33,333 were vested on such date.

Policies and Practices Related to the Grant of Certain Equity Awards

Our Board has adopted guidelines for granting equity-based awards in order to provide a clear and consistent framework for various types of equity awards, including incentive stock options, stock appreciation rights, and share awards. These awards may be granted either under the Incentive Equity Plan or as inducement grants outside of the Incentive Equity Plan. The guidelines are designed to ensure that all equity awards comply with relevant laws and regulations, stock exchange requirements, the Company's governance policies, and the terms outlined in the Incentive Equity Plan. The guidelines provide for the grant of equity awards in connection with the Company's annual compensation process, annual grants to directors, in connection with new hires and for promotions, retention or purposes other than annual or new hire grants, and further provide that all such grants may only occur at a time when the Company is not in possession of material nonpublic information.

During the fiscal year ended October 31, 2025, no named executive officer received a grant of stock options during the period beginning four business days before, and ending one business day after, the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that disclosed material nonpublic information (excluding disclosure of any material new option award grant under Item 5.02(e) of Form 8-K). The Company does not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K is set forth under the heading "Securities Authorized For Issuance Under Equity Compensation Plans" in Part II - Item 5 - "Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities" in the Original Form 10-K.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information known to the Company regarding the beneficial ownership of the Company's Common Shares as of February 17, 2026 by:

(1) each person known to the Company to be the beneficial owner of more than 5% of outstanding Common Shares;

(2) each director and each of the Company's named executive officers; and

(3) all executive officers and directors of the Company as a group.

As of February 17, 2026, 66,989,466 Common Shares were issued and outstanding. Unless otherwise indicated, we believe that all persons named in the below table have sole voting and investment power with respect to all Common Shares beneficially owned by them. Except as otherwise noted herein, the number and percentage of Common Shares beneficially owned is determined in accordance with Rule 13d-3 of the Exchange Act, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, a person is deemed to be a beneficial owner of a security if that person has sole or shared voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. In determining beneficial ownership percentages, we deem shares that a person will have the right to acquire within 60 days following February 17, 2026, if any, to be outstanding and to be beneficially owned by the person with such right to acquire additional Common Shares for the purposes of computing the percentage ownership of that person (including in the total when calculating the applicable beneficial owner's percentage of ownership), but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each person named below is 4868 Rue Levy, Suite 220, Saint-Laurent, QC, Canada H4R 2P1.

Name and Address of Beneficial Owner	Number of Shares	Percent of Total Voting Power
enGene greater than 5% holders		
Forbion Growth [1]	9,201,434	13.2%
Perceptive Advisors LLC and affiliates [2]	6,770,605	9.9%
Lumira Ventures III, L.P. and affiliates [3]	4,181,853	6.2%
Forbion Capital Fund III Coöperatief U.A. [4]	3,369,275	5.0%
Venrock Healthcare Capital Partners III, L.P. and affiliates [5]	4,771,414	7.1%
Deep Track Biotechnology Master Fund, Ltd. and affiliates [6]	4,317,332	6.4%
Cormorant Asset Management, LP [7]	4,000,000	5.9%
Invus and affiliates [8]	4,244,559	6.3%
enGene directors and named executive officers		
Philip Astley-Sparke [9]	20,000	*%
Gerald Brunk [3][10]	4,201,853	6.2%
Dr. Richard Glickman [11]	110,436	*%
Dr. William Grossman	-	-%
Paul Hastings [12]	13,333	*%
Michael Heffernan	-	-%
Wouter Joustra [13]	13,333	*%
Lota Zoth [14]	46,666	*%
Ronald H.W. Cooper [15]	812,124	1.2%
Dr. Hussein Sweiti	-	-%
Ryan Daws [16]	226,165	*%
enGene directors and executive officers as a group (18 persons) [17]	6,857,006	9.8%

* Less than 1%.

