enGene Holdings Inc.

2023 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, 2023

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 Saint-Laurent, QC, Canada	**H4R 2P1**
(Address of principal executive offices)	**(Zip Code)**

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, 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 January 25, 2024 was $43,848,040.

The number of the Registrant's Common Shares outstanding as of January 25, 2024 was 23,197,976.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K 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 on Form 10-K may include, for example, statements about:

- the ability of enGene to recognize the anticipated benefits of the Business Combination and related transactions, which may be affected by, among other things, competition and the ability of the combined business to grow and manage growth profitably;
- enGene's financial performance following the Business Combination, including financial projections and business metrics and any underlying assumptions thereunder;
- the ability to maintain the listing of the Common Shares and Warrants on Nasdaq or another national securities exchange;
- enGene's success in recruiting and retaining, or changes required in, officers, key personnel or directors following the completion of the Business Combination;
- enGene's plans and ability to execute product development, manufacturing process development, preclinical and clinical development efforts successfully and on anticipated timelines;
- enGene's ability to design, initiate and successfully complete clinical trials and other studies for its product candidates and its plans and expectations regarding its ongoing or planned clinical trials;
- enGene's plans and ability to obtain and maintain marketing approval from the U.S. Food and Drug Administration and other regulatory authorities, including the European Medicines Agency, for its product candidates;
- enGene's plans and ability to commercialize its product candidates, if approved by applicable regulatory authorities;
- the degree of market acceptance of enGene's product candidates, if approved, and the availability of third-party coverage and reimbursement;
- the ability of enGene's external contract manufacturers to support the manufacturing, release testing, stability analysis, clinical labeling and packaging of enGene's products;
- enGene's future financial performance and the sufficiency of enGene's cash and cash equivalents to fund its operations;
- the outcome of any known and unknown litigation and regulatory proceedings, including any legal proceedings that may be instituted against enGene or any of its directors or officers following the Business Combination; and
- enGene's 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:

- enGene is 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, its programs;
- enGene is able to enroll a cohort of patients in the Phase 2 LEGEND trial to assess EG-70's efficacy and safety in the BCG-naïve patient population to evaluate its ultimate potential as a monotherapy in first line patients and expanding EG-70's opportunity;
- enGene is able to file a Biologics License Application in 2025 with the FDA for approval to market EG-70 in the United States as a monotherapy to treat BCG-unresponsive NMIBC;
- EG-70's product profile can be integrated seamlessly into community urology clinics where the vast majority of NMIBC patients are treated;
- enGene is able to retain commercial rights to EG-70 in the United States and commercialize EG-70 independently, while selectively partnering outside of the United States;
- enGene is able to execute the "pipeline-in-a-product" development strategy for EG-70; and

- enGene is able to utilize the DDX gene delivery platform to develop effective, new agents 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 on Form 10-K 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"), could affect future performance and actual results to differ materially and adversely from those expressed in, anticipated or implied by forward-looking statements:

- the risk that the Business Combination disrupts current plans and operations of enGene as a result of consummation of the Business Combination;
- the ability to recognize the anticipated benefits of the Business Combination;
- risks applicable to enGene's business, including the extensive regulation of all aspects of enGene's business, competition from other existing or newly developed products and treatments;
- risks associated with the protection of intellectual property, enGene's ability to raise additional capital to fund its produce development activity, and its ability to maintain key relationships and to attract and retain talented personnel;
- the possibility that enGene may be adversely affected by changes in domestic and foreign business, market, financial, political, geopolitical, legal conditions and laws and regulations;
- the risk that any regulatory approvals are not obtained, are delayed or are subject to unanticipated conditions that could adversely affect enGene or the expected benefits of the Business Combination; or
- other risks and uncertainties set forth in the section entitled "Risk Factors" in this Annual Report on Form 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 Annual Report on Form 10-K. 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 on Form 10-K 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 on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K 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 Relating to Our Business

- The sizes of the markets and forecasts of market growth for the demand of our novel gene therapy platform, product candidates and other key potential success factors are based on a number of complex assumptions and estimates, and may be inaccurate.
- We expect to make significant investments in our continued research and development of EG-70, a novel non-viral gene therapy for the purpose of stimulating the adaptive immune system, EG-i08, a pulmonary program, and other new product candidates and gene therapies and services, 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 any 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.
- 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.
- Our recurring losses from operations and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern.
- We identified material weaknesses in our internal control over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may determine that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and the price of our Common Shares.
- 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 our product candidates.
- 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.
- 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 our gene therapy platform and our therapeutic product candidates among many potential options. As a result, we may forego or delay pursuit of other gene therapy technologies or other therapeutic product candidates that provide significant advantages over our platform, which could materially harm our business and results of operations.
- Our gene therapy platform is based on novel technologies that are unproven, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.
- 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 and any clinical trials or experience delays in completing or ultimately be unable to complete, the development and commercialization of any product candidates.
- 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.
- Our most advanced product candidates are complex to manufacture 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 provide supply of our product candidates 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 market opportunities for our product candidates 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 rely on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.
- 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. Once developed, our gene therapy platform and therapeutic product candidates will require regulatory approval, which is a lengthy, expensive, and inherently unpredictable process with uncertain outcomes and cost and 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 a 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 our product candidates, we will not be able to commercialize or will be delayed in commercializing our product candidates and our ability to generate revenue will be adversely affected. Even if we eventually gain approval for any of our product candidates, we may be unable to commercialize them.
- We may not obtain or maintain regulatory approval in all jurisdictions in which such approval may be required. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will obtain and/or maintain regulatory approval of our product candidates in other jurisdictions, while a failure or delay in obtaining or maintaining regulatory approval of our product candidates in one jurisdiction may have a material adverse effect on the regulatory approval or maintenance process in other jurisdictions.
- 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 the conflict between Russia and Ukraine 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 gene therapy 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.

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 enGene at prices below the current trading price of such securities, and may experience a positive rate of return based on the current trading price. Future investors in our Company may not experience a similar rate of return.
- The Warrants are not currently in the money and 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; the Warrants may expire worthless.
- enGene's management team has limited experience managing a public company, and the additional requirements for public companies may strain resources and divert management's attention.
- enGene may be unable to satisfy Nasdaq's continued listing requirements in the future, which could limit investors' ability to effect transactions in enGene's securities and subject it to additional trading restrictions.

PART I

Item 1. Business.

On October 31, 2023 (the "Closing Date"), enGene Holdings Inc. consummated the previously announced business combination (the "Reverse Recapitalization") with Forbion European Acquisition Corp., a Cayman Islands exempted company and a special purpose acquisition corporation, and enGene Inc., a corporation incorporated under the laws of Canada, pursuant to the Business Combination Agreement, dated as of May 16, 2023 (as amended, the "Merger Agreement"). Throughout this section, unless otherwise noted, "we," "us," "our" and similar words refer to, for periods prior to the Closing Date, enGene Inc. and its subsidiary, and for periods following the Closing Date, to enGene Holdings Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage biotechnology company focused on developing gene therapies to improve the lives of patients. We are developing non-viral gene therapies based on our 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. We believe our DDX platform, with its broad tissue and disease application, has the potential to take gene therapy beyond rare genetic diseases into oncology and other underserved therapeutic areas. We have established integrated capabilities with this platform to support the clinical development and potential commercialization of our gene therapies.

Our lead product candidate, detalimogene voraplasmid, or "EG-70," which is comprised of three gene cargos delivered via our proprietary DDX platform, is a therapy designed to generate a local immune reaction in proximity to tumors. We believe this enables the immune system to reduce or clear the tumor and develop memory to resist recurrence. Because this treatment does not need to deliver the therapeutic gene directly into tumor cells, it is applicable to many tumor types. We are currently developing EG-70 as a monotherapy to treat non-muscle invasive bladder cancer ("NMIBC") with carcinoma in situ ("Cis") in patients that have been unresponsive to treatment with Bacillus Calmette-Guerin, or "BCG," or what is referred to as "BCG-unresponsive NMIBC with Cis."

In NMIBC, carcinoma in situ, or Cis, is a flat, high-grade, sessile tumor that has a high likelihood of invading the deeper layers of the bladder wall. 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 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 this treatment, many of these cancers recur and are unresponsive to additional BCG, allowing the cancer to spread throughout and deeper into the bladder and often requiring surgical removal of the bladder (radical cystectomy). We believe BCG-unresponsive NMIBC with Cis is currently an underserved therapeutic segment with limited treatment options, and that there is a market opportunity for EG-70 as a monotherapy for this condition. While the potential market for EG-70 may not be limited to these patients, that is our current initial focus in working to bring EG-70 to market.

We estimate there are approximately 60,000 new patients globally each year with BCG-unresponsive NMIBC, of which up to 70% have Cis at the time of diagnosis of BCG-unresponsiveness. We derived this estimate from the overall global bladder cancer incidence of 550,000 patients per year, estimating the percentage of such patients with NMIBC, and further estimating the percentage of such patients who later develop BCG- unresponsiveness. See *"— Product and Pipeline Development — Lead Program: NMIBC Background and Unmet Need*."

EG-70 program is enrolling patients in a combined Phase 1/2 open label registrational study, referred to as "LEGEND" (ClinicalTrials.gov identifier NCT04752722). In addition, our preclinical research is focused on expanding the cancer indications that can be treated with EG-70. We are also in early stages of developing a second product candidate referred to as EG-i08 for treatment of Cystic Fibrosis.

Our Competitive Strengths

- **Proprietary "Next-Generation" DDX Platform** — We believe our DDX platform has the potential to be the next generation platform that takes gene therapy beyond rare diseases. It has a high degree of payload flexibility, by which we mean the capacity to include multiple genes per drug product (including DNA and RNA) 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. We believe products developed using the DDX platform can overcome many of the significant challenges that have historically faced gene therapy, including the inability to re-dose, safety concerns, limited efficacy, high cost of goods, lack of commercially viable manufacturing technology, limited ability to effectively target localize diseases, systemic toxicity, and difficulties with effective administration.
- **Fast Tracked Product Candidate in Underserved Market** — We are developing EG-70, which has received FDA Fast Track designation, as a monotherapy for BCG-unresponsive NMIBC with Cis, which currently is an underserved therapeutic segment with limited drug and other treatment options. Although Fast Track designation may expedite the development or

review process, there can be no assurance accelerated approval designation will lead to a faster development, regulatory review or approval process or increase the likelihood EG-70 will receive marketing approval. The 3-month data collected from all patients in the Phase 1 portion of the ongoing LEGEND trial demonstrate that EG-70 is well-tolerated across all tested doses. Across all dose levels tested in the Phase 1 study, a 3-month complete response, or "CR," rate of 68% (N=22) was observed. Importantly, 70% of patients (7 out of 10) treated in the recommended dose planned for Phase 2 (RP2D) experienced a 3-month CR. Phase 1 patients who were treated in the RP2D cohort and who elected to continue treatment and receive an additional 12-week cycle had a 60% CR rate at 6-months (6 out of 10). While we are encouraged by these results, the Phase 1 portion of this study was designed to evaluate safety and was not designed to evaluate efficacy in a statistically meaningful way.

- **Product Profile Tailored to the Practical Needs of Clinicians and Patients** — Gene therapies and gene therapy 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 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 gene therapy product, preparative treatment of tissues with a solvent or wash agent, enhanced refrigeration/cold chain storage requirements, and guidance to avoid close personal contact with the patient during the treatment period. By contrast, EG-70 can be handled in accordance with biosafety level 1 guidelines, does not require the aforementioned precautions in handling or decontamination of fluids or bodily surfaces following dosing, and has no ultra cold chain storage requirements. We believe these product characteristics will position EG-70 as a preferred choice among both physicians and patients.
- **"Pipeline-in-a-Product" Potential** — Through the LEGEND study, we have demonstrated that EG-70 is able to traverse and transfect mucosal epithelia, express multiple cargos in the mucosal tissue and simultaneously activate multiple arms of the immune system. We have demonstrated in pre-clinical models the potential for expanding EG-70 to treat multiple additional solid tumors.
- **Scalable, Proprietary Manufacturing Process** — We developed the DDX platform in-house, and in addition, have developed manufacturing processes to produce EG-70 that we believe are robust, cost- effective and scalable. These manufacturing processes which involve incorporation of plasmid DNA (API) with the DDX carrier at a defined concentrations 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 expression of transgene in target tissues. We believe we have scaled up our manufacturing processes to a level that will be able to meet the needs of commercial launch for EG-70. We believe our manufacturing process is in accordance with Good Manufacturing Practice (cGMP) and quality system regulations for drugs and biologics.
- **Experienced Management Team** — Our management team has extensive experience across oncology, respiratory and multiple other therapeutic areas and modalities and are well-equipped to lead our drug development and commercialization efforts.

Our Strategy

- **Focus on advancing our lead product candidate EG-70 through late-stage clinical development and seek regulatory marketing approval in the United States**. We are focused on bringing EG-70 to market as a monotherapy for BCG-unresponsive NMIBC with Cis, which currently is an underserved therapeutic segment with limited treatment options. According to published reports, currently available drug options have been characterized by limited effectiveness and durability, unfavorable toxicity, manufacturing challenges, and/or practical limitations including lack of re-dosability and tropism for particular organ systems such as the liver. As a result, the primary treatment option available for most BCG-unresponsive NMIBC is a radical cystectomy, which can often result in negative outcomes, mortality, and a reduced quality of life. In response to this urgent unmet medical need, the FDA has issued guidance for the design of clinical studies for development of novel NMIBC treatments, with a goal of encouraging development of alternative treatments to this drastic surgery. We have followed this guidance and discussed our EG-70 development plan with the FDA, and subsequent to these discussions, the FDA cleared us to initiate the pivotal, Phase 2 portion of the LEGEND clinical trial. In this trial, we are evaluating the safety and efficacy of EG-70 in a single arm, open label, multicenter, Phase 2 pivotal portion of our LEGEND trial using the RP2D, given to patients in multiple cycles. We currently aim to file a Biologics License Application ("BLA") in 2025 with the FDA for approval to market EG-70 in the United States as a monotherapy for BCG-unresponsive NMIBC with Cis, and we believe EG-70's product profile will integrate seamlessly into community urology clinics where the vast majority of NMIBC patients are treated.
- **Build a fully integrated company by independently commercializing approved products in indications and key geographies where we believe we can maximize our product candidates' value**. We currently own all development and commercialization rights for our product candidates and programs. To maximize the potential of EG-70, we currently plan to retain commercial rights to EG-70 in the United States and commercialize EG-70 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.

- **Expand the application of EG-70 to additional bladder cancer indications**. Given the high unmet need in NMIBC, we plan to enroll a cohort of patients in the Phase 2 LEGEND trial to assess EG-70 in the BCG-naïve patient population to evaluate its ultimate potential as a monotherapy in first line patients and expanding EG-70's opportunity.
- **We also believe we could potentially develop EG-70 as a treatment for locally advanced muscle invasive bladder cancer (MIBC)**. Preclinically, we have shown in an orthotopic model of locally advanced bladder cancer that mice receiving EG-70 exhibit profound and durable anti-tumor immunity, with cured mice developing resistance to subsequent local or distal re-challenge with bladder tumor cells. This pre-clinical observation supports the potential clinical evaluation of EG-70 in patients with intact bladders diagnosed with locally advanced or metastatic bladder cancer. Furthermore, based on the well-defined mechanism of action of EG-70, we expect that to the extent EG-70 proves to be both safe and effective in the high-risk NMIBC population, we could potentially also study its use in the earlier stage low- and intermediate-grade NMIBC populations.
- **Pursue "pipeline-in-a-product" strategy in expanding EG-70 as immuno-oncology therapy to address unmet needs in a wide range of solid tumors**. The demonstrated mechanism of action of EG-70, namely, synergistic activation of innate and adaptive immune system to turn "cold" tumor microenvironments "hot," stimulates cancer antigen recognition, creates a pro tumor-killing environment in the local milieu, and induces immunological memory against the cancer. We believe it is therefore potentially applicable across a wide range of indications in oncology and enables us to pursue a "pipeline-in-a-product" development strategy for EG-70. We have already demonstrated strong proof-of-concept data for EG-70 in other solid tumor models, and plan to advance EG-70 to other cancer indications with significant unmet needs. We are evaluating EG-70's potential application in genitourinary (prostate, upper urinary tract) and gynecological (cervical, ovarian, endometrial, vaginal vulvar) cancers. This potentially would allow for rapid entry of EG-70 into new areas of clinical development.
- **Apply our proprietary DDX platform to other mucosal tissues**. We believe that our early clinical data combined with our preclinical proof-of-concept studies demonstrate the value and the breadth of our DDX platform in delivering genetic medicines to mucosal tissues. We believe this could potentially allow us to use this DDX platform to develop effective new agents beyond EG-70, thereby unlocking better outcomes for historically difficult-to-treat conditions. Our belief is driven by our DDX platform's several key advantages and points of differentiation relative to others in the gene therapy field, which we believe will enable us to bring gene therapy to tissues beyond the liver, muscle, and central nervous system, and will enable repeat dosing of such genetic medicines. For example, our platform's lack of significant vector-based immune response supports the ability to dose repeatedly. Furthermore, the tolerability of DDX in the clinic is bolstered by the lack of genomic integration concerns. Importantly, we have also developed a streamlined, end-to-end cGMP manufacturing process that can support commercial launch of EG-70 and that can be readily applied to new drug products.

Our Gene Therapy Platform for Mucosal Tissues

Historically, gene therapy has been hampered by several significant challenges associated with the use of viral vectors as gene delivery vehicles.

- Early gene therapies using viral vectors (i.e., viruses used as carriers and delivery agents in gene therapies) were found to have led to cancers in patients due to insertional mutagenesis, and in at least one case, a severe innate immune response that led to multiple-organ failure and death. More recently, high doses of the frequently used adeno-associated virus (AAV) viral vector have been found to lead to many serious adverse events, including hepatotoxicity, hemolytic anemia, acute kidney failure, neurotoxicity and myocarditis. These safety issues received significant attention and we believe they negatively influenced public perception of gene therapy's overall safety.
- In addition, because patients' immune systems react to the proteins in the vector shell, most viral-based gene therapies can only be applied once. This limit on the ability to re-dose the therapy or titrate it to a patient's needs impedes the ability to achieve long-term consistent expression of delivered genes in the target tissues.
- Constraints on the size of genetic cargos that can be delivered by viral vectors, such as AAV, limit the number of indications for which they may be applicable and can often require the use of truncated, non-natural proteins to overcome this packaging limitation.
- Finally, the high manufacturing costs of viral vectors and historical lack of scalable manufacturing systems capable of withstanding regulatory scrutiny and meeting possible market demand limits patient access to and market adoption of many gene therapies.

We believe our proprietary DDX platform can overcome these limitations of traditional viral gene delivery platforms. As described in more detail below, unlike viral vectors, we believe the delivery vehicle we have developed is:

- non-viral, consisting of synthetic polymeric carriers;
- non-immunogenic, and therefore, as has already been demonstrated in human clinical trial, re-dosable;

- able to carry large genetic payload — our EG-70 leverages a DNA payload that comprises three distinct expressed genes delivered as a single drug product; manufactured based entirely on synthetic chemistry (rather than complex biological production systems), in a process that is highly controlled, reproducible, cost-effective and scalable; and
- able to traverse mucosal barriers, allowing the targeting of organs traditionally intractable for gene therapy.

Mucosal tissues such as the bladder, lungs, and gut, comprise a vast surface area across the human body. Their relative ease of accessibility makes these tissues attractive targets for modalities that have the potential to be locally targeted such as tissue-localized gene therapy. In spite of these properties, gene therapies have struggled in mucosal tissues, as the biological barrier function of the tissues has rendered them an inhospitable environment to most drug products or gene delivery modalities. Thus, although gene therapy has revolutionized other fields of medicine, it has left behind many patients suffering from illnesses that manifest in mucosal tissues.

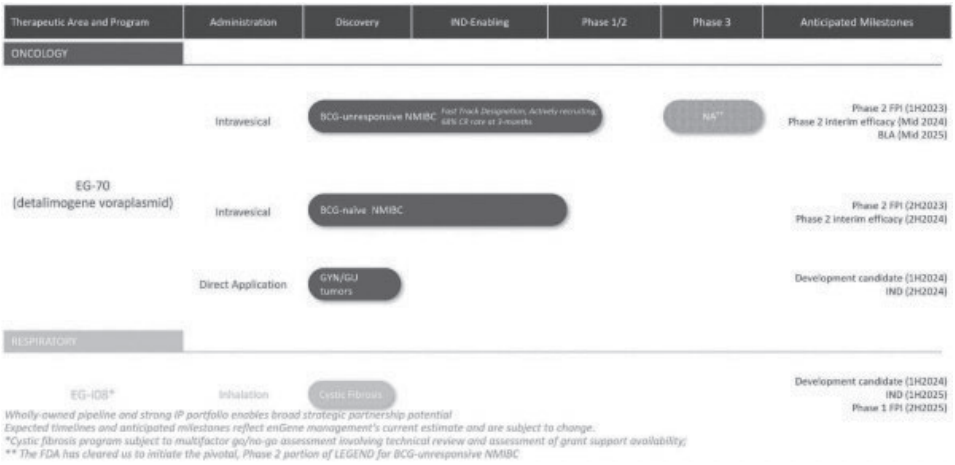
enGene was founded to seek to address these underserved patients with novel genetic medicines. Our DDX platform allows non-viral gene therapies to be dosed directly into the lumen of the targeted mucosal tissue. Once inside the lumiral cavity, the DDX nanoparticles transport nucleic acid medicines (DNA or RNA) into the mucosal epithelial cells. For example, the transported genetic medicines can encode for proteins, peptides, antibodies, and other non-coding RNA molecules.

Product and Pipeline Development

Our lead product candidate program is EG-70 (detalimogene voraplasmid), which we are developing as a monotherapy for the treatment of BCG-unresponsive NMIBC with Cis. This lead program is currently enrolling in a combined Phase 1/2 open label registrational study, "LEGEND" (ClinicalTrials.gov identifier NCT04752722), the data from which we will incorporate in a Biologics License Application to be submitted at the conclusion of the Phase 2 portion of the trial. This trial also includes a BCG-treatment naïve arm to assess EG-70 as a potential first-line therapeutic for high-risk NMIBC. We currently expect to make an additional Investigational New Drug application ("IND") in 2024 for the application of EG-70 to an additional as-yet unnamed indication, most likely in the gynecological or genitourinary cancer space. Until such time as we finalize and announce this second indication, it will be difficult to forecast or predict further clinical development timelines, as we expect they will be determined by the ultimate indication we elect to pursue.