1. Pursuant to a Schedule 13D/A filed with the SEC on November 1, 2024, Forbion Growth Sponsor FEAC I B.V., or FEAC Sponsor, is the record holder of 3,765,932 Common Shares. Forbion Growth Opportunities Fund I Cooperatief U.A. ("FGOF") is the record holder of 3,032,430 Common Shares. Also includes warrants held by FEAC Sponsor that may be exercised to acquire 1,736,406 Common Shares, and warrants held by FGOF that may be exercised to acquire 666,666 Common Shares. FGOF wholly owns the FEAC Sponsor and therefore the FEAC Sponsor and FGOF have shared voting and investment power over the enGene Common Shares held by the FEAC Sponsor. Forbion Growth Management B.V. ("Forbion Management") is the sole director of FGOF and therefore shares voting and investment power (i) with

FGOF over the enGene Common Shares that will be held by FGOF and (ii) with FGOF and, indirectly, the FEAC Sponsor, over the enGene Common Shares that will be held by the FEAC Sponsor. Forbion Management exercises voting and investment power through its investment committee (the "Investment Committee") consisting of Sander Slootweg, Martien van Osch, Geert-Jan Mulder, Vincent van Houten, Dirk Kersten, Nanna Lüneborg, Wouter Joustra and Jasper Bos. None of the members of the Investment Committee has individual voting and investment power with respect to the FEAC Shares, and each such member disclaims beneficial ownership of the FEAC Shares except to the extent of his or her proportionate pecuniary interest therein. Jasper Bos, Cyril Lesser, Sander Slootweg and Wouter Joustra, who are directors of the FEAC Sponsor, have voting and investment discretion with respect to the enGene Common Shares owned by the FEAC Sponsor and may be deemed to have indirect shared beneficial ownership of the enGene Common Shares owned by the FEAC Sponsor. Jasper Bos, Cyril Lesser, Sander Slootweg and Wouter Joustra each disclaim beneficial ownership over the enGene Common Shares except to the extent of their pecuniary interest therein. FGOF, FEAC Sponsor, Forbion Management and such members of the Investment Committee each disclaims any affiliation with Forbion III and its directors, officers or other affiliates. The business address of the above-named Forbion persons is c/o Forbion, Gooimeer 2-35, 1411 DC Naarden, The Netherlands.

2. Pursuant to a Schedule 13G filed with the SEC on November 18, 2025, by Perceptive Advisors LLC and its affiliates, Perceptive Life Sciences Master Fund, Ltd. (the "Perceptive Master Fund") and Joseph Edelman (collectively, the "Perceptive Reporting Persons"), consists of (i) 5,869,076 Common Shares and (ii) 2,735,295 pre-funded warrants immediately exercisable for Common Shares at an exercise price of $0.0001 per share (the "Pre-Funded Warrants"), subject to the Beneficial Ownership Limitation (as defined below) held by the Perceptive Master Fund. The Pre-Funded Warrants may not be exercised if, after such exercise, the Perceptive Reporting Persons would beneficially own, as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, more than 9.99% of the Common Shares of the Company then issued and outstanding (the "Beneficial Ownership Limitation"). As of the date of the Schedule 13G, the Perceptive Reporting Persons reported that the Beneficial Ownership Limitation permits the Perceptive Reporting Persons to exercise Pre-Funded Warrants for an aggregate of not more than 901,529 Common Shares and that, in providing the beneficial ownership information set forth therein, the Perceptive Reporting Persons assumed that the aggregate remaining Pre-Funded Warrants held by the Perceptive Reporting Persons were not exercisable due to the Beneficial Ownership Limitation. Perceptive Advisors LLC serves as the investment manager to the Perceptive Master Fund. Mr. Edelman is the managing member of Perceptive Advisors LLC. The address of the principal business office of aforementioned entities and individual is 51 Astor Place, 10th Floor, New York, NY 10003.