A second product candidate, EG-i08, is in preclinical development for cystic fibrosis, with development candidate nomination expected in 2024 subject to a multifactor go/no-go assessment involving technical review and assessment of grant support availability. As above, given the early stage of this program, it will be difficult to forecast or predict further clinical development timelines at this time.

The following chart shows the current status of our product development to the extent we can estimate key actions and milestones at this time:

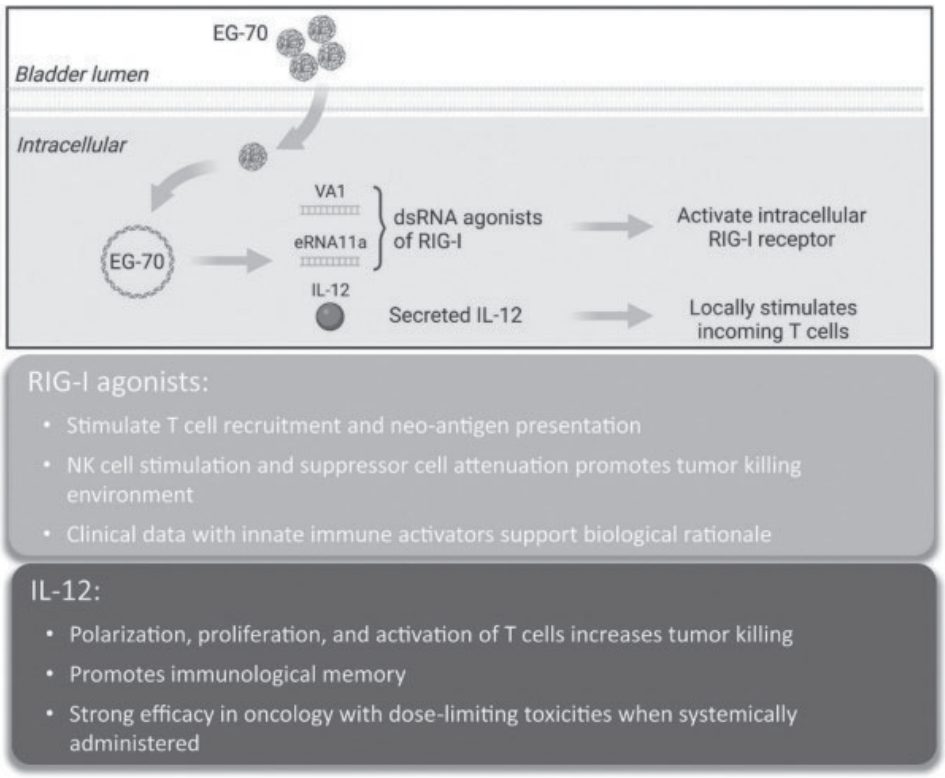


EG-70 (detalimogene voraplasmid): Immuno-oncology

Mechanism of action

Our EG-70 drug product candidate comprises nanoparticles, with a DNA nanoplasmid encapsulated by a non-viral, DDX polymer-based delivery vehicle. The DDX delivery vehicle consists of a highly derivatized chitosan backbone and includes reversible PEGylation (where PEG stands for polyethylene glycol) to facilitate diffusion through protective epithelial shields, such as mucous in the lung and the GAG (glycosaminoglycan) layer in the bladder.

The EG-70 drug substance plasmid DNA encodes multiple open reading frames expressing three distinct transcripts: a single-chain interleukin-12 protein (IL-12) and two non-protein coding RNA products, eRNA11a and VA1, which coordinate to stimulate the retinoic acid-inducible gene I (RIG-I) pathway. Together, this combination of RIG-I activation and IL-12 secretion serves to activate both innate and adaptive immunity, creating a pro-inflammatory, tumor-killing environment:



RIG-I is expressed in most cell types and highly expressed in epithelial cells. It is also expressed in tumor cells and recognizes double stranded RNA molecules with an uncapped 5′ triphosphate (5′PPP) or 5′ diphosphate (5′PP) end to initiate a signaling cascade that results in the production of Type I interferons (IFN) and proinflammatory cytokines. The activation of RIG-I 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. IL-12 is an immunomodulatory cytokine primarily produced by antigen presenting cells, such as dendritic cells (DCs) and macrophages, following bacterial or viral infection. Signaling through the IL-12 receptor complex, expressed on natural killer (NK), NK-T, and activated effector CD4+ and CD8+ T cells, enhances the cytotoxicity of effector cells and results in T cell proliferation, polarization to a type 1 helper (Th1) phenotype, and interferon-gamma (IFNγ) production. The production of IFNγ is central to the potent anti-tumor and anti-angiogenic functions of IL-12. 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 IL-12 protein is intended to 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").

Clinical trials using systemic or subcutaneous administration of IL-12 to treat various solid malignancies have resulted in severe dose-limiting toxicities, resulting in a marginal therapeutic window. In contrast, local delivery of IL-12 has emerged as a clinical strategy to enhance immunological activity within the TME, promote systemic immunity, and minimize systemic toxicity. Using preclinical models, we have demonstrated a therapeutic benefit of co-expression of RIG-I activators and IL-12 in bladder urothelium to localize therapeutic effect and exposure within the bladder TME without systemic toxicity. We believe these clinical trials demonstrated that coupling the potent stimulation of the innate immune system by RIG-I agonism to stimulation of the adaptive immune response by IL-12 provides robust and persistent anti-tumor activity in a murine orthotopic bladder cancer model. Moreover, we also demonstrate translatable expression across multiple species, including humans.

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 is expected 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; and for women, the chance is about 1 in 91.

Fortunately, due to early warning signals such as hematuria, many instances of bladder cancer are diagnosed while still localized to the bladder urothelium, and these NMIBCs represent approximately 80% of newly diagnosed bladder tumors.

Unmet Medical Need

Since NMIBC is often diagnosed early, it can be treated in its early stage to prevent invasive therapy or organ removal. The initial treatment plan for these patients involves local therapy to the inside of the bladder to treat the disease before it can become invasive, while limiting systemic side effects. Since the 1970s, the primary therapy for high-risk NMIBC has been intravesical BCG therapy, despite the adverse effects with which it is associated and a >50% failure rate. Due to the increased use of BCG in this setting and loss of several manufacturers of BCG, supply constraints have resulted in a shortage of the 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 revised their treatment guidelines to recommend that BCG should be prioritized for patients with high-risk disease and they should receive full-strength BCG induction, but subsequent maintenance doses could be one-half to one-third the standard dose. This situation is projected to continue into 2026 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.

In general, while most patients are free of recurrence at 1 year with induction and maintenance full-dose BCG, as many as 75% develop a new tumor in 5 years and unfortunately a second course of BCG is unlikely to provide further benefit. This population represents a population of patients with a profound medical need to keep their cancer from becoming invasive while being able to preserve their bladders. In addition, patients receiving local salvage therapy for NMIBC with Cis who failed BCG induction and maintenance generally do not respond to more BCG, or to other intravesical chemotherapy agents.

We estimate there are approximately 60,000 new patients globally each year with BCG-unresponsive NMIBC, of which up to 70% have Cis at the time of diagnosis of BCG-unresponsiveness. We derived this estimate from the overall global bladder cancer incidence of 550,000 patients per year, estimating the percentage of such patients with NMIBC, and further estimating the percentage of such patients who later develop BCG- unresponsiveness. At the anticipated time of EG-70's BLA application in 2025, we estimate that there will be approximately 9,800 new NMIBC patients with BCG-unresponsive NMIBC in the United States per year, of which up to 70% will have Cis at time of diagnosis. Outside of the United States, we believe the market will be comparable on a population-adjusted basis, although per-capita bladder cancer incidence has been known to vary across countries. Of note, these are only our current estimates and 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. For individuals with BCG-unresponsive NMIBC with Cis, treatment options are currently quite limited. In the case of papillary bladder tumors, a frequent precursor condition to BCG-unresponsive NMIBC with Cis, gemcitabine and mitomycin are given as a single-dose of intravesical chemotherapy shortly after surgical removal of the tumor to reduce the recurrence rate; however, they are not FDA-approved to be used for NMIBC with Cis. VALSTAR® (valrubicin) was approved by the FDA for salvage therapy in BCG-unresponsive NMIBC patients with Cis, but is not recommended by the National Comprehensive Cancer Network (NCCN) in their guidelines due to the low CR rate.

The FDA approval of Keytruda® (pembrolizumab) in 2020 for the treatment of patients with BCG- unresponsive NMIBC with Cis (with or without papillary tumors) provided a systemic, intravenous option for therapy. However, we believe the adverse event profile of Keytruda combined with its relatively limited durability and its systemic route of administration, typically by medical oncologists rather than urology clinics, may limit its widespread adoption as a treatment option.

Adstiladrin® (nadofaragene firadenovec-vncg) was recently approved by the FDA for patients with BCG-unresponsive NMIBC with Cis. However, Adstiladrin® has faced manufacturing challenges which limited its availability at its product launch.

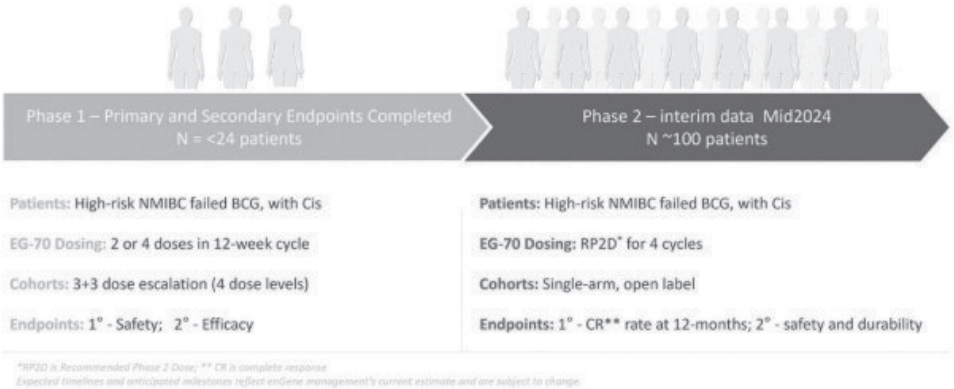
In summary, despite these recent FDA approvals, for patients with BCG-unresponsive NMIBC, treatment options are limited, and so the standard therapy has been radical cystectomy, which is associated with significant complications, including a lower quality of life, and risk of death. Therefore, we believe the development and discovery of new treatment options for BCG-unresponsive NMIBC with Cis is still a high priority to decrease the morbidity, burden of health-care expenditures, and mortality related to bladder cancer.

In response to this urgent unmet medical need due to the lack of treatment options and BGC shortage, the FDA has issued guidance for the design of clinical studies for development of novel NMIBC treatments, with a goal of encouraging development of alternative treatments to radical cystectomy. We have followed this guidance and discussed with the FDA our EG-70 development plan, and subsequent to these discussion, the FDA cleared us to initiate the pivotal, Phase 2 portion of the LEGEND study. We believe EG-70 has the potential to serve as a safe and effective immuno-oncology therapy to directly address this unmet need. We are encouraged by these results; however, the Phase 1 portion of this study was designed to evaluate safety and was not designed to evaluate efficacy in a statistically meaningful way.

LEGEND: A Phase 1/2 Study of EG-70 in NMIBC

Study Design

LEGEND is a Phase 1/2, open-label, multicenter, safety and dose-finding study conducted in the United States and initiated in February 2021 to determine the safety, tolerability, and efficacy of EG-70 in adult patients with NMIBC with Cis who have failed BCG therapy and are recommended for radical cystectomy, or high- risk NMIBC patients with Cis who are BCG-naïve or have received incomplete BCG treatment. The study consists of two phases, beginning with a Dose-Escalation Phase (Phase 1). The key objective for the Phase 1 portion of the study is evaluation of safety and tolerability. While not statistically powered for efficacy, an evaluation of efficacy was a secondary objective, with a Phase 2 study to be conducted at the RP2D. Eligible BCG-unresponsive NMIBC patients with Cis have been enrolled in Phase 1 and will continue to be enrolled in Cohort 1 of Phase 2, which has already begun. Eligible high-risk NMIBC patients with Cis who have been incompletely treated or are BCG-naïve will be enrolled starting in Phase 2 in a separate single-arm cohort (Cohort 2). The schema, with key design features, for the cohorts that are unresponsive to BCG is defined below.



All patients in Phase 1 received at least one cycle of treatment with EG-70. A cycle is 12 weeks in duration. Those patients who have complete response or stable disease (SD) at the end of Cycle 1 (Week 10) may (in association and consultation with their physician) choose to continue receiving treatment for up to a total of 4 cycles, provided they do 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.

Study Endpoints

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

Result: Safety

Twenty-four patients have received at least one dose of EG-70 in the Phase 1 study, with the total number of AEs and most commonly reported AEs across all 24 patients defined in the table below. The majority (97%) of AEs have been Grade 1 or 2 and largely consistent with the same events seen with instrumentation, catheterization, and intravesical instillation of any agent. Four Grade 3 SAEs have been observed in Phase 1. However, on review, it was observed that the renal failure was present at baseline before treatment with EG-70. The other three Grade 3 SAEs were considered unrelated to the study drug. There was no association between the severity or incidence of AEs and the dose level. In addition, AEs were not more frequent or severe later cycles of dosing. The following table summarizes the Phase 1 safety results.

Reported AEs to-date are largely consistent with instrumentation/intravesical administration

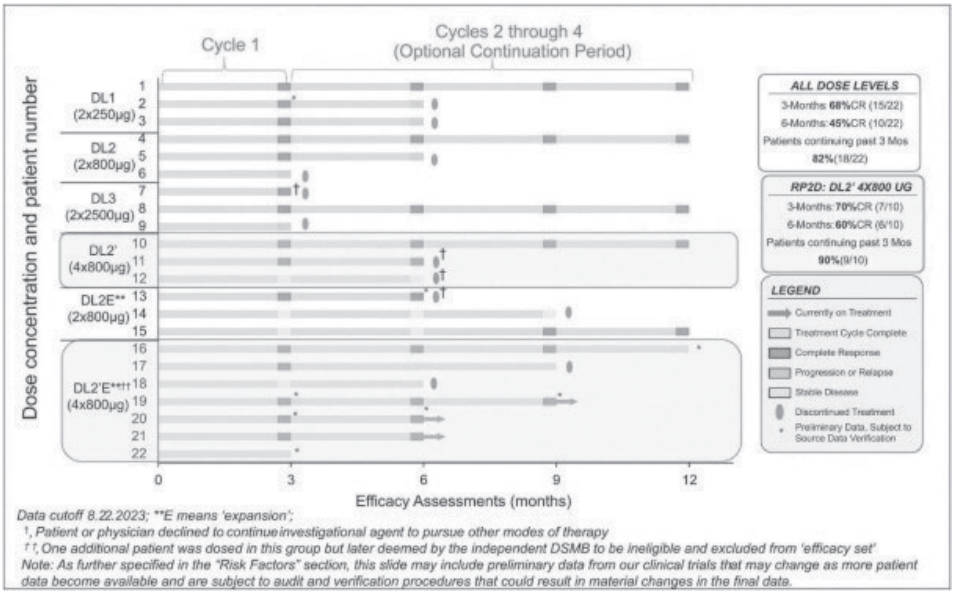
	Grade 1 AEs (mild)	Grade 2 AEs (moderate)	Grade 3 AEs (severe)	Grade 4 AEs (life-threatening)	Grade 5 AEs (result in death)
Aggregate Data (N, all dose-levels)	99	29	4	0	0
Most commonly reported AEs (%)	• Hematuria (8%) • Dysuria (6%) • Arthalgia (4%) • Contusion (4%) • Constipation (3%) • Flank pain (3%) • Micturition urgency (3%) • Pyrexia (3%) • Fatigue (3%)	• UTI (17%) • Urinary tract infection-enterococcal (3%) • Micturition urgency (7%)	• Renal failure* • Pneumonia** • Pneumonitis** • Meniscus injury**	-	-

*Data cutoff 08.22.2023; *patient had a history of renal failure – enrollment criteria for Phase 2 amended to exclude history of renal failure; ** Deemed Not Related to study drug*

Results: Efficacy

Efficacy was assessed by the standard three criteria 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 on 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, see the footnote to the table below.

The plot below captures individual subjects in each row, organized chronologically from the first patient enrolled (#1) to the last enrolled in Phase 1 (#22). The dose group is captured on the left-hand side of the plot, with DL1, DL2, DL3 reflecting half-log increments in amount of plasmid DNA instilled, as dose. Each of these three regimens reflects delivery of a dose on Weeks 1 and 2 of each 3-month cycle, whereas the 'prime' dosing schedule indicated as DL2' reflects 4 instillations of EG-70 in each 3-month cycle, namely at Weeks 1, 2, 5, and 6. Expansion cohorts after safety had been demonstrated in the initial cohort of 3 patients is indicated by the suffix 'E'. Overall, across all doses, 16 of 22 patients dosed with EG-70 achieved a Complete Response, or "CR," for a best overall CR rate of 73%. Specifically, at the 3-month timepoint, this CR rate was 68% (15 of 22), with 82% (18 of 22) of patients continuing to receive additional doses of the study drug beyond 3 months. Within the dose selected for the pivotal portion of the study (DL2'), the CR rate at 3 and 6 months was 70% and 60%, respectively, with 90% of patients continuing on the study drug beyond 3 months. Of note, patient #1 has maintained a CR for 18 months after the first dose of EG-70.



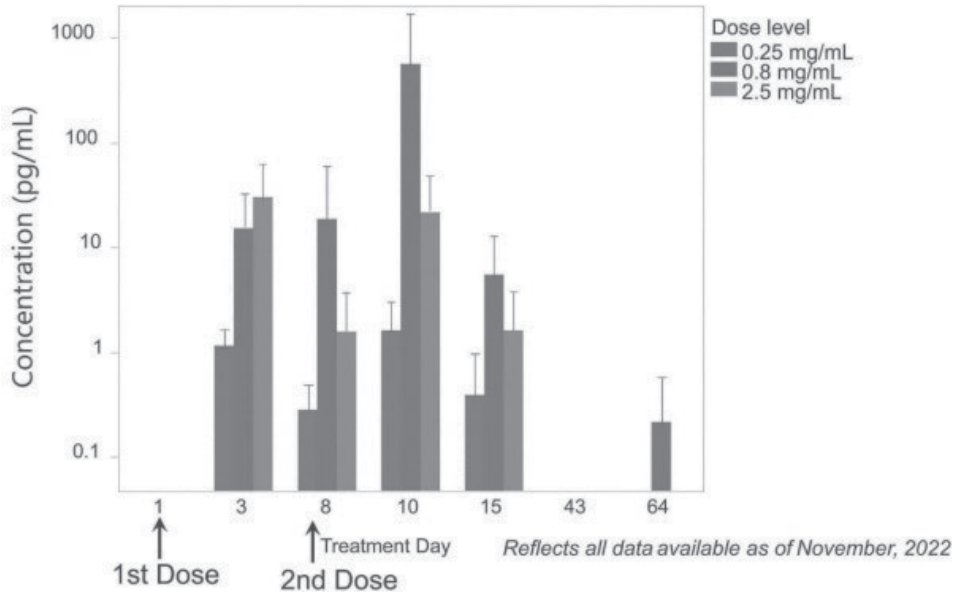
*Data cutoff 8.22.2023; **E means 'expansion';*
†, Patient or physician declined to continue investigational agent to pursue other modes of therapy
††, One additional patient was dosed in this group but later deemed by the independent DSMB to be ineligible and excluded from 'efficacy set'
Note: As further specified in the "Risk Factors" section, this slide may include preliminary data from our clinical trials that may 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.

Pharmacodynamics

Urine was monitored during the Phase 1 study to assess expression of our secreted, therapeutic transgene protein product, IL-12. As can be seen in the figure below, IL-12 was not detected in any patient at the baseline, pre-treatment timepoint. By contrast, after treatment, IL-12 was detected in the urine of all patients dosed, with dose levels (DL) 2 and 3 (800 and 2500 mg of plasmid DNA, respectively) demonstrating an order of magnitude higher levels of IL-12 than dose level 1. Together, we believe these data demonstrate:

- proof-of-concept that the EG-70 drug product is transfecting human cells and expressing therapeutic products; and

- proof-of-concept that the route of administration drives local expression, without the liability of systemic exposure to immune-modulating agents.



Phase 2 Trial

The Phase 2 portion of the study is open-label and is comprised of two independent single arm cohorts of patients with Cis-containing NMIBC (with or without papillary disease). Cohort 1 is BCG-unresponsive patients. Cohort 2 is BCG-naïve or BCG-incompletely treated patients. Although the treatment is the same for each cohort, an independent set of analysis will occur for each cohort.

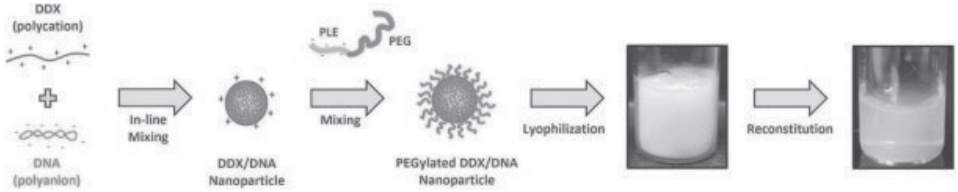
In Phase 2, cycles will be 12 weeks in duration. Patients in either cohort who have exhibited SD or CR at Week 12 will continue treatment with EG-70 until Week 24, whereas patients with PD will discontinue treatment. Patients who experience and maintain CR at Week 24 will receive additional cycles every 12 weeks until Week 48. Percentage of patients with CR at 48 weeks, based on cystoscopic appearance, urine cytology, and appropriate biopsies will be the co-primary endpoint together with the nature, incidence, relatedness, and severity of treatment emergent adverse events. Secondary endpoints will include progression free survival, CR rates at 12, 24, 36, and 96 weeks, as well as CR rate by 24 weeks, and the duration of response of the responding patients.

Preclinical Validation of Mechanism of Action: EG-70 for bladder cancer

We have characterized EG-70 preclinically so as to validate that the combination of RIG-1 agonism and IL-12 secretion eradicates preclinical tumor models.