3. Pursuant to a Schedule 13D/A filed with the SEC on February 21, 2024, consists of 1,341,790 Common Shares held by Lumira Ventures III, L.P. ("Lumira III"), 44,647 Common Shares held by Lumira Ventures III (International), L.P. ("Lumira III Int'l"), 993,651 Common Shares held by Lumira Ventures IV, L.P. ("Lumira IV"), 238,851 Common Shares held by Lumira Ventures IV (International), L.P. ("Lumira IV Int'l"), 1,077,386 Common Shares held by Merck Lumira Biosciences Fund, L.P. ("Merck-Lumira"), and 152,974 Common Shares held by Merck Lumira Biosciences Fund (Québec), L.P. ("Merck-Lumira B" and, together with Lumira III, Lumira III Int'l, Lumira IV, Lumira IV Int'l, and Merck-Lumira, the "Lumira entities"). The number of enGene Warrants reported includes warrants held by Lumira III that may be exercised to acquire 114,945 Common Shares, warrants held by Lumira III Int'l that may be exercised to acquire 3,825 Common Shares, warrants held by Lumira IV that may be exercised to acquire 38,301 Common Shares, warrants held by Lumira IV Int'l that may be exercised to acquire 9,207 Common Shares, warrants held by Merck-Lumira that may be exercised to acquire 145,603 Common Shares, and warrants held by Merck-Lumira B that may be exercised to acquire 20,673 Common Shares. Lumira III and Lumira III Int'l are controlled by their general partner, Lumira Ventures III GP, L.P., and managed by Lumira Capital Investment Management Inc. ("Lumira Mgmt"). Lumira Ventures III GP, L.P. is controlled by its general partners, Lumira III GP Inc. and Lumira III GP Holdings Co. Lumira IV and Lumira IV Int'l are controlled by their general partner, Lumira IV GP 2020 Inc., and managed by Lumira Mgmt. Merck-Lumira and Merck-Lumira B are controlled by their general partner, Lumira Capital GP, L.P., and managed by Lumira Mgmt. Lumira Capital GP, L.P. is controlled by its general partners, Lumira GP Inc. and Lumira GP Holdings Co. Mr. Brunk is an executive officer of each of Lumira III GP Inc., Lumira III GP Holdings Co., Lumira IV GP 2020 Inc., Lumira GP Inc., Lumira GP Holdings Co. and Lumira Mgmt. Each of Lumira III GP Inc., Lumira III GP Holdings Co., Lumira IV GP 2020 Inc., Lumira GP Inc., Lumira GP Holdings Co., Lumira Mgmt and Mr. Brunk may be deemed to beneficially own the securities held by the respective Lumira entities, but each disclaims beneficial ownership except to the extent of their respective pecuniary interests therein, if any. The business address of the Lumira entities is 141 Adelaide Street West, Suite 770, Toronto, Ontario, Canada M5H 3L5.

4. Pursuant to a Schedule 13G/A filed with the SEC on February 14, 2024, consists of 2,894,199 Common Shares and warrants that may be exercised to acquire 475,076 Common Shares. Forbion III Management B.V. ("Forbion III") is the director of Forbion Capital Fund III Coöperatief U.A. ("Forbion III COOP") with voting and investment power over the shares held by Forbion III COOP. Such voting and investment power are exercised by Forbion III through its investment committee, consisting of H. A. Slootweg, M. A. van Osch, G. J. Mulder, H.N. Reithinger, Dr. M. Boorsma and S. J. H. van Deventer. None of the members of the investment committee have individual voting and investment power with respect to such shares, and the members of the investment committee, including Dr. Boorsma, who is a former director of enGene Inc., disclaim beneficial ownership of such shares except to the extent of their proportionate pecuniary interests therein. Forbion III COOP disclaims any affiliation with FEAC, FEAC Sponsor, or any of FEAC's or FEAC Sponsor's direct or indirect directors, officers or other affiliates. The business address of Forbion III COOP and Forbion III is Gooimeer 2-35, 1411 DC Naarden, The Netherlands.

5. Pursuant to a Schedule 13G/A filed with the SEC on February 17, 2026 by Venrock Healthcare Capital Partners III, L.P. and its affiliates, consists of (i) 1,052,538 shares held by Venrock Healthcare Capital Partners III, L.P. ("VHCP III"); (ii) 105,269 shares held by VHCP Co-Investment Holdings III, LLC ("VHCP Co-Investment III"); and (iii) 3,613,607 shares held by Venrock Healthcare Capital Partners EG, L.P. ("VHCP EG"). VHCP Management III, LLC ("VHCP Management III") is the general partner of VHCP III and the manager of VHCP Co-Investment III. VHCP Management EG, LLC ("VHCP Management EG") is the general partner of VHCP EG. Messrs. Nimish Shah and Bong Koh are the voting members of VHCP Management III and VHCP Management EG. The address of the principal business office of aforementioned entities and individuals is 7 Bryant Park, 23rd Floor, New York, NY 10018.

6. Pursuant to a Schedule 13G filed with the SEC on November 18, 2025 by Deep Track Capital, LP, Deep Track Biotechnology Master Fund, Ltd., and David Kroin, as the control person for Deep Track Capital, LP. Deep Track Capital, LP is the investment manager of Deep Track Biotechnology Master Fund, Ltd. The business address of Deep Track Capital, LP is 200 Greenwich Avenue, 3rd Floor Greenwich, CT 06830; the business address of Deep Track Biotechnology Master Fund, Ltd. is c/o Walkers Corporate Limited, 190 Elgin Ave, George

Town, KY1-9001, Cayman Islands, and the business address of Mr. Kroin is c/o Deep Track Capital, LP, 200 Greenwich Avenue, 3rd Floor Greenwich, CT 06830.

7. Pursuant to a Schedule 13G filed with the SEC on February 17, 2026 by Cormorant Asset Management, LP (“Cormorant”), and the investment adviser to certain funds (the "Cormorant Funds"), with respect to the shares directly held by the Cormorant Funds and (ii) Bihua Chen with respect to the shares directly held by the Cormorant Funds. The Cormorant Funds have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of the shares. Cormorant Global Healthcare Master Fund, LP, a Cormorant Fund, has the right to receive or the power to direct the receipt of dividends or the proceeds from the sale of more than 5% of the shares. The business address of Cormorant and Ms. Chen is 200 Clarendon Street 52nd Floor, Boston, Massachusetts 02116.

8. Pursuant to a Schedule 13G filed with the SEC on January 27, 2026 by Invus Public Equities, L.P. (“Invus Public Equities”); Invus Public Equities Advisors, LLC (“Invus PE Advisors”); Invus Global Management, LLC (“Global Management”); Siren, L.L.C. (“Siren”); Avicenna Life Sci Master Fund LP (“Avicenna Fund”); Avicenna Life Sci Master GP LLC (“Avicenna GP”); Ulys, L.L.C. (“Ulys”); and Mr. Raymond Debbane. As of the reporting date, Invus Public Equities directly held 3,675,408 shares and Avicenna Fund directly held 569,151 shares. Invus PE Advisors, as the general partner of Invus Public Equities, controls Invus Public Equities and, accordingly, may be deemed to beneficially own the shares directly held by Invus Public Equities. Global Management, as the managing member of Invus PE Advisors, controls Invus PE Advisors and, accordingly, may be deemed to beneficially own the shares that Invus PE Advisors may be deemed to beneficially own. Siren, as the managing member of Global Management, controls Global Management and, accordingly, may be deemed to beneficially own the shares that Global Management may be deemed to beneficially own. Avicenna GP, as the general partner of Avicenna Fund, controls Avicenna Fund and, accordingly, may be deemed to beneficially own the shares directly held by Avicenna Fund. Ulys, as the managing member of Avicenna GP, controls Avicenna GP and, accordingly, may be deemed to beneficially own the shares that Avicenna GP may be deemed to beneficially own. Mr. Raymond Debbane, as the managing member of Siren and Ulys, controls Siren and Ulys and, accordingly, may be deemed to beneficially own the shares that Siren and Ulys may be deemed to beneficially own. The business address of each of the reporting persons is 750 Lexington Avenue, 30th Floor, New York, NY 10022.