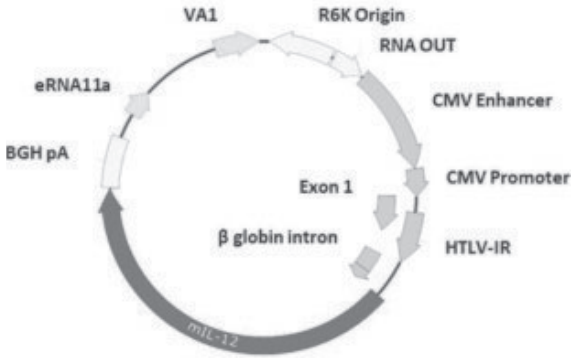
Preparation and characterization of polymer-based nanoparticles loaded with plasmid DNA

EG-70 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.

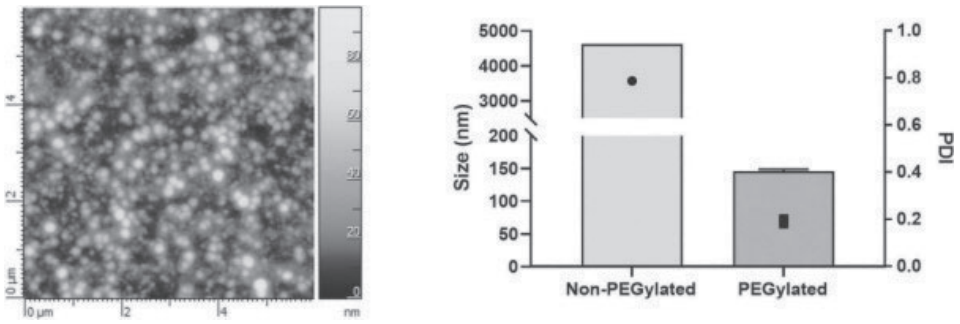


The pDNA of EG-70 encodes the two subunits (p40 and p35) of the human (h) IL-12 cytokine. Encoded within the same plasmid are two RNA products (adenoviral VA RNA1 (VA1) and eRNA11a; annotated together as eRNA41H) that coordinate to activate RIG-I. The dsRNA directly induces the intracellular protein 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 and increase transgene expression. Of note, the eRNA11a and VA1 sequences are not species specific and thus identical in the plasmids encoding for either human or mouse IL-12 protein.

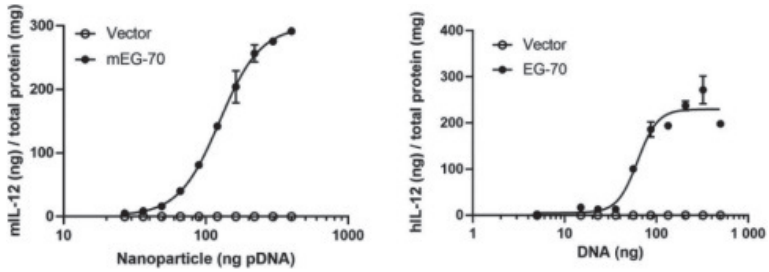


Formulating DDX with pDNA results in mostly spherical nanoparticles, as shown in the figure below (left) with an average diameter (Z-average ± SD) of 115 ± 9 nm and an average polydispersity index (PDI ± SD) of 0.15 ± 0.03 (figure below, right panel, left and right axes, respectively). The near-neutral zeta potential following non-covalent PEGylation by adsorption of PEG-b-PLE to the core nanoparticle surface (average 3.4 ± 0.9 mV) significantly improved nanoparticle colloidal stability following instillation and incubation for 1 hour in mouse bladder.



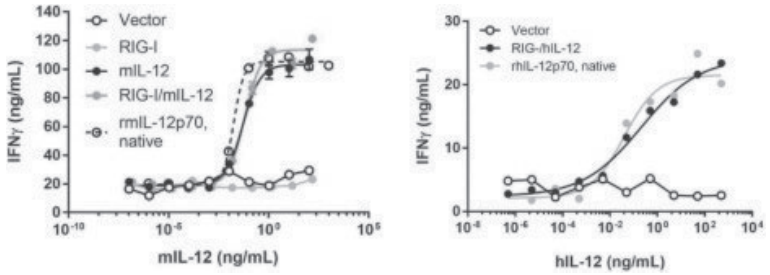
IL-12 expression and function: Nanoparticles mediate the expression of transgene products and bioactivity in cultured cells

Given that human hIL-12 lacks biological activity in mice, a surrogate plasmid that encodes murine IL-12 (mIL-12) was used to generate nanoparticles for preclinical studies in mice (referred to herein as "mEG-70" to indicate the mouse proxy for EG-70 drug product). To evaluate the dose-dependent expression of transgene mIL-12 protein, secreted mIL-12 was measured in murine urothelial carcinoma cells (MB49) transfected with increasing DNA concentration. As shown in the left panel of the figure below, a dose-dependent increase in secreted mIL-12 protein was observed following dosing of MB49 cells. Similarly, hIL-12 protein was expressed in a dose-dependent manner following transfection of human primary bladder epithelial cells with EG-70 (right panel). No IL-12 protein was detected in supernatants of cells transfected with control nanoparticles containing an empty plasmid ('Vector' negative controls), demonstrating transgene-specific IL-12 production.



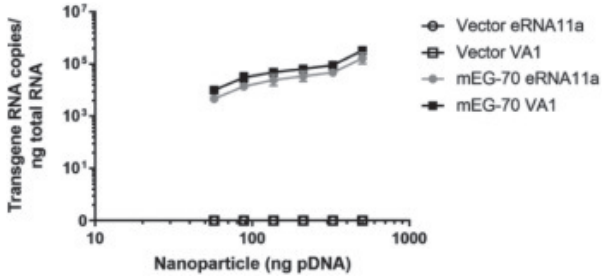
The production of IFNγ is central to the potent anti-tumor activity of IL-12. The figures below demonstrate the downstream function of the IL-12 produced from the in vitro transfections described above, with mouse and human experiments captured in the left and right panels, respectively. Transgene mIL-12 protein recovered from supernatant of transfected cells as described in the above figure elicited a dose-dependent increase in IFNγ production that was comparable to IFNγ levels observed with recombinant IL-12 protein, both in the presence (RIG-I/mIL-12) or absence (mIL-12) of transgene RIG-I agonists. In contrast, only baseline IFNγ was produced from cells exposed to an equivalent volume of supernatant from cells transfected with control plasmids lacking IL-12 (left panel).

Similarly, hIL-12 protein stimulated human peripheral blood mononuclear cells (PBMCs) to produce IFNγ in a dose-dependent manner with comparable potency to recombinant hIL-12 protein (right panel).



RIG-I agonist expression and function: Nanoparticles mediate the expression of transgene products and bioactivity in cultured cells

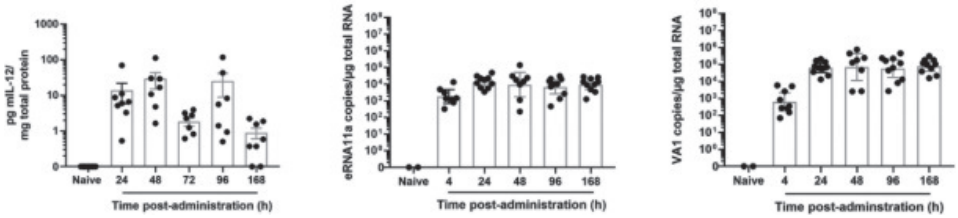
Dose-dependent expression of both RIG-I agonists was also observed in MB49 cells by RT-qPCR (figure below). Similar to IL-12, no eRNA11a or VA1 expression detected in cells transfected with negative control nanoparticles.



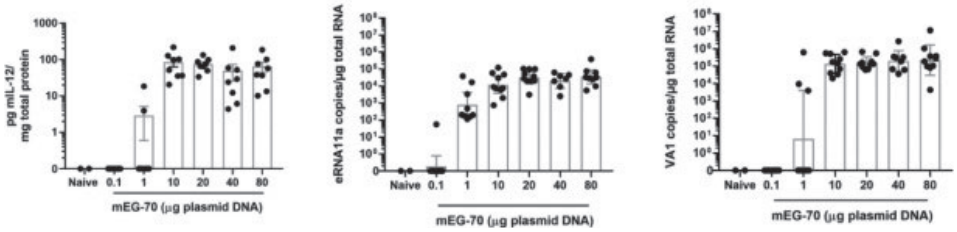
RIG-I agonists eRNA11a and VA1 RNA stimulate the production of IFNß. Consequently, IFNß production was measured in MB49 cells transfected with mEG-70 or control plasmids to confirm bioactivity of EG-70 encoded RIG-I agonists. Transfection of cells with nanoparticles containing pDNA encoding RIG-I agonists (either mEG-70 or RIG-I) resulted in a dose-dependent production of IFNß (figure below, left panel) and IFNα (figure below, right panel) confirming RIG-I activation. Conversely, production of IFNß and IFNα was not observed in cells transfected with control nanoparticles- including those encapsulating plasmids with only mIL-12 without RIG-I agonists (labeled 'mIL-12' in plots). We believe this demonstrates that the RIG-I activation was not due to stimulation of DNA-sensing pathways or signaling of mIL-12 protein through the IL-12 receptor but driven specifically by RIG-I agonism.

In vivo expression of transgene products in mouse bladder

We evaluated the expression of transgene products in murine bladder following intravesical instillation (IVI) of mEG-70. As shown in the figure below, and assessed by MSD immunoassay from bladder tissue, mIL-12 protein expression peaked 48 hours after a single IVI, with sustained levels through the end of assessment at 7 days (168 hours; right panel). Transgene RIG-I agonists were expressed as early as 4 hours post-administration, reaching peak expression levels by 24 hours that were sustained through 7 days (middle and left panels). Of note, these levels of expression were obtained without the use of a mucolytic agent and surfactant, as required for adenoviral-mediated gene therapies in the bladder.

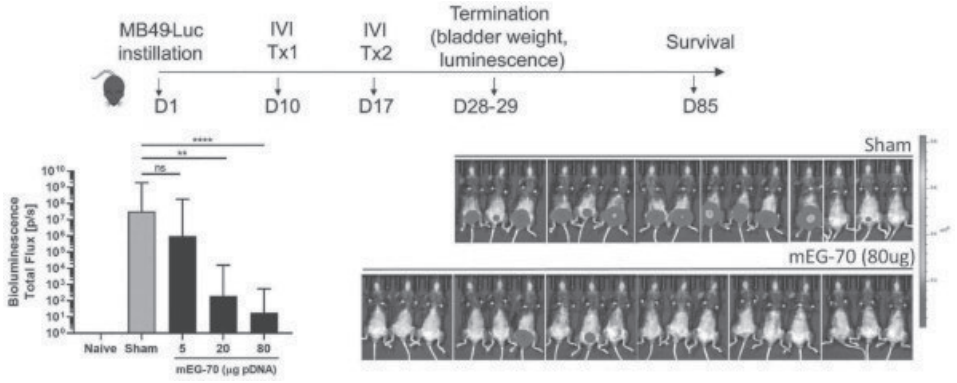


IVI administration of mEG-70 also stimulated a dose-dependent increase in transgene mIL 12 protein expression, reaching a plateau at doses exceeding 10 µg of plasmid DNA (Figure below, left panel). Expression of transgene RIG-I agonists exhibited a similar dose-dependent expression pattern in murine bladders (middle and right panels).



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

To evaluate the therapeutic benefit of mEG-70, an orthotopic model of murine bladder cancer was established by implanting syngeneic MB49 urothelial carcinoma cells that stably express luciferase (MB49luc) into murine bladders, utilizing non-invasive imaging (IVIS) to measure luciferase activity as a proxy for tumor burden. Baseline tumor burden was confirmed by bioluminescence using in vivo imaging before two weekly IVI of mEG-70, with the study design captured in the top panel of the figure below. Only animals with successful tumor engraftment were used in subsequent analyses, with the level of bioluminescence used to randomize mice across treatment groups (bottom panels). Mouse EG-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.



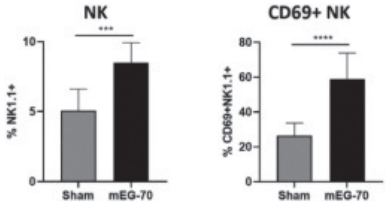
Bladder weights were assessed post-necropsy on Day 29 as an additional surrogate readout for tumor burden (figure below, top left panel). Microscopic evaluation revealed that sham-treated animals had carcinoma in the bladder, which extended to the urethra. In mEG 70- treated animals, a dose-dependent reduction in the number of tumor-bearing animals was observed, with no visible lesions observed in animals treated at the highest dose level (figure below, bottom panel displaying H&E staining). These data recapitulated the dose-dependent anti-tumor activity of mEG-70 observed by in vivo imaging. Consistent with the dose-dependent therapeutic benefit of mEG-70, we also detected dose-dependent expression of mouse IL-12 protein in tumor-bearing bladders.

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 (figure below, top right panel). 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.

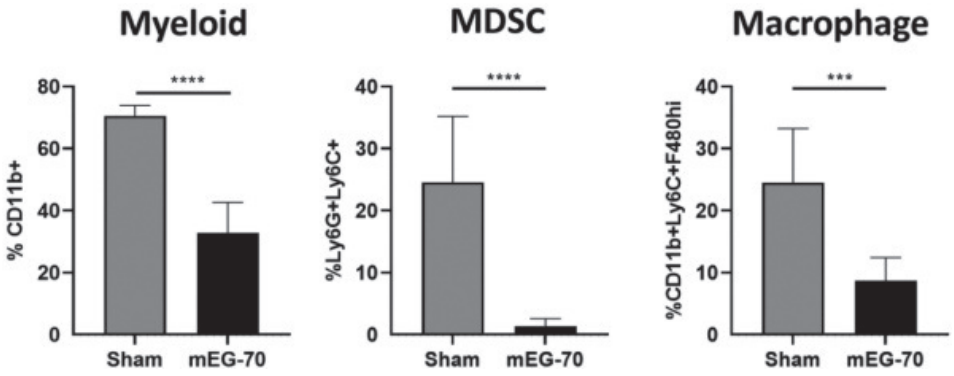
Immune profiling following mEG-70 treatment of tumor-bearing mice

Given that mEG-70 mediated the induction of IL-12 and RIG-I signaling, we assessed the immune cell repertoires of mEG-70-treated animals to further explore the mechanistic basis for anti-tumor activity. Flow cytometry analyses revealed a higher frequency of NK cells (CD3-NK1.1+) (3 days post first IVI of mEG-70; figure below, left panel; Average ± StDev) and an increased proportion of activated CD69+ NK cells (figure below, right panel) in the bladders of mEG-70-treated mice compared to sham-treated mice. Further evidence of NK cell activation in the bladder was demonstrated by an increase in mature CD11b+CD27+ NK cells. This was

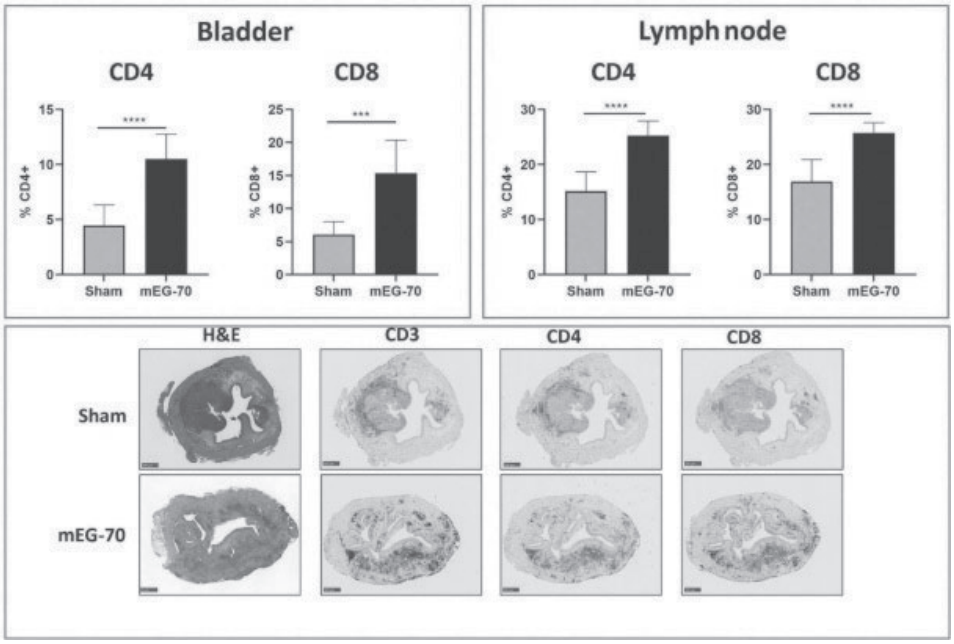
accompanied by a decrease in immature CD11b-CD27- NK cells in mEG-70-treated mice compared to sham controls. Assessment of the proportion of cells expressing CD69 and KLRG1 markers further suggested that NK cells had a mature phenotype in the TME.



These changes in the bladders of mEG 70-treated mice were followed by a significant decrease in myeloid cells (CD11b+) homing to the bladder in mEG-70-treated mice compared to sham-treated mice (3 days post second IVI of mEG-70, figure below, left panel). In addition, a decreased frequency of CD11b+Ly6C+Ly6G+ cells was observed in mouse bladders, consistent with a myeloid-derived suppressor cell (MDSC) phenotype (Figure below, middle panel). The proportion of tumor-associated macrophages (CD11b+F4/80+Ly6C+) was also reduced in mEG-70-treated bladders compared to sham controls (Figure below, right panel).

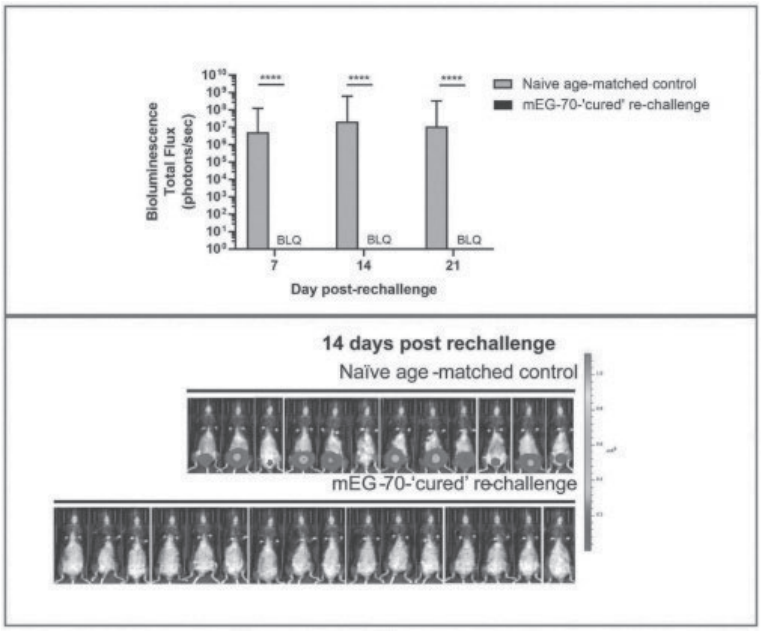


We analyzed tumor-bearing bladders for changes in T cell populations following mEG-70 treatment. Frequencies of both CD4+ and CD8+ T cells were strongly enhanced in mEG 70-treated bladders compared to sham controls (13 days after initiation of mEG-70 treatment, figure below, top left panel). The spatial localization of these T cells was analyzed by immunohistochemistry and revealed pervasive infiltration in mEG-70-treated animals. In contrast, in sham-treated animals, there was poor T cell infiltration, with a marginal localization of cells in the tumor periphery (figure below, bottom panel comparison of 'Sham' and 'EG-70'). Both CD4+ and CD8+ T cells were also present at increased proportions in the tumor-draining lymph nodes of mEG-70-treated mice compared to sham-treated controls (figure below, top right panel).

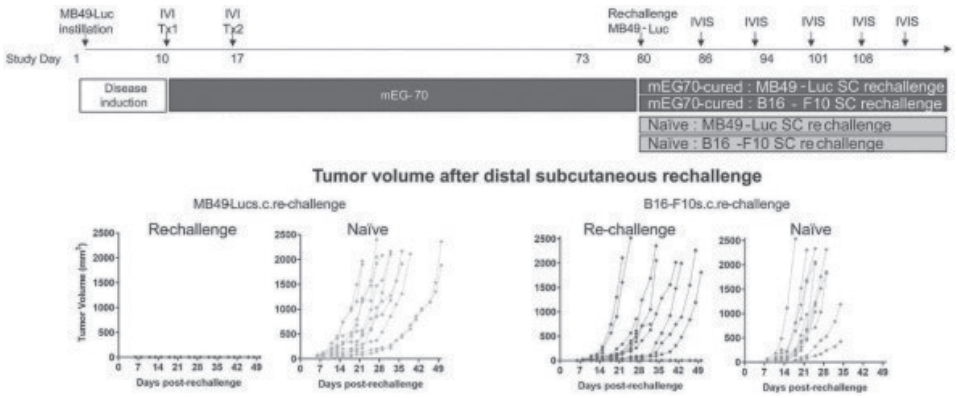


Long-term effects, immunological memory, and systemic immunity mediated by mEG-70

We believe 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).



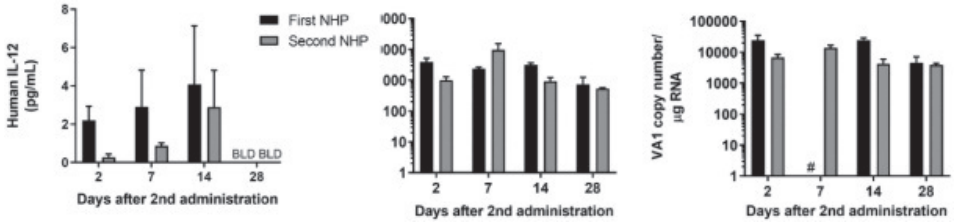
As shown in the figure below, to determine if local treatment to the bladder results in systemic anti-tumor immunity, mice cured of orthotopic bladder cancer by mEG-70 were challenged with MB49luc cells subcutaneously on the flank and tumor growth was monitored. Although age-matched naïve controls showed 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.



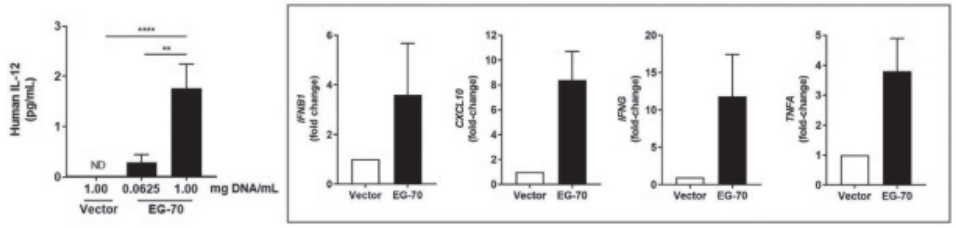
Expression of Transgene Products in Cynomolgus Monkey Bladders

To evaluate the translation of EG-70-mediated expression of transgene products from mouse to non-human primate (NHP) bladders, expression was evaluated in bladders of cynomolgus monkeys treated with two IVI of EG-70 separated by one week (Study Days 1 and 8), the same dosing paradigm established in mice. For each harvest timepoint, two monkeys were dosed, and bladders were harvested on study days 10, 15, 22, and 36 (2, 7, 14, and 28 days after the second dose, respectively). Bladder tissue from each monkey was divided into multiple fragments and pulverized to assess protein or RNA expression at the indicated timepoints. Robust levels of hIL-12 protein were detected up to 14 days following the second dose of EG-70 and cleared by 28 days after the second EG-70

administration (figure below, left panel). Expression of the RIG-I agonists was observed in the bladder up to 28 days after the second administration (figure below, middle and left panels).



Expression of hIL-12 protein was dose-dependent and there was no expression of transgene products observed in NHPs dosed with vector control formulations (figure below, left panel). Human IL-12 protein was also detected in the urine of NHP following a single EG-70 administration and the level of IL-12 in the urine trended higher at a dose of 1.0 mg/mL than the level measured following administration of a low dose of EG-70 (0.0625 mg/mL) or empty vector control nanoparticles. Furthermore, EG-70-encoded hIL-12 protein expression is restricted to the bladder, as no IL-12 protein was quantified in the plasma of NHPs treated with EG-70. Transgene-specific upregulation of downstream cytokines was also observed in an NHP bladder following administration of EG-70 compared to an NHP bladder dosed with empty vector control nanoparticles (Figure below, boxed panels). We believe these data show translation of expression of transgene products from mouse to NHP.



Fast Follower Programs: Bladder, Gynecological, and Genitourinary Cancers

We believe these preclinical and Phase 1 data demonstrate the following, which we believe significantly de-risk the DDX platform and EG-70 as drug product:

- EG-70 has been demonstrated to be well tolerated when instilled intravesically.
- Redosability of EG-70 has been demonstrated, with EG-70 administered up to 16 times to individual patients and with repeated expression of the transgene observed even after multiple doses.
- The mechanism of anti-tumor activity driven by agonism of RIG-I and secretion of IL-12 has been successfully demonstrated clinically with the high rate of complete response observed in the LEGEND trial.

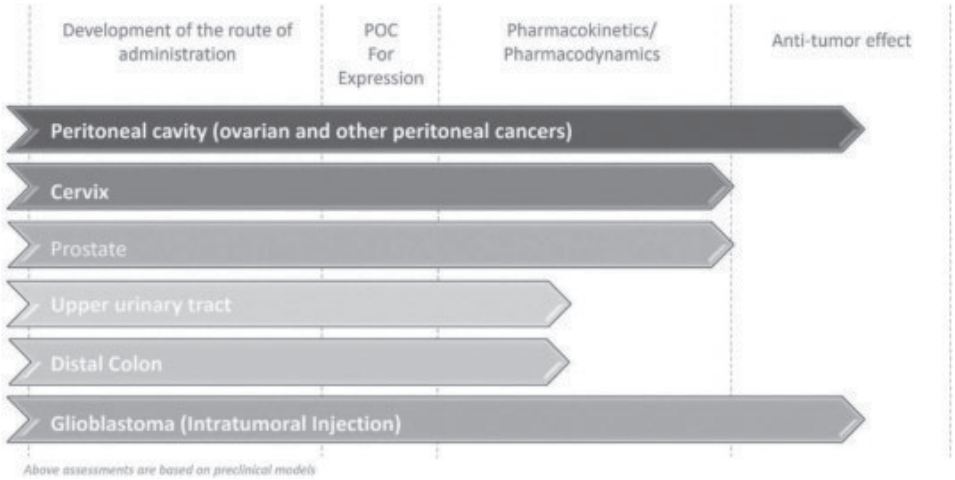
Together, we believe these data support broader utilization of EG-70 for multiple additional oncology indications. As a result, we are exploring advancing EG-70 into additional bladder cancer indications and have performed preclinical experiments that support application of EG-70 to additional organs.

Other Bladder Cancer Indications

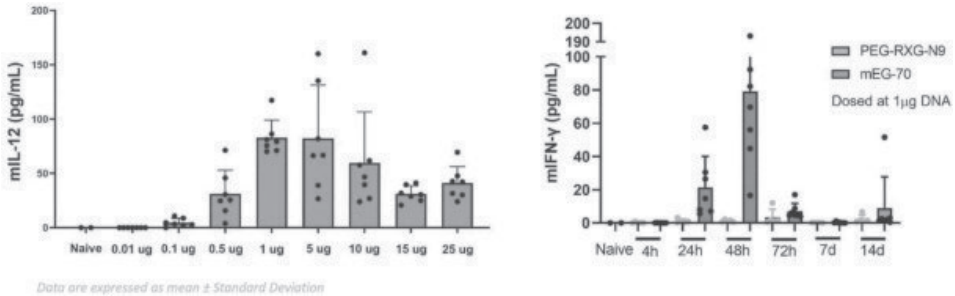
Our preclinical data package utilizes the MB49 cancer cell line, which when instilled into the bladder, can generate tumors reflective of muscle invasive bladder cancer. We believe that this preclinical data could potentially support the use of EG-70 in advanced bladder cancer, such as muscle invasive disease.

Gynecological, Genitourinary

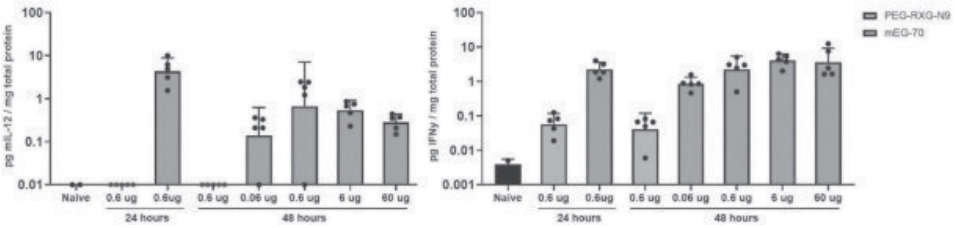
In preclinical in vitro and in vivo studies, we have delivered EG-70 to multiple additional organs via multiple routes of administration and have demonstrated expression of IL-12 in multiple additional organs, as indicated in the figure below. In addition to demonstration of expression, we have also demonstrated anti-tumor effect in models of ovarian cancer and glioblastoma.



Illustrative examples of these data are displayed in the chart below. In the left panel, IL-12 can be measured in intraperitoneal lavage fluid after intraperitoneal delivery of mEG-70 (which encodes the murine surrogate of IL-12). Because this murine surrogate is physiologically active in mice, we can also detect expression of downstream pharmacodynamic markers, as evinced by expression of IFN-gamma in the mEG-70 treated animals (right panel), in contrast to the PEG-RXG-N9 negative control animals, which are dosed with 'empty' plasmids. We believe that local delivery of EG-70 could be an effective treatment for cancers of multiple intraperitoneal organs, including ovarian cancer.



Similarly, as shown in the figure below, direct injection of mEG-70 into the prostate results in expression of IL-12 (left panel) and IFN-gamma (right panel). These results demonstrate that direct injection into a solid organ may be another approach for targeting solid tumors of multiple organs.



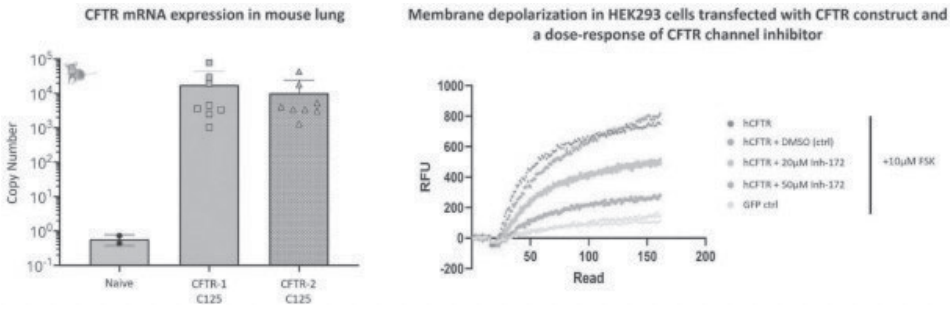
EG-i08: Cystic Fibrosis

The LEGEND study has demonstrated that the RXG backbone contained in detalimogene voraplasmid can successfully traverse extracellular barriers of mucosal organs and transfect epithelial cells. Cystic fibrosis is caused by genetic lesions in the cystic fibrosis conductance transmembrane regulator (cftr) gene, resulting in malfunction in the corresponding protein product ("CFTR"). Cystic fibrosis remains a significant unmet medical need for a subset of patients whose underlying genetics preclude treatment with CFTR modulators. When CFTR is missing or not functional, the lack of CFTR in the airways results in fluid imbalance that manifests as dehydrated mucus, and ultimately, inflammation and infection. CFTR modulators, which can affect the function or quantity of CFTR proteins with certain genetic defects, have emerged as effective treatment options for a subset of patients. According to the Cystic

Fibrosis Foundation, it is estimated that 10% of patients have mutations that are not amenable to CFTR modulators, such as frameshift or truncation mutations.

This estimate notwithstanding, EG-i08 remains at an early stage in development and is challenging or impossible for enGene to provide additional specificity with respect to possible treatable patients or markets.

We are leveraging our mucous permeable delivery vehicle to develop a medicine for cystic fibrosis by encoding the full length *cftr* gene in a plasmid. As shown in the figure below, we have demonstrated with an in vitro membrane depolarization assay that the CFTR protein encoded within plasmid is functional, and wherein the membrane depolarization can be inhibited in a dose-dependent manner with the addition of a CFTR inhibitor (Inh-172). Further, we have demonstrated that after intratracheal instillation when delivering this plasmid in our proprietary delivery vehicle that we can detect CFTR mRNA expression in all animals dosed (left panel, displaying 2 separate nucleotide variants of *cftr*). We believe these data support our ability to deliver and express a functional CFTR protein.



Commercialization Strategy

In accordance with our clinical development plan, we are currently working towards the filing of a BLA for EG-70 for the treatment of patients with BCG-unresponsive with Cis in 2025 based on the Phase II results from the pivotal LEGEND study. If the FDA grants us marketing approval for EG-70 in the United States, we currently plan to commercialize EG-70 in the United States ourselves. Our current plan is to establish a U.S.- focused sales and marketing organization to coordinate with high-prescribing urology centers in the United States. Our plan is to have a specialty urologic medical science liaison team coupled with a commercial sales force to simultaneously educate physicians and scientists about EG-70 while marketing the drug for the approved label. 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 EG-70 versus alternative therapies.

We plan to explore selective partnerships with third parties to commercialize EG-70 outside of the United States, both in Europe and the rest of the world, with the goal of leveraging a potential partner's regional expertise and existing salesforce to the extent appropriate.

The second open-label cohort in Phase 2 of the LEGEND study, in which we propose to treat BCG-naïve (or incompletely treated) NMIBC patients with Cis, provides an additional opportunity to demonstrate the potential use of EG-70 in an indication grappling with critical drug shortages and unmet need and thus represents another important component of our commercialization plan. To the extent that EG-70 shows promise in this patient population, we will share the results of the study with key opinion leaders and urology community leaders, with the aim of building credibility and support for our therapy and increasing interest in its use among urologists and healthcare providers in FDA-approved indications. We believe the urology community will benefit from EG-70's relative ease of use and handling as, among other benefits, it does not require the containment procedures that are required for BCG. If supported by the data, we may choose to pursue further trials in first line BCG-naïve NMIBC patients, some of which may be registrational.

We also believe we could potentially develop EG-70 as a treatment for locally advanced muscle invasive bladder cancer (MIBC). We have shown in an orthotopic model of locally advanced bladder cancer that mice receiving EG-70 exhibit profound and durable anti-tumor immunity, with cured mice developing resistance to subsequent local or distal re-challenge with bladder tumor cells, which we believe was driven primarily by T-cell mediated immune activity. This promising pre-clinical observation supports the potential clinical evaluation of EG-70 in patients with intact bladders diagnosed with locally advanced or metastatic bladder cancer. Furthermore, based on the well-defined mechanism of action of EG-70, we expect that to the extent EG-70 proves to be both safe and effective in the high-risk NMIBC population, we could also study its use in the earlier stage low- and intermediate-grade NMIBC population.

Manufacture and Supply

Detalimogene voraplasmid is a nanoparticle suspension containing the plasmid deoxyribonucleic acid (pDNA) drug substance or active pharmaceutical ingredients (API) 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 CMOs. Additionally, we have conducted 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 EG-70 for the BCG-unresponsive NIMBC indication in the United States following FDA approval.

We believe 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 Good Manufacturing Practice (cGMP) and quality system regulations for drugs and biologics.

We currently rely on individual purchase orders 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 current suppliers of excipients, API and finished products will be capable to provide sufficient quantities of each component to meet our clinical trial supply needs. We have supply agreements in place with multiple CMOs to support manufacturing, release testing, stability analysis, clinical labeling and packaging of EG-70 for the pivotal Phase 2 trial of LEGEND study. We will enter into long term commercial supply agreements with selected qualified CMOs to supply EG-70 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 EG-70. 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 EG-70.

- First, as of October 31, 2023, we own two patent families comprising six 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, 2023, 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 non-covalent, reversible coating of our nanoparticle technology for enhanced delivery, which we have recently developed and incorporated into EG-70, which enhances transfection and gene expression. The pending claims include compositions of matter and methods of use, and the patents issuing from this patent family, if any, will expire in 2040, absent any applicable patent term extension or patent term adjustment.
- Third, as of October 31, 2023, 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 EG-70, 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, 2023, we own one patent family comprising one granted U.S. patent, one pending U.S. non-provisional application, and six corresponding foreign patent applications pending 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, 2023, 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, we have one pending PCT application directed to the use of EG-70 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, 2023, 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.
- Finally, as of October 31, 2023, 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.

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 nine patent families, which include approximately 133 issued patents and 49 pending patent applications, including 12 issued U.S. patents, four issued European patents (with country coverage within Europe), six non-provisional pending U.S. applications, five European pending applications and one pending PCT application. enGene exclusively owns all nine 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 respecting 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 detalamogene 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 $50,000 until the first sale of a product for which a royalty is due and make a payment to NTC of $50,000 upon assigning the License Agreement to a third-party. We are also required to make a one-time payment of $50,000 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 I clinical trial or, if there is no Phase I clinical trial, in a Phase II clinical trial, as well as a one-time payment of $450,000 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 been achieved as of the year ended October 31, 2023. 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.

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 EG-70 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 geographies 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 three FDA-approved products, as well as multiple companies that have drugs in clinical development for the treatment of high risk NMIBC patients that are unresponsive to BCG. While many of these products represent a different modality and may not be either intravesical or monotherapy, they may nonetheless compete with us for patient recruitment in our clinical trials as well as for commercial sales. Competing products include, among other things, the following:

FDA-Approved:

- Adstiladrin® (nadofaragene firadenovec) is a non-replicating adenoviral vector-based gene therapy that is manufactured and marketed by Ferring Pharmaceuticals A/S.
- Keytruda® (pembrolizumab), a Merck product, for the treatment of patients with high-risk BGG- 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, is 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.

Multiple companies have reported drugs in clinical development, including the following:

- Aura Biosciences is developing AU-011 for patients with intermediate or high-risk NMIBC.
- ImmunityBio has submitted a BLA for their drug Anktiva® in combination with BCG in patients with BCG unresponsive high grade NMIBC based on the results of their QUILT 3.032 study.
- Sesen Bio presented Phase 3 data for their lead candidate, Vicineum™, as a treatment for BCG-unresponsive NMIBC. In July 2022 Sesen Bio announced that it decided to pause the further clinical development of Vicineum™.
- UroGen Pharma has UGN-301, an anti-CTLA-4 immunotherapy that it is developing for the treatment of patients with recurrent NMIBC gel as both a single agent and in combination with UGN-201, Urogen's investigational TLR7 agonist.
- CG Oncology has CG0070 that is being investigated in a global Phase 3 clinical trial as a monotherapy for the treatment of BCG-unresponsive NMIBC, as well as in Phase 2 studies in combination with pembrolizumab.
- Seagen has Padcev® (enfortumab vedotin), a NECTIN-4 targeted antibody-drug conjugate, which is being investigated via an intravesical route of administration in NMIBC.
- Protara has TARA-002, an investigational cell therapy in development for the treatment of NMIBC and lymphatic malformations (LMs).
- Janssen has TAR-200, an investigational drug delivery system enabling controlled release of gemcitabine into the bladder. Janssen is also developing TAR-200 and cetrelimab as a combination therapy.

- Theralase has TLD-1433, a light-activated photodynamic compound that is activated in the bladder via the proprietary TLC-3200 medical laser system.
- Bristol Myers Squibb has Opdivo® (nivolumab or nivolumab plus) the experimental medication BMS-986205 with or without BCG.
- Janssen Pharmaceuticals (part of Johnson & Johnson) is developing Balversa® (erdafitinib) versus investigator choice of intravesical chemotherapy in participants who received BCG and recurred with HR NMIBC.
- Pfizer has sasanlimab, an anti-PD-1 antibody.
- AstraZeneca is evaluating the efficacy and safety of Imfinzi® (durvalumab plus BCG) compared to standard therapy with BCG in NMIBC.
- Intravesical BCG vs GEMDOCE in NMIBC is being investigated via the BRIDGE trial to determine the event free survival of BCG-naïve high grade NMIBC patients treated with intravesical BCG vs Gemcitabine + Docetaxel; the estimated study completion date is October 2030.

See "*Risk Factors — Risks Relating 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 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, 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 FDCA and PHSA, and other federal, state, and local regulations also apply. Our product candidate, EG-70 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 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 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 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 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 connecting with the item's science, assembling, controls, and proposed naming, in addition to other things. Information might come from organization supported clinical preliminaries planned to test the wellbeing and viability of an item's utilization or from various elective sources, including review started by examiners. 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 Physician Endorsed Medication Client Expense Act, or PDUFA, the FDA targets ten months from the documenting date in which to finish its underlying survey of a unique BLA and answer the candidate, and

a half year from the recording date of a unique BLA petitioned for need audit. The FDA doesn't generally meet its PDUFA objective dates for standard or need BLAs, and the survey interaction is frequently stretched out by FDA demands for extra data or explanation.

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 allude an application for a biologic to a warning board of trustees. A panel of independent experts, such as clinicians and other scientific experts, is known as an advisory committee. 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. The FDA may recommend actions the applicant can take to improve the BLA's chances of approval. Even with additional information, the FDA may still reject the application.

If the FDA approves a product, they 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 and review of new drugs and biologics for serious or life-threatening diseases. These programs include Fast Track designation, Breakthrough Therapy designation, priority review, and Accelerated Approval.

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. Fast Track designation 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. Our lead product candidate, EG-70, has been granted Fast Track designation by the FDA. There can be no assurance that EG-70's Fast Track designation will lead to a faster development, regulatory review or approval process or increase the likelihood EG-70 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.

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 promoting products for unapproved uses. Although physicians can prescribe drugs for off-label use, companies cannot market or promote them for these purposes. Failure to comply with these requirements can result in penalties and liability under the False Claims Act. 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 EG-70, due to the rare incidence of bladder cancer in children, we may 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, or untitled letters, as well as 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.

We believe that one or more indications for which we may develop a drug product based on the DDX platform may qualify for ODD.

Biosimilars and Exclusivity

The Patent 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 (CMS), other divisions of the Department of Health and Human Services (HHS), the Drug Enforcement Administration (DEA), the Consumer Product Safety Commission, the Federal Trade Commission (FTC), the Occupational Safety & Health Administration (OSHA), 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 payers 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 payers 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 payers 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 payers 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, which prohibits offering or receiving remuneration for referrals or purchases that may be paid under federal and state healthcare programs. The False Claims Act 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. 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 gene therapy 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, and the Biden administration has initiated a special enrollment period and ordered reviews of policies and rules that limit access to healthcare. 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 believe our current facilities are sufficient for our need in the foreseeable future. However, if we need more space for our business in the future, we may choose to rent or lease additional or different space. We expect that there will be appropriate options available to us at reasonable prices if we need to expand our operations.

Employees

As of October 31, 2023, we had 33 employees, including 31 full-time employees, 25 of whom were primarily engaged in research and development activities. Twenty-four of our employees are based in Canada and nine 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, 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 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 on Form 10-K 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

The sizes of the markets and forecasts of market growth for the demand of our novel gene therapy platform, product candidates and other key potential success factors are based on a number of complex assumptions and estimates, and may be inaccurate.

We estimate total addressable markets and forecasts of market growth for our novel gene therapy platform and differentiated product candidates. Our 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, develop and generate revenue from our gene therapy platform, product candidates and related services 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 for our novel gene therapy platform and differentiated product candidates may prove to be incorrect. For example, if the annual total addressable markets or the potential market growth for our gene therapies 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.

We expect to make significant investments in our continued research and development of EG-70, a novel non-viral gene therapy for the purpose of stimulating the adaptive immune system, EG-i08, a pulmonary program, and other new product candidates and gene therapies and services, 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 any 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 gene therapy development efforts, which may be unsuccessful. Developing new product candidates 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 U.S. Food and Drug Administration ("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 of competing products or services. 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 share instruments. Our net losses were $99.9 million and $24.5 million for the fiscal years ended October 31, 2023 and October 31, 2022, respectively. As of October 31, 2023, we had an accumulated deficit of $199.6 million. Our lead product candidate, EG-70, is in clinical trials. Our other programs are in preclinical research and we plan on filing an investigational new drug application ("IND") with the FDA for a pulmonary program during the first-half of 2025, subject to a multifactor go/no-go assessment involving technical review and assessment of grant support availability. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. 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 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.

Our recurring losses from operations and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern.

In our audited consolidated financial statements as of and for the year ended October 31, 2023, we concluded that our net loss, negative cash flows from operating activities, accumulated deficit and need for additional financing in order to fund our future expected negative cash flows raised substantial doubt about our ability to continue as a going concern. Similarly, in its report on such annual financial statements, our independent registered public accounting firm included an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.