9. Includes 20,000 Common Shares held by Mr. Astley-Sparke.

10. Includes 20,000 Common Shares underlying stock options exercisable by Mr. Brunk within 60 days of February 17, 2026.

11. Includes 24,675 Common Shares held by Dr. Glickman and 85,761 Common Shares underlying stock options exercisable by Dr. Glickman within 60 days of February 17, 2026.

12. Includes 13,333 Common Shares underlying stock options exercisable by Mr. Hastings within 60 days of February 17, 2026.

13. Includes 13,333 Common Shares underlying stock options exercisable by Mr. Joustra within 60 days of February 17, 2026.

14. Includes 46,666 Common Shares underlying stock options exercisable by Ms. Zoth within 60 days of February 17, 2026.

15. Includes 10,000 Common Shares held by Mr. Cooper and 802,124 Common Shares underlying stock options exercisable by Mr. Cooper within 60 days of February 17, 2026.

16. Includes 226,165 Common Shares underlying stock options exercisable by Mr. Daws within 60 days of February 17, 2026.

17. Includes directors and current executive officers as of February 17, 2026.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Other than as discussed below and the compensation arrangements discussed under “Item 11. Executive Compensation,” since November 1, 2024 (i.e. the first date of our last completed fiscal year), there have not been any transactions to which we are a party, nor are there any proposed transactions to which we would be a party, with related parties and which we are required to disclose pursuant to the rules of the SEC and the Canadian Securities Administrators.

Director Indemnification

enGene has entered into indemnification agreements with each of its directors and certain of its executive officers, which require enGene to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permissible under Canadian law and the *Business Corporations Act* (British Columbia) against liabilities that may arise by reason of their service to enGene or at enGene’s direction, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Policies and Procedures for Related Party Transactions

Pursuant to its charter, the Board has authorized the audit committee to review and approve transactions between the Company and its officers, directors, principal shareholders and affiliates and any other related party, in accordance with the terms of the Company’s Code of Conduct.

Director Independence

The information required by Item 407(a) of Regulation S-K is set forth above under the headings “Item 10. Directors, Executive Officers and Corporate Governance - Independence of the Members of the Board of Directors” and “Item 10. Directors, Executive Officers and Corporate Governance - Board Committees.”

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is KPMG LLP, Montreal, Canada, Auditor Firm ID: 85.

The following table presents fees for professional audit services rendered by KPMG LLP for the services described in the table. Fees disclosed below include fees actually billed or expected to be billed for services pertaining to the applicable fiscal year. The amounts were billed in Canadian dollars and translated at an average rate of 1.4013 for fiscal 2025 and 1.3698 for fiscal 2024. The figures below are presented in US dollars.

	2025 (US $)	2024 (US $)
Audit fees [1]	$873,823	$934,000
Audit-related fees [2]	-	-
Tax fees [3]	-	$49,000
All other fees [2]	-	-
Total	$873,823	$983,000

(1) Audit fees consisted of professional services rendered for the audit of our consolidated financial statements, reviews of interim financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as consents in connection with the filing of registration statements and related amendments, as well as other filings.

(2) There were no audit-related or other fees incurred in fiscal 2025 or 2024.

(3) Tax fees consisted of services related to tax compliance, including the preparation of tax returns, tax planning, and advice.

Audit Committee Pre-Approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval details the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

During our 2025 and 2024 fiscal years, no services were provided to us by KPMG LLP other than in accordance with the pre-approval policies and procedures described above.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this report:

(1) Financial Statements-All financial statements are omitted because they are either not required or the information is otherwise included in the Original Form 10-K.

(2) Financial Statement Schedules - All financial statement schedules are omitted because they are either not required or not applicable, or the information is otherwise included in the consolidated financial statements or the notes thereto included in the Original Form 10-K.

(3) Exhibits-The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference as part of this report.