We expect to continue to incur net operating losses for at least the next several years and will need substantial additional funding to support our continuing operations and pursue our growth strategy. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. If we cannot continue as a going concern, we may not be able to continue operations, which may result in us winding down, selling or out-licensing our technology or pursuing an alternative strategy. If we fund our operations through debt financings, including senior secured debt, any liquidation of our assets could result in us receiving less than the value at which those assets are carried on our financial statements, and it is likely that our shareholders may lose some or all of their investment in us.

We identified material weaknesses in our internal control over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may determine that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and the price of our common shares.

Prior to the consummation of the Business Combination, we had been a private company with limited accounting personnel and other resources with which to address internal control over financial reporting. In connection with the preparation and the audit of the consolidated financial statements as of and for the years ended October 31, 2023 and 2022, we and our independent registered public accounting firm identified material weaknesses, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in the internal control over financial reporting, and such material weaknesses remain unremediated. A material weakness is defined as 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 financial statements will not be prevented or detected on a timely basis. The material weaknesses identified related to: lack of formal policies, procedures and controls related to the design of internal controls over financial reporting including risk assessment process and control activities for certain key financial reporting processes; lack of sufficient accounting and financial reporting personnel to perform appropriate accounting analysis and review procedures; lack of personnel with requisite knowledge and experience in the application of GAAP; general information technology controls that were not designed appropriately (access and system changes); and lack of appropriate segregation of duties in the preparation and review of account reconciliations and journal entries. We have corrected previously presented financial results due to immaterial errors.

We intend to implement in the near term measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel with requisite knowledge and experience in the application of complex areas of GAAP, managing and collaborating with our financial consultants to enable the implementation of internal control over financial reporting and improve the segregation of duties amongst accounting and finance personnel in the preparation and review of account reconciliations and journal entries. We will also review and improve the design of our general information technology controls including managing user access and privileged access, managing changes in the information system and segregation of duties. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. For example, to maintain and improve the effectiveness of our financial reporting, we will need to commit significant resources, implement and strengthen existing reporting processes, train personnel and provide additional management oversight. We will incur additional costs to remediate these weaknesses, primarily personnel costs and external consulting fees. We cannot assure you that any measures we may take in the future will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control over financial reporting or to avoid potential future material weaknesses. In addition, neither our management nor an independent registered

public accounting firm has ever performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or 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, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result. We also could become subject to investigations by the applicable stock exchange upon which our securities are traded, the SEC or other regulatory authorities.

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 our product candidates.

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 launch and commercialize any products for which we receive regulatory approval. As of October 31, 2023, we had $81.5 million in cash and cash equivalents. 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 defending 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, as agent and lender, and several financial institutions. The Amended Loan Agreement subjects us to fixed payment obligations covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For additional information, see "*Management's Discussion and Analysis of Financial Condition and Results of Operations – 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 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 gene therapies for administration into mucosal tissues, 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 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 gene therapies 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 gene therapy platform's leading program is in the area of immuno- oncology and we are developing additional programs focused on diseases of the respiratory, urogenital and gastrointestinal mucosal tissues. Our lead product candidate, EG-70, for the treatment of BCG-unresponsive non-muscle invasive bladder cancer, or "NMIBC", faces competition from numerous companies and specialty biotechnology companies.

We understand that our competitors use their gene therapy candidates in numerous therapeutic applications, some of which may directly compete with our product candidates and early-stage programs. Competing therapeutic applications include cancer, respiratory disease, metabolic diseases, various rare diseases, central nervous system disorders, neuromuscular disorders, diseases of the immune system and infectious diseases. Competitors using genetic medicines for mucosal tissues include CG Oncology, Inc. and Ferring Pharmaceuticals Inc. We also face competition outside of the gene therapeutics field, in particular for our lead indication of BCG-unresponsive NMIBC with Cis, including from some of the largest pharmaceutical companies and other specialty biotechnology companies, such as Merck & Co., Inc., AstraZeneca, Pfizer, Roche, Bristol Myers Squibb, Johnson & Johnson and Janssen.

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 are likely to be their efficacy, safety, convenience and availability of reimbursement.

If our current programs are approved for the indications for which we are currently 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. For additional information regarding our competition, see "*Business of enGene — Competition*."

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 our gene therapy platform and our therapeutic product candidates among many potential options. As a result, we may forego or delay pursuit of other gene therapy technologies or other therapeutic product candidates that provide significant advantages over our platform, 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 European Medicines Agency ("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 not previously conducted any IND-enabling studies or clinical trials, including any 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, 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 product candidates that we may develop. We may also rely on third-party vendors or service providers, including contract research organizations ("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 our product candidates.

Because we have limited financial and managerial resources, we focus on research programs and on gene therapy technologies and product candidates that we identify for specific indications among many potential options. 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. 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.

Our gene therapy platform is based on novel technologies that are unproven, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

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

However, the technologies that comprise our platform are new and largely unproven. These technologies have not been 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 a number of issues, including proving the safety and efficacy of our treatments for BCG-unresponsive NMIBC and expanding our mucosal tissue delivery system to treat patient tissues beyond the bladder, such as respiratory, 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 gene therapy 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 respiratory, 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 gene therapy 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 enGene's programs, may change, be cancelled or evolve. Only a small number of gene therapies 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 and any clinical trials or experience delays in completing or ultimately be unable to complete, the development and commercialization of any product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective. Many of our product candidates are in early stages of development 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.

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 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;
- regulators or Institutional Review Boards ("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, purity or potency 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;
- 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. 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 results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues 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 or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we have previously published. As a result, interim 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 viewed with caution until the final data is available. Adverse differences between preliminary 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.

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 development and manufacturing organizations (CDMOs), suppliers, clinical investigator sites and governing regulatory bodies.

An 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.

Use of our novel gene therapy platform and therapeutic product candidates 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.

Our product candidates 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 any 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 any 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 any product candidates or products 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 a 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 any of our current or future therapeutic product candidates 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 any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any 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 any 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 any 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 any product candidates to find market acceptance could harm our business, financial condition, results of operations and prospects.

Negative developments in the field of gene therapy, intravesical or NMIBC therapeutic development could damage public perception of any product candidates that we develop, which could adversely affect our ability to conduct our business and our results of operations, or to obtain regulatory approvals for such product candidates.

Our novel gene therapy platform is comprised of new and largely unproven technologies, with 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 gene therapy 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 gene therapy platform, product candidates and related services can overcome these challenges.

If one of our current or future product candidates 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 gene therapy 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 gene therapy platform and gene therapeutics in general.

Additionally, our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates, if approved, prescribing treatments that involve the use of our 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 our product candidates 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 any 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 gene therapy 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 any of our product candidates.

We may not be successful in our efforts to utilize our novel gene therapy 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 EG-70, which may prove to be the wrong choice and may adversely affect our business and results of operations.

A key element of our strategy is utilizing our gene therapy 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 the product candidates we are currently developing, 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, gene therapy and gene editing mechanisms, we have not yet successfully advanced any proprietary enGene developed drug candidate incorporating these cargoes into clinical trials beyond EG-70, 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 gene therapy 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 gene therapy 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 any product candidates on a commercial scale. We rely, and expect to continue to rely, on third-party manufacturers to produce our product candidates or other product candidates that we may identify for clinical trials, as well as for commercial manufacture if any product candidates 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 of our product candidates, 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 party of its suppliers;
- risk of single sourced critical raw materials, drug substance and drug product, where secondary back-up vendors are not 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 our product candidates are subject to review by the FDA and other non-U.S. authorities pursuant to inspections that will be conducted after we submit an NDA, or other marketing application to the FDA and other non-U.S. authorities. We do not directly control or 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 our product candidates 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 no 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 our product candidates or if any agency withdraws its approval in the future, 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.

Our product candidates 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 our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Our most advanced product candidates are complex to manufacture 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 provide supply of our product candidates 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 manufacturing processes used to produce our product candidates are complex and novel and have not been validated for clinical or commercial production. 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 EG-70 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 our other product candidates, that can lead to failure. Failure in the production of any of our product 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 EG-70 requires careful and complex combination of DS with DDX and PEG-b-PLE to yield the intermediate 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 our product candidates or in the manufacturing facilities in which our 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 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, 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 our product candidates 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 reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized.

The manufacturing processes 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, 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 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 product candidate manufacturing or formulation 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 our product candidates 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 our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Our most advanced product candidates are 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 our product candidates 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 our product candidates are complex and many are novel and have not been validated for clinical or commercial production. For example, in addition to several complex physico-chemical tests for EG-70, DS and novel excipients, we must also test EG-70 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 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 our product candidates. 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 complete 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 our product candidates 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 reduce the cost of goods for our product candidates 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 any of our product candidates, 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 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 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 our product candidates 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 our product candidates 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 higher 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, EG-70, is being developed to treat patients with BCG-unresponsive NMIBC. 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 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 our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because certain of the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. For example, we believe there are approximately 60,000 new patients globally each year with BCG-unresponsive NMIBC with limited available therapies. The prevalence of patients experiencing this condition implies high unmet medical need. If the market opportunities for any product candidates we may develop are smaller than we believe they are, our potential revenues may be adversely affected and our business may be harmed.

We rely on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

Our success depends on the skills, experience and performance of members of our senior management team and key personnel. The individual and collective efforts of these and other members of our senior management team and key personnel will be important as we continue to develop product candidates, establish strategic partnerships and build out our operations. 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. In connection with the Business Combination, it is anticipated that we will significantly expand our senior management team in a manner commensurate with our needs as a clinical-stage biotechnology company that will soon be public 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, such as the coronavirus (COVID-19) pandemic, 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, such as the COVID-19 pandemic or similar outbreaks, could have an adverse effect our business. Quarantines, travel restrictions and other public health and safety measures implemented in response to a pandemic, including a resurgence of COVID-19, could adversely impact our operations, and the ultimate impact is highly uncertain and cannot be predicted with confidence. Effects of a pandemic, including a resurgence of COVID-19, 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, including those hired during the COVID-19 pandemic.

Any of these effects, and other effects of a pandemic, including a resurgence of COVID-19, 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 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, in late February 2022, Russian military forces launched its significant military invasion of Ukraine. The impact to Ukraine, 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 Russia, Belarus and occupied areas of Ukraine, 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 on Form 10-K, we (i) are not conducting clinical or non-clinical studies in Ukraine, Belarus or Russia, (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 Ukraine, Belarus or Russia, 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, our gene therapy platform and therapeutic product candidates will require regulatory approval, which is a lengthy, expensive, and inherently unpredictable process with uncertain outcomes and cost and 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.

Regulatory requirements governing gene and cell therapy products, and in particular any novel gene therapy products we may develop, have changed frequently and may continue to change in the future. We are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and EMA. Even with respect to more established products in the gene therapy 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 gene therapy 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 gene therapy workload. Gene therapy 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 gene therapy 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 gene therapy 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 gene therapy medicinal products and require that we comply with these

new guidelines. As a result, the procedures and standards applied to gene therapy 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 any product candidates we may develop or lead to significant post-approval limitations or restrictions. As we advance any 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 any product candidates we may develop. Similarly, the EMA 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 gene therapy products or cell therapy products may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of any product candidates we may develop or limit the use of products utilizing non-viral gene therapy 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 the 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 gene therapy 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 any 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 any product candidates we may develop under development. 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 any 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 any 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 EG-70, our most advanced product candidate in accordance with the FDA's 2018 Guidance Document entitled "Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry." This document 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. 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 a 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 any 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 any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for any 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 our product candidates, we will not be able to commercialize or will be delayed in commercializing our product candidates and our ability to generate revenue will be adversely affected. Even if we eventually gain approval for any of our 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 any of our product candidates, we must obtain marketing approval. All of the product candidates that we are developing, or may develop in the future, require research and development, pre-clinical 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 none of our product candidates or any 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, our product candidates 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. Our product candidates 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 a product candidate 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;
- 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 our product candidates 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 our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We expect the novel nature of our product candidates 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 therapeutics 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 any 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 any of our product candidates 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 a 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 our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our 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. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will obtain and/or maintain regulatory approval of our product candidates in other jurisdictions, while a failure or delay in obtaining or maintaining regulatory approval of our 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 our product candidates 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. 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 our product candidates will be harmed.

We may seek priority review designation for one or more of our product candidates, 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 our product candidates 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.

Even if we receive regulatory approval of any product candidates or therapies, 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 product candidates, we may be subject to substantial penalties, fines, delays, suspensions, refusals and withdrawals of approvals.

If any of our product candidates 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 Good Clinical Practice ("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 our product candidates 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 our product candidates, 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 maybe 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 discontinuation of development of our product candidates or therapies, 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 gene therapy 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 gene therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy 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 gene therapy 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 gene therapies and product candidates is new, we may face even more cumbersome and complex regulations than those emerging for cell therapy products.

Furthermore, even if our product candidates 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 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 Centers for Medicare & Medicaid Services ("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 payers 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 payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (as amended, 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 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 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, once approved, or additional pricing pressures.

Any product candidates we develop 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 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 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, 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 Anti-Kickback Statute ("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. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU member states, 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"), 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. 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 EG-70, 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 EG-70. The guidance was updated on January 15, 2021. Nadofargene firadenovec, sold under the brand name Adstiladrin, is a FDA-approved gene therapy 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 EG-70, 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 EG-70, 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 the Health Insurance Portability and Accountability Act ("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 Federal Trade

Commission ("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, in response to the changes in workforce habits driven by the COVID-19 pandemic, 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.

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 and other regulatory bodies in non-U.S. jurisdictions, provide true, complete and accurate information to the FDA and other similar regulatory bodies in non-U.S. jurisdictions, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar non-U.S. laws, or 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 False Claims Act ("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, 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 federal health care programs and substantial civil and criminal penalties.
- 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, the exclusion from participation in federal and state healthcare programs, 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 intime, 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 EG-70 and other current and future products under development 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 conflict between Russia and Ukraine 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. 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. Inflation rates have increased recently to levels not seen in years. Among other potential effects, increased inflation may result in reduced liquidity and limits on our ability to access credit or otherwise raise capital. The Federal Reserve has 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. For example, on March 10, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not lose any cash or cash equivalent balances in connection with the collapse of Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain and the failure of Silicon Valley Bank and its potential near- and long-term effects on the biotechnology industry and its participants, such as certain of our vendors, suppliers, and investors, may also adversely affect our operations and stock price.

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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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.

Our rights to develop and commercialize our product candidates and gene therapy 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, 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, 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.

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 gene therapy 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. 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 gene therapy platform, our product candidates and other technologies.

The field of biotherapeutics, including the development of gene therapies, 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy platform, product candidates and other technologies might assert are infringed by our current or future product candidates, gene therapy platform or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our gene therapy 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 gene therapy platform, product candidates and other technologies, could be found to be infringed by our gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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 gene therapy 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. 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 cancer and infectious disease immunotherapies 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, 2023, we had 33 employees, two of whom worked less than full-time, and we are engaged with six consultants (contractors) on a regular basis. 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 for use in our gene therapy 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 our gene therapy platform or 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 Relating to Investment in enGene's Securities

Because enGene is a Canadian company, shareholder protections differ from shareholder protections in the United States and elsewhere, and enGene is subject to a variety of additional risks that may negatively impact enGene's operations.

Following the continuation of enGene into British Columbia, 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 or Cayman Islands law. 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. Although we believe that there have been no immediate effects on enGene's 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 enGene's 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 enGene's shares or assets or preventing a change in control.

Certain provisions of enGene Holdings Inc.'s 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 enGene's Board of Directors. As such, these provisions could also limit the price that investors might be willing to pay in the future for enGene's common shares, thereby depressing the market price of enGene's common shares. In addition, because enGene's Board of Directors is responsible for appointing the members of enGene's management team, these provisions may frustrate or prevent any attempts by enGene's shareholders to replace or remove enGene's current management by making it more difficult for shareholders to replace members of enGene's Board of Directors. Among other things, these provisions include the following:

- shareholders cannot amend enGene's Articles unless such amendment is approved by shareholders holding at least 66 2/3% of the shares entitled to vote on such approval;
- enGene's 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 enGene's 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 enGene's shareholders without enGene's prior written consent, which could limit enGene's shareholders' ability to obtain a favourable 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 enGene's behalf; (b) any action or proceeding asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of enGene's to enGene; (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 enGene's 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 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 enGene's 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 enGene's 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 enGene's shareholders' ability to bring a claim in a judicial forum that they find favorable for disputes with enGene's directors, officers or employees, which may discourage the filing of lawsuits against enGene and enGene's directors, officers and employees, even though an action, if successful, might benefit enGene's 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 enGene's 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 enGene's 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 directors of enGene are expected to reside in the United States, while others are expected to 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 enGene's 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.

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

For Canadian tax purposes, enGene currently has a substantial pool of net operating losses (known as non-capital losses) and other tax attributes. In general terms, where control of a corporation is acquired or deemed to be acquired, as is expected to apply to enGene as a result of the Transactions, 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 Transactions. Similar rules are expected to apply for Canadian provincial purposes. Consequently, enGene may not be able to utilize a material portion of its

non-capital loss carryforwards and certain other tax attributes in certain circumstances. Further, enGene may realize capital gains or foreign exchange gains as a result of the Transactions. Non-capital losses and other tax attributes arising prior to the Amalgamation will generally not be available to offset such gains. As a result, enGene may have tax payable after the Amalgamation, unless it generates non-capital losses (or other tax attributes) after the Amalgamation in an amount sufficient to offset such gains.

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 enGene 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.

There is a significant risk that enGene may be or become a passive foreign investment company (a "PFIC"), which could result in adverse U.S. federal income tax consequences to U.S. Holders of enGene's 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 any of enGene's drug candidates its income may be primarily passive. Accordingly, there is a significant risk that enGene will be a PFIC for its current or any future taxable year. If enGene is 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 enGene is or was 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 enGene 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 enGene's 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 enGene, to a timely filed U.S. federal income tax return for the tax year to which the election relates. In the event that enGene determines that enGene is a PFIC for U.S. federal income tax purposes for any taxable year, enGene 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.

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

Certain provisions in the articles of enGene (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 the enGene Board rather than to attempt a hostile takeover. These provisions include, among others:

- the existence of a classified or "staggered" board;
- the right of the enGene Board to issue preferred stock and to determine the voting, dividend, and other rights of preferred stock without shareholder approval;
- the ability of enGene's directors, and not shareholders, to fill vacancies on the enGene Board in most circumstances and to determine the size of the enGene Board;
- 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 enGene 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 the enGene Board determines is not in the best interests of enGene and its shareholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

Certain of enGene's financing agreements place operating restrictions on its business, which may limit its flexibility to respond to opportunities and may have a material adverse effect on its business, financial condition and results of operations.

On May 16, 2023, enGene entered into a letter agreement with Investissement Quebec ("IQ"), FEAC and enGene (the "IQ Letter Agreement"), in connection with IQ's investment in the 2023 Convertible Notes. Among the terms of the IQ Letter Agreement, enGene agreed to comply with certain covenants that may restrict its ability to expand its operations or engage and pursue certain business opportunities.

From the time that IQ first holds enGene Common Shares until the earlier of (1) the date IQ ceases to hold at least 2% of enGene's outstanding shares on a fully-diluted basis, and (2) the date that is five years after the date of the IQ Letter Agreement, unless enGene receives prior written consent from IQ: (i) enGene must maintain its head office in the Province of Québec, and (ii) enGene shall cause enGene to (A) maintain operations in the Province of Québec, (B) maintain a research and development center in the Province of Québec, and (C) engage at least 20 employees who are residents and work in the Province of Québec (the "Employment Threshold"), provided that, if in good faith, the enGene Board determines that maintaining the Employment Threshold puts enGene at risk of bankruptcy, insolvency or determines that it is in the best interests of enGene to effect a general reduction in workforce, IQ shall not unreasonably withhold consent to reduce the Employment Threshold. Additionally, IQ will, for so long as IQ holds shares representing, in the aggregate, ownership of greater than 2% of enGene on a fully diluted basis, be permitted to have an observer attend any meeting of the enGene Board subject to the terms and conditions of a board observer agreement to be negotiated in good faith between enGene and IQ.

enGene's compliance with these provisions may affect its ability to react to changes in industry conditions, take advantage of business opportunities it believes to be desirable, hire and retain critical personnel, execute or product development and commercialization initiatives, among other potential effects.

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 22, 2023, we filed a registration statement on Form S-1, as amended (File No. 333-275700) (the "resale registration statement") with the SEC to register the issuance of up to an aggregate of 10,411,641 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 our resale registration statement (the "Selling Holders") named therein of (i) up to 27,144,523 of our Common Shares (which includes 6,386,564 Common Shares that may be issued upon exercise of the enGene Warrants); and (ii) up to 6,386,564 of our Warrants. The sale of Common Shares in the public market or otherwise, including sales pursuant to the resale 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 enGene to sell equity securities in the future at a time and at a price that it deems appropriate. Resales of Common Shares may cause the market price of our securities to drop significantly, even if enGene's business is doing well.

Although the FEAC Sponsor and certain other parties named in the Selling Holders table included in the resale registration statement will be prohibited from transferring any Common Shares until April 30, 2024 (a period of six months following the Closing Date, subject to certain exceptions), pursuant to the enGene lock-up agreements entered into in connection with the Reverse Recapitalization, the Common Shares may be sold after the expiration or early termination or release of the respective applicable lock-up provisions. For additional discussion regarding the lock-up agreements, please review our resale registration statement and the form of enGene lock-up agreement incorporated by reference as an exhibit to this Annual Report on Form 10-K.

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 89.5% of our total outstanding Common Shares and approximately 61.3% of our outstanding Warrants, respectively, as of the date of such prospectus.

Following the expiration of the applicable lock-ups described herein and after the resale registration statement of which the prospectus is a part is effective, and until such time that it is no longer effective, the resale registration statement will permit the resale of these securities. 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 enGene at prices below the current trading price of such securities, and may experience a positive rate of return based on the 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 below the current trading price of such securities and may experience a positive rate of return based on the current trading price. On January 25, 2024, the closing price of our Common Shares was $7.60 per share and the closing price for our Warrants was $0.85 per warrant. Even though the current trading price is below FEAC's initial public offering price and the trading prices of Common Shares and Warrants on the date immediately following the Business Combination, certain of these private investors have an incentive to sell because they will still profit on sales due to having purchase their securities at lower prices than the public investors.