Exhibit Number	Description
2.1	Business Combination Agreement, dated May 16, 2023, by and among FEAC, enGene Inc. and enGene (incorporated by reference to Exhibit 2.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). †
3.1	Articles of enGene Holdings Inc. (incorporated by reference to Exhibit 3.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
4.1	Specimen Common Share Certificate of enGene (incorporated by reference to Exhibit 4.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
4.2	Specimen Warrant Certificate of enGene (incorporated by reference to Exhibit 4.3 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
4.3	Warrant Assignment, Assumption and Amendment Agreement, dated as of October 30, 2023, among FEAC, enGene Inc., enGene and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.3 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
4.4	Warrant Agreement, dated December 9, 2021, between FEAC and Continental Stock Transfer & Trust Company, as warrant agent (incorporated herein by reference to Exhibit 4.1 of FEAC's Current Report on Form 8-K filed with the SEC on December 14, 2021).
4.5	Form of Closing Date Warrant to Purchase Common Shares of enGene Holdings Inc., pursuant to the Amended and Restated Loan and Security Agreement dated December 22, 2023 (incorporated herein by reference to Exhibit 4.1 of enGene's Current Report on Form 8-K filed with the SEC on December 28, 2023).
4.6	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated herein by reference to Exhibit 4.6 to enGene's Annual Report on Form 10-K filed with the SEC on January 29, 2024).
4.7	Form of Indenture (incorporated by reference to Exhibit 4.1 to enGene's Form S-3 Registration Statement Registration No.: 333-283201 filed with the SEC on November 13, 2024).
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to enGene's Current Report on Form 8-K filed with the SEC on November 14, 2025).
10.1	Sponsor and Insiders Letter Agreement, dated May 16, 2023, by and among FEAC, the Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A., enGene Inc., enGene and the other parties named therein (incorporated by reference to Exhibit 10.1 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.2	Form of Subscription Agreement (incorporated by reference to Exhibit 10.2 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.3	Form of Subscription Agreement Side Letter Agreement (incorporated by reference to Exhibit 10.3 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.4	Form of enGene Lock-Up Agreement (incorporated by reference to Exhibit 10.4 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.5	Registration Rights Agreement, dated October 31, 2023, by and among enGene Holdings Inc., Forbion European Acquisition Corp. and each of the Holders identified therein (incorporated herein by reference to Exhibit 10.8 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.6	Private Placement Warrants Purchase Agreement, dated December 9, 2021, by and between FEAC and the Company and the Sponsor (incorporated by reference to Exhibit 10.4 to FEAC's Current Report on Form 8-K filed on December 14, 2021).
10.7	Non-Exclusive License Agreement, dated April 10, 2020, by and between enGene and Nature Technology Corporation (incorporated by reference to Exhibit 10.14 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +†
10.8	Master Service Agreement, dated November 11, 2019, by and between enGene and BioAgilytix Labs, LLC (incorporated by reference to Exhibit 10.15 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +†
10.9	Letter Agreement, dated May 16, 2023, by and among enGene, IQ, FEAC and enGene (incorporated by reference to Exhibit 10.16 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +†
10.10	Lease Agreement, dated December 29, 2022, by and between enGene and Are-Canada No. 5 Holdings, ULC (incorporated by reference to Exhibit 10.21 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.11	Waiver and Consent Letter, dated September 13, 2023, by and among FEAC, enGene Inc. and enGene Holdings Inc. (incorporated by reference to Exhibit 10.22 to enGene's Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023).
10.12	enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.20 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.13	Form of Nonqualified Stock Option Grant Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.21 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.14	Form of Incentive Stock Option Grant Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.22 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).

10.15	Form of Restricted Stock Award Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.23 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.16	Form of Restricted Stock Unit Award Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.24 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.17	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.25 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
10.18	Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on May 15, 2024).
10.19	enGene Holdings Inc. 2025 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on June 10, 2025).
10.20(a)	Employment Agreement, dated July 22, 2024, by and between enGene USA, Inc. and Ronald H. W. Cooper. (incorporated herein by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on July 24, 2024).#
10.20(b)	Amendment to Employment Agreement, dated October 2, 2025, by and between enGene USA, Inc. and Ronald H.W. Cooper (incorporated herein by reference to Exhibit 10.20(b) of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).#
10.21	Inducement Grant Agreement, dated July 22, 2024, by and between enGene Holdings Inc. and Ronald H. W. Cooper (incorporated herein by reference to Exhibit 10.5 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).#
10.22(a)	Employment Agreement, dated December 13, 2023, by and between enGene USA, Inc. and Ryan Daws (incorporated herein by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on December 13, 2023).#
10.22(b)	Amended Employment Agreement, dated June 10, 2025, by and between enGene USA, Inc. and Ryan Daws (incorporated by reference to Exhibit 10.3 of enGene's Quarterly Report on Form 10-Q filed with the SEC on June 12, 2025).#
10.23	Employment Agreement, dated April 22, 2024, by and between enGene USA, Inc. and Lee Giguere (incorporated by reference to Exhibit 10.2 of enGene's Quarterly Report on Form 10-Q filed with the SEC on June 14, 2024).#
10.24	Amended and Restated Employment Agreement, dated October 16, 2024, by and between enGene USA, Inc. and Alexander Nichols (incorporated herein by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on October 21, 2024).#
10.25	Amended and Restated Employment Agreement, dated October 21, 2024, by and between enGene Inc. and Anthony T. Cheung (incorporated herein by reference to Exhibit 10.32 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024).#
10.26	Employment Agreement, dated October 21, 2024, by and between enGene USA, Inc. and Joan Connolly (incorporated herein by reference to Exhibit 10.33 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024)#
10.27	Employment Agreement, dated May 21, 2025, by and between enGene USA, Inc. and Amy Pott (incorporated by reference to Exhibit 10.2 of enGene's Quarterly Report on Form 10-Q filed with the SEC on June 12, 2025).#
10.28	Employment Agreement, dated July 8, 2025, by and between enGene USA, Inc. and Jill Buck (incorporated by reference to Exhibit 10.6 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 11, 2025).#
10.29	Employment Agreement, dated July 8, 2025, by and between enGene USA, Inc. and Matthew Boyd (incorporated by reference to Exhibit 10.7 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 11, 2025).#
10.30(a)	Employment Agreement, dated November 8, 2023, by and between EnGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.01 of enGene's Current Report on Form 8-K filed with the SEC on November 9, 2023).#
10.30(b)	Transition and Modification Agreement, dated February 13, 2024 by and between enGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on February 14, 2024).#
10.30(c)	Amendment to Transition and Modification Agreement, dated July 23, 2024 by and between enGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on July 24, 2024).#
10.31	Employment Agreement, dated July 22, 2024, by and between enGene USA, Inc. and Raj Pruthi (incorporated herein by reference to Exhibit 10.3 of enGene's Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).#
10.32	Employment Agreement, dated September 15, 2025, by and between enGene USA, Inc. and Hussein Sweti (incorporated herein by reference to Exhibit 10.32 of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).#
10.33	Amended and Restated Loan and Security Agreement, dated December 22, 2023, by and among enGene Holdings Inc., enGene Inc. and enGene USA, Inc., as borrower, Hercules Capital, Inc., as agent, and the lenders from time to time party thereto (incorporated by reference to Exhibit 10.1 to enGene's Current Report on Form 8-K filed with the SEC on December 28, 2023). †+
10.34	First Amendment to Amended and Restated Loan and Security Agreement, dated December 18, 2024 (incorporated herein by reference to Exhibit 10.36 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024). †+
10.35	Form of Subscription Agreement, dated February 13, 2024 (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on February 14, 2024).
10.36	Form of Subscription Agreement, dated October 24, 2024 (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on October 25, 2024).
10.37	Open Market Sale AgreementSM, dated December 20, 2024, by and between enGene Holdings Inc. and Jefferies LLC (incorporated by reference to Exhibit 1.1 of enGene's Current Report on Form 8-K filed with the SEC on December 20, 2024).
10.38	99 High Street Office Lease, dated June 4, 2025, by and between 99 High Street Owner LLC and enGene USA, Inc. (incorporated by reference to Exhibit 10.1 of enGene's Current Report on Form 8-K filed with the SEC on June 9, 2025).
10.39	Lease Agreement Guaranty, dated June 4, 2025, by enGene Holdings Inc. in favor of 99 High Street Owner LLC (incorporated by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on June 9, 2025).
19.1	Insider Trading Policy (incorporated herein by reference to Exhibit 19.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024).
21.1	Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 21.1 of enGene's Current Report on Form 8-K filed with the SEC on October 31, 2023).
23.1	Consent of Independent Registered Public Accounting Firm (incorporated herein by reference to Exhibit 23.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (incorporated herein by reference to Exhibit 31.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (incorporated herein by reference to Exhibit 31.2 of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).
31.3*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, relating to the registrant's Amendment No. 1 to the Original Form 10-K.