Given the relatively lower purchase prices that some of our Selling Holders paid to acquire securities compared to their current trading prices, these 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 ranging from significantly below to above current trading prices, as set forth in further detail in the section titled "*Information Related to Offered Securities*." Investors who purchase our Common Shares and Warrants on the Nasdaq following the Business Combination 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.

The Warrants are not currently in the money, and 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; the Warrants may expire worthless.

The exercise price for our Warrants is $11.50 per Common Share. Our Common Shares and Warrants trade on the Nasdaq under the tickers "ENGN" and "ENGNW", and as of the close of business on January 25, 2024, the closing price of our Common Shares and Warrants on the Nasdaq was $7.60 and $0.85, respectively.

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.

As of the date of this Annual Report on Form 10-K, the Warrants are not currently in the money, and 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.

enGene's management team has limited experience managing a public company, and the additional requirements for public companies may strain resources and divert management's attention.

The individuals who constitute enGene's management have not previously managed enGene's business, or in some cases any business, as a publicly traded company. 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. enGene's 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 enGene's business and profitability.

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

In connection with the Business Combination, enGene applied for the listing of the enGene Common Shares and Warrants on Nasdaq, and such securities commenced trading on Nasdaq under the tickers "ENGN" and "ENGNW", respectively, on November 1, 2023. enGene is required to meet Nasdaq's continued listing requirements and may be unable to meet those requirements. Although enGene's securities are listed on the Nasdaq as of the date of this registration statement, enGene may be unable to maintain the listing of its securities in the future.

If enGene fails to meet the continued listing requirements and the Nasdaq delists enGene's securities from its exchange, there could be significant material adverse consequences, including:

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

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

As a privately held company, enGene Inc. was not required to comply with many corporate governance and financial reporting practices and policies required of a publicly traded company. As a publicly traded company, enGene will incur significant legal, accounting and other expenses that enGene was not required to incur in the past. 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 enGene's legal and financial costs and lead to a diversion of management time and attention from revenue-generating activities.

A market for enGene's securities may not develop, which would adversely affect the liquidity and price of its securities.

The price of enGene's securities may fluctuate significantly due to the market's reaction to the Business Combination as well as general market and economic conditions. An active trading market for enGene's securities following the Business Combination 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 enGene's securities.

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

enGene's 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. enGene 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 enGene business, financial condition, results of operations and prospects. Any adverse determination in litigation could also subject enGene to significant liabilities.

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Not applicable.

Item 2. Properties.

As of October 31, 2023, we leased approximately 10,620 sq. feet of laboratory and office space at 4868 Rue Levy Montreal, QC H4R 2P1.

We believe our current facilities are sufficient for our need in the foreseeable future. However, if we need more space for our business in the future, we may choose to rent or lease additional or different space. We expect that there will be appropriate options available to us at reasonable prices if we need to expand 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 January 25, 2024, there were approximately 23,197,976 Common Shares issued and outstanding held of record by 14 holders, and approximately 10,411,641 Warrants held of record by 14 holders, each exercisable for one Common Share at a price of $11.50 per share. Additionally, we agreed to issue the Lenders (as defined herein) Warrants to acquire up to 138,969 Common Shares, of which 62,413 have been issued. 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.

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, 2023

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)]	2,706,941	$ 2.40	2,607,943
Equity compensation plans not approved by security holders	—	—	—
Total	2,706,941		2,607,943

(1) On October 31, 2023, upon completion of the Business Combination, the enGene Incentive Equity Plan became effective, which authorizes 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.

(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.

Recent Sales of Unregistered Securities

During the three years preceding the filing of this Annual Report on Form 10-K, we granted or issued the following securities which were not registered under the Securities Act of 1933, as amended (the "Securities Act").

On October 31, 2023, in connection with the Business Combination, we participated in the PIPE Financing (as defined herein) pursuant to which we issued 6,435,441 Common Shares and 2,702,791 Warrants to purchase Common Shares to the PIPE Investors (as defined herein) for an aggregate purchase price equal to $56.9 million. Each Warrant is exercisable to purchase one Common Share at a price of $11.50 per share. The Warrants will expire on October 31, 2028, the date that is five years after the completion of the Business Combination. For additional information, see "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — PIPE Financing*."

On December 22, 2023, we entered into an agreement to issue to the Lenders Warrants to acquire up to 138,696 Common Shares, of which 62,413 were issued. The Warrants were issued to the Lenders in connection with an initial term loan advance of $22.5 million, $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement. For additional

information see, "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Hercules Loan Agreement*."

The sales of the securities described above were exempt from the registration requirements of the Securities Act in reliance on the exemptions afforded by Section 4(a)(2) of the Securities Act. No sales involved underwriters, underwriting discounts or commissions or public offerings of securities of the Registrant.

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, 2023.

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 post the consummation of the Reverse Recapitalization. enGene Holdings Inc. is the new, publicly traded parent company of the combined business in connection with 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, 2023 and 2022 and for the fiscal years ended October 31, 2023 and 2022, and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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" 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 gene therapy products. Our fiscal year is the year ended October 31.

Overview

Business Overview

We are a clinical-stage biotechnology company focused on developing gene therapies to improve the lives of patients. We are developing non-viral gene therapies based on our 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. We believe our DDX platform, with its broad tissue and disease application, has the potential to take gene therapy beyond rare genetic diseases into oncology and other underserved therapeutic areas. We have established integrated capabilities with this platform to support the clinical development and potential commercialization of our gene therapies.

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, EG-70, EG-i08 and other compounds. 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 human gene therapy products. To date, we have financed our operations primarily through proceeds received through the merger with Forbion European Acquisition Company ("FEAC") (the "Reverse Recapitalization") and concurrent PIPE Financing (as defined below), along with the issuance of convertible debt and proceeds from sales of preferred shares by enGene Inc. ("Old enGene"). From inception to October 31, 2023, we have raised aggregate gross proceeds of approximately $77.8 million through the sale and issuance of Old enGene's preferred shares, warrants, and convertible debentures, $49.0 million through Old enGene's term loan and April and May 2023 note and warrant financings, $56.9 million from the PIPE Financing and $7.4 million from the FEAC trust account, net of the redemption to FEAC's public shareholders and FEAC expenses. 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 have incurred significant operating losses since our inception. Our net losses were $99.9 million and $24.5 million for the years ended October 31, 2023 and 2022, respectively. As of October 31, 2023 and 2022, we had an accumulated deficit of $199.6 million and $99.7 million, respectively, and cash and cash equivalents of $81.5 million and $20.4 million, respectively. We expect to continue to incur net operating losses for at least the next several years, as we advance our product candidates through preclinical and clinical development and seek regulatory approvals, manufacture drug product and drug supply, maintain, enforce, defend and expand our intellectual property portfolio, as well as hire additional personnel, pay for accounting, audit, legal, regulatory and consulting services, and pay costs associated with maintaining compliance with listing rules and the requirements of the SEC, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies, our clinical trials and our expenditures on other research and development activities.

With the funds received as a result of the Reverse Recapitalization and PIPE Financing, we may be able to reach significant clinical milestones for EG-70. We could use our available capital resources sooner than we currently expect. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. As a result, we will 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 additional licensing arrangements. We may be unable to raise additional funds or enter into such arrangements when needed, on favorable terms, or at all. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations and financial condition, including requiring us to have to delay, reduce or eliminate product development or future commercialization efforts.

As of October 31, 2023, we had $81.5 million in cash and cash equivalents. Our ability to continue as a going concern depends on our ability to successfully develop and commercialize our products, achieve and maintain profitable operations, as well as the adherence to conditions of outstanding loans. We will require additional financing in order to fund our future expected negative cash flows and management's plans are to raise additional financing. 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. These conditions indicate the existence of a material uncertainty that raises substantial doubt about our ability to continue as a going concern and, therefore, that we may be unable to realize our assets and discharge our liabilities in the normal course of business. See the subsection titled "*Liquidity and Capital Resources*."

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., a corporation incorporated under the laws of Canada (now known as "enGene Inc" or "Old enGene"), consummated the merger (the "Reverse Recapitalization") pursuant to a business combination agreement, dated as of May 16, 2023 (the "Merger Agreement").

The transaction was accounted for as a "reverse recapitalization" in accordance with accounting principles generally accepted in the United States ("GAAP"). Under this method of accounting, FEAC was treated as the "acquired" company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Reverse Recapitalization, senior management of Old enGene continues as senior management of the combined company; Old enGene identifies a majority of the members of the board of directors of the combined company; the name of the combined company is enGene Holdings Inc. and it utilizes Old enGene's current headquarters, and Old enGene's operations comprise the ongoing operations of the combined company. Accordingly, for accounting purposes, the Company is considered to be a continuation of Old enGene, with the net identifiable assets of FEAC deemed to have been acquired by Old enGene in exchange for Old enGene common shares accompanied by a recapitalization, with no goodwill or intangible assets recorded. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding, prior to the Reverse Recapitalization, have been retrospectively restated to reflect an exchange ratio of approximately 0.18048 (the "Exchange Ratio") established in the Merger Agreement within the financial statements and this "Management's Discussion and Analysis of Financial Condition and Results of Operations." The redeemable convertible preferred shares, prior to the Reverse Recapitalization, have not been restated. Operations prior to the Reverse Recapitalization are those of Old enGene.

The Reverse Recapitalization was effected in the following steps: (i) two entities were incorporated to effect the transaction, Can Merger Sub, a Canadian corporation and a wholly owned subsidiary of FEAC and Cayman Merger Sub, a Cayman Islands exempt company and a direct wholly owned subsidiary of the Company; (ii) immediately prior to the Closing Date, Cayman Merger Sub was merged with and into FEAC with FEAC as the surviving entity, resulting in FEAC becoming a wholly owned subsidiary of the Company (the "Cayman Merger"); (iii) on the Closing Date, Can Merger Sub and Old enGene amalgamated pursuant to a plan of arrangement (the "Amalgamation"), resulting in Old enGene becoming a wholly owned subsidiary of the Company. As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its ordinary shares and warrants on the Nasdaq Global Market under the symbols "ENGN" and "ENGNW," respectively, commencing trading on November 1, 2023, with Old enGene, a subsidiary of the Company continuing the existing business operations.

Upon the consummation of the Reverse Recapitalization, each FEAC Class A Share and FEAC Class B Share (collectively, the "FEAC Shares") issued and outstanding immediately prior to the effective time of the Cayman Merger (including Forbion Growth Sponsor FEAC I B.V.'s, the "FEAC Sponsor") shares but excluding any dissenting FEAC Shares, was transferred to the Company and (i) for each FEAC Share, the Company issued to each shareholder one validly issued Company Common Share; (ii) each warrant to purchase one FEAC share was assumed by the Company and converted into a warrant to purchase one Company Common Share at an exercise price of $11.50 per share; with all fractional shares rounded down to the nearest whole share. Concurrently with the Cayman Merger, the Company redeemed its 10 Class B common shares held by its sole shareholder for $1 CAD per share, which was equal to the amount of capital that the sole shareholder of the Company contributed. As a result of the Reverse Recapitalization, the 3,670,927 held by FEAC Sponsor and other shareholders were converted into the same number of the Company's Common Shares and the 5,029,444 outstanding FEAC warrants held by FEAC warrant holders were converted into the same number of warrants. Each warrant may be exercised to purchase one Company Common Share.

On the Closing Date, each common share of Old enGene was cancelled and the holders thereof in exchange received approximately 0.18048 newly issued Company Common Shares. In addition, each share of Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close of the Reverse Recapitalization was exchanged for Company Common

Shares based on the same Exchange Ratio, with no dividends or distributions being declared or paid on Old enGene's redeemable convertible preferred shares. Further, certain of Old enGene's existing convertible notes outstanding immediately prior to the close of the Reverse Recapitalization were converted to Old enGene common shares at the conversion ratio in place at the time of conversion. In addition, all of Old enGene's Class C warrants outstanding at the time of the Reverse Recapitalization were terminated and all outstanding warrants exercisable for Old enGene common shares were exchanged for warrants exercisable for the Company's Common Shares with the same terms and conditions except adjusted by the aforementioned Exchange Ratio. At the closing of the Reverse Recapitalization, each share option of Old enGene common shares was cancelled in exchange for newly issued share options of the Company's Common Shares based on the same Exchange Ratio. The modification of the share options did not result in any incremental compensation expense upon closing of the Reverse Recapitalization. Upon the close of the Reverse Recapitalization, 13,091,608 Company Common Shares were issued to Old enGene's equity and convertible note holders, 2,679,432 Warrants to purchase Company Common Shares were issued to Old enGene's warrant holders (which are inclusive of the shares and warrants issued to the FEAC Sponsor), and 2,706,941 common share options of the Company were issued to Old enGene's share option holders.

As part of the Reverse Recapitalization, the Company received net proceeds of $7.4 million from the FEAC trust account, net of the redemption payment to FEAC's public shareholders and FEAC expenses.

PIPE Financing

In connection with the Merger Agreement, FEAC, the Company, and certain investors (the "PIPE Investors") entered into subscription agreements (the "Subscription Agreements") pursuant to which, the PIPE Investors agreed to purchase FEAC Class A Shares and FEAC Warrants (or the Company's Common Shares and Warrants when such obligation was assumed (the "Assumption") by the Company after the completion of the Cayman Merger and prior to the consummation of the PIPE Financing), for an aggregate commitment amount of $56.9 million. Concurrent with the execution of the Merger Agreement, FEAC, the FEAC Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A. and the other holders of FEAC Class B Shares, Old enGene, the Company and the other parties named therein entered into the sponsor and insiders letter agreements (the "Side Letter Agreements"), pursuant to which the FEAC Sponsor agreed to surrender and in effect issue to PIPE Investors, 1,789,004 FEAC Class B Shares and 5,463,381 FEAC private placement warrants, immediately prior to the closing of the Reverse Recapitalization. Pursuant to the Subscription Agreements and the Side Letter Agreements and the Assumption, in connection with the Reverse Recapitalization, the Company issued 6,435,441 Common Shares and 2,702,791 Warrants to purchase Common Shares for an aggregate purchase price equal to $56.9 million. As a result, each investor in the PIPE Financing received approximately 1.1595 Common Shares and approximately 0.4870 Warrants for each $10.25 of subscription price. The party to the Non-Redemption Agreement received 26,575 Common Shares and 81,158 Warrants in consideration of such investor's commitment to not redeem 166,665 shares of FEAC Class A Shares in connection with the consummation in connection with the consummation of the Reverse Capitalization. The Common Shares and Warrants issued to the Selling Holder party to the Non-Redemption Agreement were determined so as to put such Selling Holder in the same position had such Selling Holder invested in the PIPE Financing an amount equal to the foregone redemption proceeds.

Convertible Bridge Financing

Prior to the execution and delivery of the Reverse Recapitalization Agreement, Old enGene agreed to certain modifications of existing convertible indebtedness in an aggregate principal amount of $18.4 million (the "2022 Convertible Notes" and, together with the Old enGene warrants to be issued by Old enGene as consideration for such modifications, the "Amended 2022 Financing"). Concurrently with the execution and delivery of the Merger Agreement, Old enGene also entered into agreements pursuant to which it issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in repayment of the April 2023 Notes in an aggregate principal amount of $8.0 million (collectively, the "May 2023 Notes" and, together with the warrants purchased concurrently, the "2023 Financing"; the 2023 Financing together with the Amended 2022 Financing, the "Convertible Bridge Financing"). In connection with the Reverse Recapitalization, the Convertible Bridge Financing indebtedness was converted into 35,349,238 Old enGene common shares at the conversion ratio in place at the time of conversion, which was exchanged to 6,379,822 Company Common Shares based on the aforementioned Exchange Ratio (see Note 9 for further detail).

In relation to the Amended 2022 Financing, the holders of the 2022 Convertible Notes received warrants to purchase Old enGene common shares and the holders of the 2023 Convertible Notes were issued warrants in connection with the issuance of the 2023 Convertible Notes. As a result of the Reverse Recapitalization, these warrants were converted at closing into 2,679,432 Warrants to purchase Company Common Shares based on the aforementioned Exchange Ratio.

Immediately after giving effect to the Reverse Recapitalization and the PIPE Financing, the Company had 23,197,976 Common Shares and 10,411,641 Warrants outstanding.

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, EG-70, EG-i08 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 or 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:

Direct Costs:

- expenses incurred under agreements with Contract Research Organization (CROs) that are primarily engaged in the oversight and conduct of our clinical trials; Contract Development and Manufacturing Organization (CDMOs) 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;
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs of outside consultants, including their fees, share-based compensation and related travel expenses;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Indirect Costs:

- personnel-related expenses including, salaries, benefits, share-based compensation and other related costs for individuals involved in research and development activities; and
- facilities and other expenses not directly tied to a program.

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 EG-70. 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 CDMOs 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 research and development facility is located in Montreal, Quebec, Canada, and as such, the majority 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 EG-70, continue to discover and develop additional product candidates, expand our headcount and maintain, expand and enforce our intellectual property portfolio. If EG-70 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.

Our research and development expenses may vary significantly in the future based on factors, such as:

- the number and scope of nonclinical and IND-enabling studies;

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional collaboration or license agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

Any changes in the outcome of any of these variables with respect to the development of EG-70 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 EG-70, EG-i08 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 EG-70, EG-i08 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 EG-70, EG-i08 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. We also anticipate increased expenses associated with operating as a public company, including costs for accounting, audit, legal, regulatory, and tax-related services related to compliance with the rules and regulations of the SEC, listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums and investor relations costs. 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

Change in fair value of convertible debenture embedded derivative liabilities

Old enGene's convertible debentures consisted of a debt instrument, a minimum interest obligation, and a share conversion feature. Old enGene identified embedded derivatives related to share conversion features within the convertible notes that required bifurcation as a single compound derivative instrument and were classified as liabilities on our consolidated balance sheets. The convertible debenture embedded derivative liabilities were initially recorded at fair value upon the date of issuance using a probability weighted expected return model and were subsequently remeasured to fair value at each reporting date. The estimated probability and timing of

underlying events triggering the conversion features contained within the convertible debentures are inputs used to determine the estimated fair value of the embedded derivative. Changes in the fair value of the convertible debenture embedded derivative liabilities were recognized in change in fair value of convertible embedded derivative liabilities as a component of other expense in our consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization Old enGene's convertible debentures were exchanged for Common Shares of the Company, or settled through repayment, resulting in an extinguishment of the convertible debentures and related embedded derivative liabilities.

Change in fair value of warrant liabilities

Old enGene issued warrants to purchase redeemable convertible preferred shares as part of the issuance of certain redeemable convertible preferred shares and convertible debentures. Old enGene accounted for the redeemable convertible preferred shares warrants issued based upon the characteristics and provisions of the instrument and determined that the warrants were liability classified. The redeemable convertible preferred share warrants were recognized at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities as a component of other expense in our consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization, the preferred share warrants were surrendered for no consideration and the fair value was determined to be zero.

The warrants issued by Old enGene as part of the 2023 Financing (the "2023 Warrants") were concluded to be freestanding, liability classified instruments upon issuance, which were subsequently reclassified to equity upon the consummation of the Reverse Recapitalization. The fair value of the 2023 Warrants was estimated based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they were substantially similar to FEAC public warrants. The 2023 Warrants were initially measured at fair value and were subsequently remeasured at fair value with any changes in fair value recorded as a component of other expense in our consolidated statements of operations and comprehensive loss, so long as they remain liability classified. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the 2023 Warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815.

Change in fair value of convertible debentures

Old enGene issued convertible debentures and warrants in 2023 for which the fair value option of accounting was elected for the convertible debentures. The convertible debentures were initially recorded at fair value upon the date of issuance using a probability weighted expected return model and were subsequently remeasured to fair value at each reporting date. The estimated probability and timing of underlying events triggering the conversion contained within the convertible debentures are inputs used to determine the estimated fair value of the notes during the year ended October 31, 2023. Changes in the fair value of the convertible debentures were recognized in change in fair value of convertible debentures as a component of other expense in our consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization, convertible debentures were exchanged for Common Shares of the Company, resulting in an extinguishment of the convertible debentures.

Interest Expense

Interest expense is made 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.

Other expense, net

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

Loss on extinguishment of convertible debentures

Loss on extinguishment of convertible debentures consists of the differences between the carrying value of Old enGene's convertible debentures and the fair value of the settlement amounts upon repayment of the convertible debentures and exchange of the convertible debentures into shares of the Company.

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, 2023 and 2022, we have recorded a full valuation allowance against our deferred tax assets.

Results of Operations

Comparison of the Years Ended October 31, 2023 and 2022

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

	Year Ended October 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 16,458	$ 15,467	$ 991
General and administrative	9,602	3,960	5,642
Total operating expenses	26,060	19,427	6,633
Loss from operations	26,060	19,427	6,633
Other (income) expense, net:			
Change in fair value of convertible debenture embedded derivative liabilities	21,421	(269)	21,690
Change in fair value of warrant liabilities	(10,849)	3,326	(14,175)
Change in fair value of convertible debentures	56,212	—	56,212
Interest income	(1,117)	(129)	(988)
Interest expense	4,953	1,423	3,530
Loss on extinguishment and modifications of debentures	3,091	—	3,091
Other expense, net	129	662	(533)
Total other (income) expense, net	73,840	5,013	68,827
Net loss before provision for income tax	99,900	24,440	75,460
Provision for income tax	17	22	(5)
Net loss	$ 99,917	$ 24,462	$ 75,455

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,		
	2023	2022	Change
Direct costs:			
EG-70	$ 9,034	$ 10,060	$ (1,026)
Early stage/Other discovery R&D	620	498	122
Indirect costs:			
Personnel-related	3,818	2,801	1,017
Professional fees	2,532	1,766	766
Patent and licensing fees	370	661	(291)
Facilities and depreciation and amortization	160	207	(47)
Other	993	887	106
Refundable tax credits	(1,069)	(1,413)	344
Total research and development expenses	$ 16,458	$ 15,467	$ 991

Research and development expenses increased by $1.0 million from $15.5 million for the year ended October 31, 2022 to $16.5 million for the year ended October 31, 2023. This increase was attributable to the following:

- a $1.0 million increase in personnel-related costs primarily due to an increase in share-based compensation expenses and in employee headcount. Included within personnel-related costs is $0.8 million and $31 thousand of share-based compensation, for the years ended October 31, 2023 and 2022, respectively;
- a $0.8 million increase in indirect costs relating to professional fees, primarily relating to third party CMC research and development costs;
- a $0.3 million reduction in refundable tax credits as a result of the loss of our CCPC status and reduction in our maximum refundable tax credits due to our taxable capital, as defined by the tax authorities, which occurred in fiscal year 2023;
- a $0.1 million increase in direct costs relating to the research and nonclinical development of early stage and other discovery programs; and

- a $0.1 million increase in other expenses primarily attributable to an increase in laboratory supplies.