31.4*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, relating to the registrant's Amendment No. 1 to the Original Form 10-K.
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (incorporated herein by reference to Exhibit 32.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (incorporated herein by reference to Exhibit 32.2 of enGene's Annual Report on Form 10-K filed with the SEC on December 22, 2025).
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation (incorporated herein by reference to Exhibit 97.1 of enGene's Annual Report on Form 10-K filed with the SEC on December 19, 2024).
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

* Filed herewith.
† Certain of the exhibits and schedules to these exhibits have been omitted in accordance with Regulation S-K Item 601(a)(5). The registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.
+ Portions of this exhibit are redacted in accordance with Regulation S-K Item 601(b)(10)(iv).
Indicates a management contract or compensatory plan or arrangement

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

enGene Holdings Inc.

Date: February 19, 2026

By: /s/ Ronald H. W. Cooper
Name: Ronald H. W. Cooper
Title: Chief Executive Officer and President

Pursuant to the requirements of the Securities Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Ronald H. W. Cooper Ronald H. W. Cooper	Chief Executive Officer, President and Director *(Principal Executive Officer)*	February 19, 2026
/s/ Ryan Daws Ryan Daws	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 19, 2026
/s/ Philip Astley-Sparke Philip Astley-Sparke	Director	February 19, 2026
/s/ Gerald Brunk Gerald Brunk	Director	February 19, 2026
/s/ Dr. Richard Glickman Dr. Richard Glickman	Director	February 19, 2026
/s/ Dr. William Grossman Dr. William Grossman	Director	February 19, 2026
/s/ Paul Hastings Paul Hastings	Director	February 19, 2026
/s/ Michael Heffernan Michael Heffernan	Director	February 19, 2026
/s/ Wouter Joustra Wouter Joustra	Director	February 19, 2026
/s/ Lota Zoth Lota Zoth	Director	February 19, 2026

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Directors and Executive Officers

Philip Astley-Sparke, *Director*
Gerald Brunk, *Director*
Dr. Richard Glickman, *Director*
Dr. William Grossman, *Director*
Paul Hastings, *Director*
Michael Heffernan, *Director*
Wouter Joustra, *Director*
Lota S. Zoth, *Director*
Ronald H. W. Cooper, *Chief Executive Officer, President and Director*
Matthew Boyd, *Chief Regulatory Officer*
Jill Buck, *Chief Development Officer*
Dr. Anthony T. Cheung, *Chief Scientific Officer*
Joan Connolly, *Chief Technology Officer*
Ryan Daws, *Chief Financial Officer*
Lee G. Giguere, *Chief Legal Officer and Corporate Secretary*
Dr. Alexander Nichols, *Chief Strategy and Operations Officer*
Amy Pott, *Chief Global Commercialization Officer*
Dr. Hussein Sweiti, *Chief Medical Officer and Head of Research and Development*

CORPORATE AND SHAREHOLDER INFORMATION

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Continental Stock Transfer & Trust Company
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New York, NY 10004-1561

Common Shares Listing
Our Common Shares and Warrants are listed on the Nasdaq under the symbols “ENGN” and “ENGNW,” respectively.

Investor Inquiries
The Annual Report on Form 10-K for the fiscal year ended October 31, 2025 (the “Original 10-K”) and Amendment No. 1 to the Original 10-K on Form 10-K/A (“Amendment No. 1”, and together with the Original 10-K, our “Annual Report”), and other investor information are available free of charge at https://engene.com/sec-filings/

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