The decreases were partially offset by the following:

- a $1.0 million decrease in direct costs related to the nonclinical development of our main program, EG-70, based on the stage and progression of the drug development process; and
- a $0.3 million decrease in patent and licensing fees expenses primarily attributable to a decrease in patent applications; and

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,		
	2023	2022	Change
Personnel-related expenses	$ 4,780	$ 2,055	$ 2,725
Professional fees	3,297	863	2,434
Patent maintenance and legal fees	1,132	700	432
Other expenses	393	342	51
Total general and administrative expenses	$ 9,602	$ 3,960	$ 5,642

General and administrative expenses increased by $5.6 million from $4.0 million for the year ended October 31, 2022 to $9.6 million for the year ended October 31, 2023. This increase was primarily attributable to the following:

- a $2.7 million increase in personnel-related expenses primarily driven by share based compensation expense. Included within personnel-related costs is $2.6 million and $0.1 million of share-based compensation, for the years ended October 31, 2023 and 2022, respectively;
- a $2.4 million increase in costs related to professional fees primarily driven by accounting and audit related fees; and
- a $0.4 million increase in patent maintenance and legal expenses.

Other (Income) Expense, Net

Other (income) expenses, net increased by approximately $68.8 million from expense of $5.0 million for the year ended October 31, 2022 to expense of $73.8 million for the year ended October 31, 2023. This increase is attributable to a $56.2 million increase on the loss recorded on the change in fair value of convertible debentures as a result of using the quoted market price for FEAC's common share on October 31, 2023, which was $21.70 per share on that date, to determine the fair value of the common shares, a $21.4 million increase on the loss recorded on the change in fair value of the convertible debenture embedded derivative liabilities due to changes in the terms of the SPAC conversion option, changes in the valuation assumptions in the year ended October 31, 2023, and settlement of convertible debenture embedded derivative liabilities upon the closing of the Reverse Recapitalization, a $3.5 million increase in interest expense due to the amount of time the principal was outstanding on the 2022 Notes which were issued in October 2022, and a $3.1 million increase attributable to loss on extinguishment of convertible debentures as a result of the repayment and exchange into Common Shares of the Company upon the close of the Reverse Recapitalization. These increases were partially offset by a $14.2 million increase on the gain recorded on the change in fair value of warrant liabilities primarily driven by recording the value of the Series C preferred share warrants to zero upon the Reverse Recapitalization as a result of the cancellation of the Series C preferred share warrants, a $1.0 million increase in interest income due to increases in cash invested from financing transactions, and a $0.5 million decrease in other expenses which were primarily driven by foreign exchange losses. Changes in the valuation assumptions include an increase in the probability percentage of a SPAC transaction occurring and the decrease in probability of the other more unfavorable conversion scenarios, a decrease in the price of the underlying preferred shares caused by the increase in the probability of a SPAC transaction that results in some of the enterprise value shifting from the preferred shareholders to the common shareholders, and a decrease in the expected life of Series C preferred share warrants as a result of entering into the Merger Agreement scenario resulted in the cancellation of these warrants.

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, 2023, we had $81.5 million in cash and cash equivalents, and we had an accumulated deficit of $199.6 million. To date, we have financed our operations primarily through proceeds received through the PIPE Financing and FEAC trust account, net of redemptions, as part of the Reverse Recapitalization, along with the issuance of convertible debt and proceeds from sales of preferred shares by Old enGene. From inception to October 31, 2023, we have raised aggregate gross proceeds of approximately $77.8 million through the sale and issuance of Old enGene's preferred shares, warrants, and convertible debentures, $49.0 million

through Old enGene's term loan and April and May 2023 note and warrant financings, $56.9 million from the PIPE Financing and $7.4 million from the FEAC trust account, net of the redemption payment to FEAC's public shareholders and FEAC expenses.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, if at all. Should we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of our product candidates or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties' rights to develop or commercialize our product candidates that we would prefer to retain.

Our ability to continue as a going concern depends on our ability to successfully develop and commercialize our products, achieve and maintain profitable operations, as well as our ability to obtain additional financing and on the continued financial support of our shareholders and debt holders. 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. These conditions indicate the existence of a material uncertainty that raise substantial doubt on our ability to continue as a going concern and, therefore, that we may be unable to realize our assets and discharge our liabilities in the normal course of business.

Sources of Liquidity

Based on our current operating plan, we expect that our existing cash and cash equivalents as of October 31, 2023 together with the $50 million debt facility with Hercules Capital entered in December 2023, of which we have drawn $22.5 million, will be sufficient to fund our planned operating expenses and capital expenditure requirements and pay our debt service obligations as they become due into the second quarter of 2025, without giving effect to any potential milestone debt tranches we may be eligible to drawdown further under our debt facility with Hercules Capital. We have based this estimate on assumptions that may prove to be wrong, such as our clinical development costs, particularly as the process of testing drug candidates in clinical trials is costly and the timing of progress in these trials is uncertain. As a result, we could use our capital resources sooner than we expect.

Cash Flows

Comparison of the years ended October 31, 2023 and 2022

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

	Year Ended October 31,	
	2023	2022
Net cash used in operating activities	$ (24,743)	$ (17,592)
Net cash used in investing activities	(318)	(153)
Net cash provided by financing activities	86,147	27,967
Effect of exchange rate changes on cash	1	(805)
Net increase in cash and cash equivalents	$ 61,087	$ 9,417

Net Cash Used in Operating Activities

Net cash used in operating activities for the fiscal year ended October 31, 2023 was $24.7 million and was primarily due to our net loss of $99.9 million, partially offset by adjustments for non-cash charges totaling $75.6 million. The non-cash charges consisted of non-cash interest expense of $0.8 million, a loss on extinguishment of debt of $3.1 million, changes in fair value of convertible debentures of $56.2 million, changes in fair value of convertible debenture embedded derivative liabilities of $21.4 million, $0.9 million of debt issuance costs associated with debt for which the fair value of accounting was elected, $0.6 million of unrealized foreign exchange losses, share-based compensation expense of $3.5 million, and depreciation of property and equipment of $0.2 million, offset by changes in the fair value of warrant liabilities of $10.9 million. Further there were changes in operating assets and liabilities of $0.5 million, which was primarily associated with a $1.0 million increase in the investment tax credit receivable, and a $0.7 million increase in prepaid expenses and other assets, which was partially offset by a $1.2 million increase in accounts payable and accrued expenses and other liabilities.

Net cash used in operating activities for the fiscal year ended October 31, 2022 was $17.6 million and was primarily due to our net loss of $24.5 million, partially offset by adjustments for non-cash charges totaling $4.7 million which was primarily driven by non-cash interest expense of $0.6 million and changes in fair value of warrant liabilities of $3.3 million, as well as changes in operating assets and liabilities of $2.2 million, primarily associated with a $2.3 million increase in accrued expenses and other liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities for each of the fiscal years ended October 31, 2023, and 2022 was $0.3 and $0.2 million, respectively, consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the fiscal year ended October 31, 2023 was $86.1 million, resulting from proceeds of $38.0 million received from the issuance of convertible debentures, and $64.3 million gross proceeds received from the PIPE Financing and Reverse Recapitalization, partially offset by the repayment of scheduled principal payments of the Hercules term loan of $1.6 million, full repayment of the BDC convertible debentures of $3.2 million, payment of debt issuance costs of $0.9 million and payment of transaction costs in connection with the Reverse Recapitalization and PIPE of $10.5 million.

Net cash provided by financing activities for the fiscal year ended October 31, 2022 was $28.0 million, resulting from proceeds of $18.4 million received from the issuance of convertible debentures, and $11.0 million gross proceeds received from the issuance of our Hercules term loan, partially offset by the repayment of debt of $1.0 million and payment of debt issuance costs of $0.4 million.

Hercules Loan Agreement

On December 30, 2021, we entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules" or "the Bank" or the "Lender") for the issuance of a term loan facility of up to an aggregate principal amount of up to $20.0 million (the "Term Loan"). The Loan Agreement has remained in place upon consummation of the Reverse Recapitalization. The Loan Agreement provides for (i) an initial term loan advance of $7.0 million, which closed on December 30, 2021, (ii) subject to the achievement of certain Clinical Milestones (the "Clinical Milestone"), a right of the Company to request that the Lender make additional term loan advances to us in an aggregate principal amount of up to $4.0 million from the achievement of the Clinical Milestone through June 15, 2022, which was drawn in June 2022, and (iii) subject to the achievement of certain financial milestones (the "Financial Milestone"), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $9.0 million from achievement of the Financial Milestone through December 15, 2022, which was not achieved. We are required to pay an end of term fee (the "End of Term Charge") equal to 6.35% of the aggregate principal amount of the Term Loans advances upon repayment. The financing agreement 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 Term Loans mature on July 1, 2025, with no option for extension (the "Maturity Date").

The Term Loan bears interest at an annual rate equal to the greater of (i) 8.25% plus the prime rate of interest as reported in the Wall Street Journal minus 3.25% and (ii) 8.25% provided, that, from and after the date we achieve the financial milestone, as defined within the agreement, the reference to 8.25% in clauses (i) and (ii) is reduced to 8.15%. Borrowings under the Loan and Security Agreement are repayable in monthly interest-only payments through June 2023. After the interest-only payment period, borrowings under the Loan and Security Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. 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 of the last draw down; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the closing date of the last draw down, but on or prior to twenty-four months following the closing date of the last draw down; and 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date.

In connection with the Loan Agreement, we 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 Company's property and other assets, and certain equity interests and accounts of enGene, subject to limited exceptions including the Company's intellectual property. The Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company. The Company has been in compliance with the financial covenants and non-financial covenants since inception of the loan.

The debt discount and issuance costs are being accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Loan Agreement is approximately 18.28% and 15.90% as of October 31, 2023 and 2022, respectively.

As of October 31, 2023 and 2022 the carrying value of the note payable consists of the following:

	Year Ended October 31,	
	2023	2022
Note payable, including End of Term Charge	$ 10,144	$ 11,699
Debt discount, net of accretion	(474)	(891)
Accrued interest	108	106
Note payable, net of discount	$ 9,778	$ 10,914

During the fiscal years ended October 31,2023 and 2022, the Company recognized $1.8 and $1.0 million of interest expense related to the Loan Agreement, respectively.

During the fiscal year ended October 31, 2023, we borrowed $11.0 million under the Loan Agreement and incurred $1.1 million of debt discount and issuance costs inclusive of facility fees, legal fees, End of Term Charge and fair value of the warrant on issuance.

Estimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge as of October 31, 2023, and prior to the amendment of the Term Loan (see below) are as follows:

2024	$ 5,106
2025	5,038
Total principal payments, including End of Term Charge	$ 10,144

As of October 31, 2023, the Company classified $0.6 million of the note payable as current, which represents the principal payments due and amortization of the debt discount between October 31, 2023 and the date the Term Loan was amended in December 2023 (see below). Subsequent to the amendment to the Term Loan, we are not required to make any principal payments until at least July 1, 2025.

The Hercules term loan is our only outstanding debt instrument at October 31, 2023.

On December 22, 2023, 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 (with Hercules, the "Lenders"). The Amended Loan Agreement amends and restates in its entirety that certain Loan and Security Agreement with Hercules dated December 30, 2021 (the "Prior Loan Agreement").

The Amended Loan Agreement provides for a term loan facility of up to $50 million available in multiple tranches (the "Amended Term Loan"), as follows: (i) an initial term loan advance (the "Tranche 1 Advance") that was made on the 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") and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances to us in an aggregate principal amount of up to $7.5 million from the achievement of the Interim Milestone through the earlier of (x) 60 days following 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 (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 Loans, an end of term fee equal to 5.50% of the aggregate principal amount of the Term Loans. The Company is also required to pay on July 1, 2025 or, if earlier, the date the Company prepays the Term Loans, $0.7 million representing the end of term charge under the Prior Loan Agreement.

The Term Loans mature on January 1, 2028, with no option for extension.

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 are repayable in monthly interest-only payments through the "Amortization Date", which is either: (x) July 1, 2025 or (y) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (z) 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 Loans and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date.

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 of 1.0% - 3.0% of the principal amount being repaid, the rate depending upon the date of repayment.

In connection with the Amended Loan Agreement, 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 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 also contains certain events of default and representations, warranties and non-financial covenants of the Company. Beginning from an initial test date of October 1, 2024 (which date can be extended based on certain milestones), the Amended Loan Agreement contains a minimum liquidity covenant requiring the Company to maintain at least 35% of the aggregate outstanding principal as unrestricted cash. This percentage can be lowered based on certain milestones and other events.

In connection with the Amended Loan Agreement, the Company also agreed to issue to the Lenders in connection with each advance of Term Loans warrants ("Warrants") to purchase that number of the Company's Common Shares as shall equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrant 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 Closing Date and is subject to customary adjustments under the terms of the Warrants). Warrants are exercisable for a period of seven years from issuance.

On the Closing Date, the Company issued to the Lenders 62,413 Warrants in connection with the Tranche 1 Advance of the Term Loans.

Under the terms of the Amended Loan Agreement, the maximum number of Warrants and resultant underlying Common Shares of the Company that could be issued is 138,696.

April 2023 Notes

On April 4, 2023, we entered into a note purchase agreement (the "April 2023 Notes") for a principal amount of $8.0 million with Merck Lumira Biosciences Fund, L.P., Merck Lumira Biosciences Fund (Quebec), L.P., Lumira Ventures III, L.P., Lumira Ventures III (International), L.P., Lumira Ventures IV, L.P., Lumira Ventures IV (International), L.P., Fond de solidarité des travailleurs du Québec (F.T.Q.), and Forbion Capital Fund III Cooperatief U.A. (collectively the "April 2023 Investors"). The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, is to accrue interest at a rate of 15% per annum. The April 2023 Notes were classified as current as they mature on the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the financing in May 2023, we issued convertible debentures and warrants of the Company to the April 2023 Note Investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, as repayment of the April 2023 Notes.

We elected the fair value option of accounting under ASC 825 for the April 2023 Notes. We recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be $8.0 million. As part the 2023 Financing, the terms of the April 2023 Notes were modified, in which the extinguishment of the April 2023 Notes resulted in the issuance of convertible debentures and warrants of the Company to the April 2023 Note Investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing. Upon the completion of the 2023 Financing in May 2023, we issued $8.0 million in convertible notes and warrants in extinguishment for the April 2023 Notes. No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, and prior to the repayment of the April 2023 Notes given the short period of time that the April 2023 Notes were outstanding. No gain or loss was recorded as a result of the extinguishment of the April 2023 Notes as the fair value of the notes upon extinguishment was determined to be equal to the fair value of the repayment amount.

May 2023 Notes

On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, we entered into agreements pursuant to which we issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in extinguishment of the April 2023 Notes in an aggregate amount of $8.0 million (collectively, the "2023 Notes" and, together with the warrants purchased concurrently, the "2023 Financing"; the 2023 Financing together with the Amended 2022 Financing, the "Convertible Bridge Financing").

The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash, of which

Forbion Growth Sponsor FEAC I B.V. funded an aggregate amount of $20.0 million of the total $38.0 million. The 2023 Notes issued as part of the 2023 Financing have an initial maturity date of three years from the closing date and are to accrue interest at 10% per annum, which is payable upon maturity. The 2023 Notes have the same conversion terms as the 2022 Notes (as described in Note 9 of the consolidated financial statements).

The warrants issued as part of the 2023 Financing were for the purchase of common shares of Old enGene. The number of 2023 Warrants issued to each participating investor in the 2023 Financing was equal to the number of warrants in the Company the investor would receive had they invested the same amount in the PIPE Financing, divided by the Company Exchange Ratio. The 2023 Warrants were only to become exercisable upon the completion of the merger. Upon the close of the Reverse Recapitalization the 2023 Warrants were exchanged for 2,679,432 warrants of the Company and have the same terms as the public warrants issued upon the FEAC initial public offering, with an exercise price of $11.50, and which will expire five years after the completion of the merger. The warrants issued as part of the 2023 Financing were concluded to be liability classified upon issuance, as they failed the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815. The terms of the warrants initially required the Company to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants became fixed. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities. Refer to Note 3 of the consolidated financial statements. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815.

We elected the fair value option of accounting for the May 2023 Notes. We recorded May 2023 Notes at fair value upon the date of issuance. At inception the fair value of the May 2023 Notes was determined to be $37.0 million and the fair value of the related warrants was determined to be $1.4 million, of which $0.5 million related to the fair value of the warrants issued to the holders of the 2022 Notes, as described above. During the year ended October 31, 2023, we recorded a change in fair value of the May 2023 Notes of $56.2 million, which is recorded as a component of other income and expense within the condensed consolidated statement of operations. The Company incurred $0.8 million of debt issuance costs associated with the May 2023 Notes which have been expensed and are included within general and administrative expenses. Refer to Note 3 of the consolidated financial statements.

On October 31, 2023 upon the close of the Reverse Recapitalization, the 2023 Notes were converted into 4,298,463 Common Shares of the Company. We accounted for the conversion as an extinguishment, with no gain or loss recorded on extinguishment as the fair value of the Common Shares issued was determined to equal the fair value of the 2023 Notes at the time of conversion.

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. In addition, we expect to incur additional costs associated with operating as a public company subsequent to the closing of the Reverse Recapitalization. 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.

Based on our current operating plan, we believe that our cash on hand is sufficient to fund our operations for twelve months from the date of issuance of our financial statements. We could use our available capital resources sooner than we currently expect. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business 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 EG-70;
- 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 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 involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of commercialization activities if our lead candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates; 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.

The Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation ("CCPC") on eligible scientific research and development expenditures ("SR&ED") through September 2023, at which time the Company lost its status as a CCPC in connection with the Reverse Recapitalization. As such, the Company will no longer be eligible for cash refunds on federal tax credit earned with respect to federally eligible SR&ED expenditures. Following the loss of CCPC status, the Company's federal SR&ED tax credits will be earned at a lower rate and may only be used to offset future federal taxes payable. Provincial tax credits earned in Québec in relation to SR&ED are anticipated to continue to result in a cash refund to the Company, albeit at a reduced rate.

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.

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 detalamogene voraplasmid to research, develop, make, use, import, sell and offer and 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 $50,000 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 $50,000 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 $50,000 upon assigning the License Agreement to a third-party. The License Agreement provides for a one-time payment of $50,000 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 I clinical trial or, if there is no Phase I clinical trial, in a Phase II clinical trial, as well

as a one-time payment of $450,000 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, 2023. 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 the section titled Business of enGene – Intellectual Property – Strategic License Agreement and Note 7 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Lease Obligations

Our leases are comprised of all operating leases for office and lab space. We have a month-to-month office and lab space lease located in Montreal, Quebec, Canada, which commenced in November 2021 and had an initial term of 12 months that expired on October 31, 2022. The lease includes options to renew for consecutive twelve-month periods upon landlord consent, at new lease rates. In October 2022, we entered into a lease amendment to extend the lease for an additional term of six months through April 2023, with an option to extend the lease through September 2023. In April 2023, the Company extended the lease through September 2023. In September 2023, the Company extended the lease term through November 5, 2023. The amendment resulted in $0.2 million of additional lease commitments to be paid during the extended term, inclusive of the extension through November 5, 2023.

On December 29, 2022, we 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 Canadian Dollar ("CAD") per square foot, which is subject to annual increases of 2%. As of October 31, 2023, the term of the lease had not commenced and we did not have access to the space as of that date.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, CDMOs 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 does not have material capital expenditure commitments at October 31, 2023.

Critical Accounting Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with 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 on Form 10-K, 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.

Warrant Liabilities

Old enGene issued warrants to purchase shares of redeemable convertible preferred shares as part of the issuance of certain of its redeemable convertible preferred shares, convertible debentures, and term loan (the "Preferred Share Warrants"). The fair value of the Preferred Share Warrant liabilities was estimated using a Modified Black-Scholes option-pricing model, which includes assumptions that are based on the individual characteristics of the Preferred Share Warrants on the valuation date, and assumptions related to the fair value of the underlying redeemable convertible preferred shares, expected volatility, expected life, dividends, risk-free interest rate and discount for lack of marketability ("DLOM"). Due to the nature of these inputs, the Preferred Share Warrants are considered a Level 3 liability. The weighted average expected life was estimated based on the weighting of scenarios considering the probability of different terms up to the contractual term of 10 years in light of the expected timing of a future exit event, which includes a SPAC transaction. The expected volatility was determined based on an analysis of reported data for a group of guideline companies that have issued instruments 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 risk-free interest rate is determined by reference to the Canadian Treasury yield curve in effect at the time of measurement of the warrant liabilities for time periods approximately equal to the weighted average expected life of the warrant. Old enGene did not pay any cash dividends on its redeemable convertible preferred shares; therefore, the expected dividend yield was assumed to be zero.

Because there was no public market for the underlying redeemable convertible preferred shares of Old enGene, its Board of Directors determined their fair value based on third-party valuations. Initially, the enterprise equity value of Old enGene 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 Old enGene. This value was then allocated towards Old enGene'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 preferred shares include volatility, DLOM, and the expected timing of a future liquidity event such as an initial public offering, SPAC transaction or sale of Old enGene, in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios.

In addition to considering the results of these valuations, Old enGene's Board of Directors considered various objective and subjective factors to determine the fair value of our preferred shares as of each valuation date, including the prices at which Old enGene sold redeemable convertible preferred in the most recent transactions, external market conditions, the progress its research and development programs, our financial position, including cash on hand, and our historical and forecasted performance and operating results, and the lack of an active public market for its redeemable convertible preferred shares, among other factors. As part of entering into the Merger Agreement with FEAC, the holders have agreed to surrender the preferred share warrants for no consideration immediately prior to the completion of the Reverse Recapitalization. Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration and the fair value was determined to be zero.

The warrants issued by Old enGene as part of the 2023 Financing (the "2023 Warrants") were concluded to be freestanding, liability classified instruments upon issuance, as they failed the fixed-for-fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815. The terms of the warrants initially required Old enGene to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants became fixed, and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities.

Old enGene estimated the fair value of the 2023 Warrants based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they are substantially similar to FEAC public warrants. The price used to value the 2023 Warrants as of the issuance date and immediately prior to the consummation of the Reverse Recapitalization was $0.53 and $0.74, per warrant, respectively, which represented the quoted market price of the FEAC public warrants on each date.

Convertible Debentures Embedded Derivative Liabilities

Old enGene's convertible debentures contain equity conversion options and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the host contract for the convertible debentures for which the fair value has not been elected. The convertible debenture embedded derivative liabilities is initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization the 2022 Notes were exchanged for Common Shares of the Company, resulting in an extinguishment of the 2022 Notes and related embedded derivative liability, and the BDC Note was repaid in full.

Old enGene estimated the fair value of the convertible debenture embedded derivative liabilities on issuance and at each reporting period using a probability weighted scenario expected return model. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features and probability of exercise of the extension features within the convertible debentures, as well as discount rates, volatility and share prices, are inputs used to determine the estimated fair value of the embedded derivative. Immediately prior to the conversion and exchange of the 2022 Notes for Common Shares of the Company upon the Reverse Recapitalization, the Company remeasured the convertible debenture embedded derivative liability using a 100% probability of conversion upon the Reverse Recapitalization and the quoted market price for FEAC's common share on October 31, 2023, which was $21.70 per share, as the fair value of the common shares.

Fair Value Option

Old enGene elected the fair value option of accounting of ASC 825 for the April 2023 Notes and the May 2023 Notes from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the April 2023 Notes and May 2023 Notes, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. We have not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, we did not record any changes in fair value related to instrument-specific credit risk.

No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, given the close proximity between the issuance date of the notes and the repayment date. As of October 31, 2023, the April 2023 Notes are no longer outstanding.

Old enGene initially estimated the fair value of the May 2023 Notes using a probability weighted scenario expected return model. The estimated probability and timing of underlying events within the convertible debentures as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the May 2023 Notes. Due to the nature of these inputs, the May 2023 Notes initially represented a Level 3 measurement within the fair value hierarchy.

Immediately prior to the conversion and exchange of the May 2023 for Common Shares of the Company upon the Reverse Recapitalization, the Company remeasured the fair value of the convertible debentures using the quoted market price for FEAC's common share on October 31, 2023, which was $21.70 per share, as the fair value of the common shares for which the May 2023 Notes were exchanged for.

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 the April 2023 and May 2023 Notes could have been materially different.

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, 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 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, 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 Old enGene'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 Old enGene 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 will be determined based on the quoted price of our Common Shares.

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 $3.5 million and $0.1 million for the fiscal years ended October 31, 2023 and 2022, respectively.

Old enGene's Board of Directors granted 1,046,764 options to employees on July 7, 2023 for non-voting common shares of Old enGene at an exercise price of $5.87 CAD ($4.24 USD). The exercise price of $5.87 CAD ($4.24 USD) was approved by Old enGene's

Board of Directors and determined to be equal to the fair value of its common shares on the grant date based on a valuation performed by an independent third-party valuation specialist and considering (i) the lapse of time between the date of the valuation as of May 31, 2023 and the grant of the award was limited , and (ii) events between the valuation date and grant date that would affect the valuation of common shares. Significant assumptions used in the valuation to determine the fair value of common shares include expected value of common shares, discount rate, DLOM, and the expected timing of a future liquidity event such as an initial public offering, SPAC transaction or sale of Old enGene, in light of prevailing market conditions. These options are not exercisable unless and until the completion of the Merger Agreement and there is an effective registration statement for the shares underlying such granted options and the options would have terminated automatically in the event of the termination of the Merger Agreement. We have valued these awards at the grant date using Black-Scholes pricing model in which the fair value of the stock on the grant date was equal to the exercise price of the award. Upon meeting the exercisability conditions, 794,643 of the issued options will be fully vested and exercisable, and the remaining 252,121 options will vest over varying terms up to four years. We recognize compensation 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. During the year ended October 31, 2023, $2.6 million of stock-based compensation expense associated with the 1,046,764 stock options granted in July 2023 was recorded because the Merger Agreement was effected and while an effective registration statement was not in place as of October 31, 2023, the Company determined that it is probable to occur. As of October 31, 2023, there was $0.6 million of unrecognized compensation expense related to outstanding stock options, which is expected to be recognized over a weighted-average period of 3.68 years.

Recoverability of Investment Tax Credits Receivable

In September 2023 we lost our status as a Canadian controlled private corporation ("CCPC") and as a result, the rates at which we can claim Canadian federal and provincial tax credits on eligible research and development expenditures are reduced. 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. Upon the loss of our CCPC status, the federal tax credit is no longer refundable. 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, and as we continue to grow and expand our research and development activities outside of Canada, we anticipate our eligible research and development expenditures tax credits to decrease over time.

During the fiscal years ended October 31, 2023, and 2022, we recorded $1.1 million and $1.4 million, respectively, as a reduction of research and development expense associated with research and development investment tax credits. We have outstanding investment tax credits receivable of $2.3 million and $1.3 million as of October 31, 2023, and 2022, respectively.

Emerging Growth Company and Smaller Reporting Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. However, we do not elect this exemption in relation to accounting standards. We will continue to be an "emerging growth company" until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of FEAC's initial public offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.07 billion; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

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 on Form 10-K 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.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, resulting from the Federal Reserve's rising of interest rates. Our Term Loan has a variable interest rate that fluctuates with the U.S. prime rate.

Credit Risk

Our primary exposure to credit risk is through financial instruments and consist primarily of cash and cash equivalents. We regularly maintain deposits in accredited financial institutions in excess of federally insured limits. As of October 31, 2023, we held cash deposits in Canada at the National Bank of Canada, or NBC in excess of CDIC insured limits, and in the United States at Silicon Valley Bank, or SVB, in excess of FDIC insured limits. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or FDIC, was appointed as receiver. No losses have been incurred by us on deposits that were held at SVB to date.

We are dependent on third-party CDMO's ("Contract Development and Manufacturing Organization") and CRO's ("Contract Research Organization") with whom we do business. In particular, we rely and expect to continue to rely on a small number of manufacturers to supply us with the requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. We also rely 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.

Foreign Currency Exchange Risk

Prior to November 1, 2022, the functional currency of enGene Inc. was the Canadian Dollar and the functional currency of the Company's subsidiary, enGene U.S., Inc. is the U.S. Dollar ("USD"). During the current reporting period, enGene Inc. reassessed its functional currency and determined that the functional currency of enGene Inc. changed from the Canadian dollar to the U.S. dollar based on management's analysis as a result of evaluating criteria within Accounting Standards Codification ("ASC") 830, and considering our increased exposure to the USD through increased research and development activities in the United States, the recent financings in USD and contemplated future financings in USD, and the business combination with FEAC. The change in functional currency is accounted for prospectively from November 1, 2022, and prior year financial statements have not been restated for the change in functional currency. All assets and liabilities were reported using the same USD values as previously reported under the USD reporting currency described above. As a result, the cumulative translation adjustment balance as of October 31, 2022, is carried forward and will remain unchanged. The reporting currency is the US Dollar throughout all periods presented.

Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions that are conducted in a currency other than the Company's functional currency are included in other expenses, net in the Consolidated Statements of Operations and Comprehensive Loss. Prior to November 1, 2022, the financial statements of subsidiaries which had a functional currency other than the Canadian Dollar were translated from their functional currency into the parent company's functional currency of CAD, and then into the reporting currency as follows: assets and liabilities were translated at the exchange rates at the balance sheet dates, revenue and expenses were translated at the average exchange rates and shareholders' (deficit) equity was translated based on historical exchange rates. Translation adjustments were not included in determining net loss but were included as a foreign exchange adjustment to accumulated other comprehensive income, a component of shareholders' (deficit) equity. Beginning on November 1, 2022, due to the change in functional currency of the parent company to USD, all entities in the reporting group have a functional currency in USD and the cumulative translation adjustment balance as of October 31, 2022, is carried forward and will remain unchanged.

Our operating expenses are denominated in the currencies of the countries in which our operations are located, which are primarily in Canada and the United States. Our consolidated results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. To date, we have not entered into any hedging arrangements with respect to foreign currency risk or other derivative financial instruments, although we may choose to do so in the future.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We have experienced a general increase in costs as a result of global inflation however we believe that inflation has not had a material effect on our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the reports of our independent registered public accounting firms, appear beginning on page F-1 of this Annual Report on Form 10-K.

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 October 31, 2023, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures.

In connection with our preparation and the audit of our consolidated financial statements as of and for the years ended October 31, 2023 and 2022, management and our independent registered public accounting firm identified material weaknesses, as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), in 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 our consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses identified related to: lack of formal policies, procedures and controls related to the design of internal controls over financial reporting including risk assessment process and control activities for certain key financial reporting processes; lack of sufficient accounting and financial reporting personnel to perform appropriate accounting analysis and review procedures; lack of personnel with requisite knowledge and experience in the application of GAAP; general information technology controls that were not designed appropriately (access and system changes); and lack of appropriate segregation of duties in the preparation and review of account reconciliations and journal entries.

We intend to and have begun to implement in the near term measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including formalizing our processes and internal control documentation and strengthening supervisory reviews by our financial management; hiring additional qualified accounting and finance personnel with requisite knowledge and experience in the application of complex areas of GAAP, engaging financial consultants to enable the implementation of internal control over financial reporting and improving segregation of duties among accounting and finance personnel in the preparation and review of account reconciliations and journal entries. We will also review and improve the design of our general information technology controls including managing user access and privileged access, managing changes in the information system and segregation of duties.

While we are implementing these measures, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all, or prevent restatements of our financial statements in the future. If we are unable to successfully remediate our material weaknesses, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our Common Shares may decline as a result.

Based on this evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that, as of October 31, 2023, the Company did not have effective disclosure controls and procedures designed and implemented as of that date due to the material weakness previously identified which has not yet been remediated.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Principal Executive Officer and Principal Financial Officer, concluded that, as of October 31, 2023, our disclosure controls and procedures and internal control over financial reporting were not effective at a reasonable assurance level due to the material weakness described above. 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. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management's Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. On October 31, 2023, we completed the business combination with Forbion European Acquisition Corporation ("FEAC") and enGene Inc. ("Old enGene"). Prior to the business combination, we were a private corporation formed for the purpose of consummating the business combination and to become the parent company of the combined operating business following consummation of the business combination. The business combination is accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, FEAC is treated as the acquired company for financial reporting purposes, whereas Old enGene is treated as the accounting acquirer and predecessor. As a result, we are not a successor to FEAC, and as a result, the prior reports of FEAC are not considered when evaluating our internal control over financial reporting obligations.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors and Management

The following table sets forth, as of January 25, 2024, certain information regarding our directors and executive officers who are responsible for overseeing the management of our business.

Name	Age	Position
Executive Officers		
Jason D. Hanson	54	Chief Executive Officer and Director
Ryan Daws	49	Chief Financial Officer
Dr. Alex Nichols	38	President and Chief Operating Officer
Dr. Richard Bryce	66	Chief Medical Officer
Dr. Anthony T. Cheung	52	Chief Technology Officer
Dr. James C. Sullivan	45	Chief Scientific Officer
Non-Executive Directors		
Jasper Bos	49	Director
Gerry Brunk	55	Director
Dr. Richard Glickman	65	Director
Lota Zoth	64	Director

Executive Officers

Jason D. Hanson has served as Chief Executive Officer and as a Director of enGene since August 8, 2023. Mr. Hanson has served as Chief Executive Officer and as a Director of enGene Inc. since July 2018. He also served as President of enGene Inc. from July 2018 to December 2022. From August 2016 to November, 2017, Mr. Hanson served as President and Chief Executive Officer of Ohana Biosciences, a biotechnology company based in Cambridge, MA, and as member of the Ohana Board of Directors and consultant to Ohana from November 2017 to June 2018. Mr. Hanson previously served as Executive Vice President and Chief Strategy Officer for NuVasive, Inc. from November 2015 to August 2016. Mr. Hanson served as Corporate Vice President of General Electric Company and member of the senior executive team of GE Healthcare, a global pharmaceutical, medical device and healthcare services business from May 2014 to October 2015. In January 2013, Mr. Hanson served as Company Group Chairman and Executive Vice President of Valeant Pharmaceuticals International, Inc. (now Bausch Health Companies Inc.). Previously, he served in various roles at Medicis Pharmaceutical Corporation, including as Executive Vice President and Chief Operating Officer between July 2006 and December 2012. Mr. Hanson also served in numerous roles at GE Healthcare, including General Counsel roles, from April 1999 to July 2006. Mr. Hanson holds a B.S. from Cornell University and a J.D. from Duke University School of Law.

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.

Dr. Alex Nichols has served as President and Chief Operating Officer of enGene since November 1, 2023 and in the 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). Alex holds a B.A. in Biochemistry from Oberlin College and Ph.D. in Biophysics from Harvard University.

Dr. Richard Bryce has served as Chief Medical Officer of enGene since November 1, 2023 and in the same capacity for enGene Inc. since September 2023. From April 2021 to June 2023 Dr. Bryce served as Chief Medical Officer at Rain Oncology, a late-stage company developing precision oncology therapeutics, where he built a clinical development team and oversaw multiple clinical studies. From August 2017 to April 2021, Dr. Bryce was Chief Medical & Scientific Officer at Puma Biotechnology, where he led the development strategy for neratinib. Dr. Bryce also served as Senior Vice President, Clinical Research & Development at Puma Biotechnology from June 2012 to July 2017. Earlier in Dr. Bryce's career, from August 2008 to June 2012, he served as Senior Director of Clinical Science for Onyx Pharmaceuticals, where he oversaw the Phase 3 registrational studies for carfilzomib. Dr. Bryce obtained his Bachelor of Medicine and Bachelor of Surgery (MBChB) Degrees from the University of Edinburgh and is certified in the EU in primary care/general practice and pharmaceutical medicine. He holds numerous postgraduate specialist clinical qualifications including

those from the Royal College of Obstetricians & Gynaecologists and the Royal College of Physicians. Dr. Bryce also served as a Surgeon Lieutenant Commander in the Royal Navy.

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 has served as Chief Technology Officer of enGene since August 7, 2023 and in the 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. From November 1999 to March 2004, Dr. Cheung served as the President and Chief Executive Officer of enGene Inc. Dr. Cheung has co-authored numerous book chapters, review articles and peer-reviewed journals, and is named investor 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.

Dr. James C. Sullivan has served as Chief Scientific Officer at enGene since November 1, 2023 and in the same capacity for enGene Inc. since February 2022. In this role, Dr. Sullivan oversees Research and Preclinical Development. From January 2021 to January 2022, Dr. Sullivan served as Vice President, Head of Pulmonary Discovery at Translate Bio, Inc. Before joining Translate Bio, Dr. Sullivan was Executive Director, Head of Translational Biology at Sana Biotechnology, Inc from August 2019 to January 2021. He also served at Vertex Pharmaceuticals, Inc. from January 2008 to August 2019, where he where he was an IND and/or s/NDA team member for several products, including, for cystic fibrosis, Kalydeco®, Orkambi® and Symdeko®, as well as Incivek® for Hepatitis C. Dr. Sullivan was also an IND team member for multiple assets currently in clinical development to treat alpha-1-antitrypsin (AAT) deficiency and the first-ever CRISPR-based gene editing therapeutic product for the treatment of certain hemoglobinopathies (exagamglogene autotemcel). Dr. Sullivan holds a B.S. in Biology from Boston College, a M.Sc. from University College Dublin, and a Ph.D. from Boston University.

Non-Employee Directors

Jasper Bos, Ph.D., has served as a member of enGene's Board since August 8, 2023. Mr. Bos, the former Chief Executive Officer of FEAC, is a former Merck executive and joined Forbion Growth as a General Partner in May 2021. Before joining Forbion's Naarden-based headquarters, Mr. Bos was Senior Vice President and Managing Director at M Ventures, leading the venture capital arm of pharmaceutical company Merck, which he joined in 2009. At M Ventures, he led a team of 21 investment professionals and with a fund size of €400 million invested in over 50 portfolio companies spanning biotech, life sciences tools, and tech companies with investment activities ranging from seed-stage to cross-over and IPO. In addition, as Country Speaker Merck Netherlands, he assumed responsibility and liaised between all Merck activities in the Netherlands. His track record as an investor includes the successful exits of Prexton Therapeutics, Epitherapeutics, Galecto, ObsEva, Translate Bio, and F-Star, and has served on multiple boards of privately-owned biotech companies. He has experience in several operational roles in portfolio companies and played a key role in the creation of multiple successful spin-out companies out of Merck. Mr. Bos holds a Ph.D. in Pharmacy from the University of Groningen, the Netherlands.

Gerry 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. He currently serves as chair of the Board's Compensation Committee. 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.

Dr. Richard M. Glickman has served as a member of enGene's Board since April 24, 2023, and as chair of the board of enGene Inc. since January 2015, where he also served as a member of that board since October 2011. He currently serves as chair of the Board's Nominating and Corporate Governance Committee. Dr. Glickman was a co-founder of Aurinia Pharma Corp. where he served as its Chairman and CEO since February 2017. He was also the founding and current Chairman of the Board of Essa Pharmaceuticals Inc. 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.S. in Microbiology and Immunology from the McGill University.

Lota Zoth has served as a member of enGene's Board and as chair of the Board's Audit Committee since December 18, 2023. Ms. Zoth is a Certified Public Accountant and has also served as a member of the board of directors of 89BIO, Inc. (Nasdaq: ETNB), a clinical-stage biopharmaceutical company, since June 2020. She has served as a member of the board of directors and as chair of the audit committee of Lumos Pharma, Inc. (Nasdaq: LUMO) (previously, NewLink Genetics Corporation), a biopharmaceutical company, since November 2012. She 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 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 nonprofit 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.

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 (the "Audit Committee") 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 (the "Compensation Committee") 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 consists of (i) Jason D. Hanson, the Chief Executive Officer of enGene, (ii) Jasper Bos, (iii) Gerry Brunk (iv) Dr. Richard Glickman and (v) Lota Zoth. Pursuant to the Business Combination Agreement, as amended by the Waiver and Consent Letter, enGene will elect a full slate of directors no later than on or immediately following enGene's 2024 annual meeting of shareholders. The full slate of directors will consist of seven (7) directors. Under the 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. Following the continuance of enGene under the BCBCA, the director residency requirements in the CBCA have now ceased to apply.

Staggered Board Provisions

Under the Articles, for the purposes of facilitating staggered terms of the directors on the board, the following provisions, or the staggered board provisions, shall apply:

(i) one-third of the directors (or if the number of directors is not divisible by three, then that number of directors that is one-third of the directors rounded up to the next whole number) shall initially hold office for a three-year term expiring on the third annual general meeting of enGene following the date noted at the end of the Articles;

(ii) one-third of the directors (or if the number of directors is not divisible by three, then that number of directors that is one-third of the directors rounded up to the next whole number) shall initially hold office for a two-year term expiring on the second annual general meeting of enGene following the date noted at the end of the Articles; and

(iii) the remaining number of directors shall initially hold office for a one-year term expiring on the first annual general meeting of enGene following the date noted at the end of the Articles.

While the staggered board provisions apply, at every annual general meeting and in every unanimous shareholder resolution in lieu thereof, all of the directors whose terms expire shall 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 resignations of a director, the remaining directors may fill the casual vacancy resulting from such resignation for the remainder of the unexpired term.

Following the expiry of the directors' initial terms of office as set out above, the directors may be elected in the manner provided in Article 14.2 of the Articles to hold office for three-year terms expiring on the third annual general meeting following their election.

Accordingly, in accordance with the preceding, the initial terms of office for each of the enGene directors are as follows:

(i) Jason D. Hanson and Jasper Bos have terms expiring on the third annual general meeting following the Closing Date.

(ii) Gerry Brunk and Richard Glickman have terms expiring at the second annual general meeting following the Closing Date; and

(iii) Lota Zoth has a term expiring at the first annual meeting following the Closing Date.

Upon the expiry of the initial terms described above, the 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 will 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.

Diversity

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. enGene's nominating and corporate governance committee and management team are expected to take gender and other diversity representation into consideration as part of their overall recruitment and selection process.

enGene expects to facilitate the representation of women on its board and in executive officer positions by ensuring that diversity considerations are taken into account in senior management, monitoring the level of female representation on the board and in senior management positions, continuing to broaden recruiting efforts to attract and interview qualified female candidates, and committing to retention and training to ensure that enGene's most talented employees are promoted from within the organization.

Director Term Limits and Other Mechanisms of Board Renewal

enGene's Board of Directors 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, enGene expects that the nominating and corporate governance committee of its board of directors will develop a skills and competencies matrix for enGene's Board of Directors as a whole and for individual directors. enGene further expects that the nominating and corporate governance committee will also conduct a process for the assessment of its board of directors, each committee and each director regarding their or its effectiveness and contribution, and will report evaluation results to its board of directors on a regular basis.

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 NI 58-101, 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 each of Gerry Brunk, Richard Glickman and Lota Zoth is an independent director under applicable Nasdaq rules and pursuant to NI 52-110.

The independent directors of enGene's Board of Directors will 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 of Directors 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:

- appointing enGene's Chief Executive Officer;
- 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;
- 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;
- 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;
- 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
- 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 enGene's Board of Directors 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 enGene's Board of Directors 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.

Board Committees

The standing committees of the board of directors consist of an audit committee, a compensation committee and a nominating and corporate governance committee. The board of directors 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 and the nominating and corporate governance 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 regulation 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 will be to assist its Board of Directors in its oversight of:

- the quality and integrity of enGene's financial statements and related information;
- the independence, qualifications, appointment and performance of enGene's external auditor;
- 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;
- enGene's compliance with applicable legal and regulatory requirements; and
- enGene's enterprise risk management processes.

enGene's Board of Directors has established a written charter setting forth the purpose, composition, authority and responsibility of its audit committee, consistent with the rules of the Nasdaq, the SEC and NI 52-110.

enGene's audit committee has access to all of its 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, Gerry Brunk and Richard Glickman. 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:

- reviewing and making recommendations with respect to compensation policy and programs and determining and recommending option grants under enGene's incentive stock plan;
- reviewing and recommending to enGene's Board of Directors the manner in which executive compensation should be tied to corporate goals and objectives;
- 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;
- making recommendations to enGene's Board of Directors regarding the compensation of all other executive officers;
- reviewing and making recommendations to enGene's Board of Directors regarding incentive compensation plans and equity-based plans;
- 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
- reviewing director compensation for service on enGene's Board of Directors and board committees at least once a year and to recommending any changes to its Board of Directors.

enGene's Board of Directors has established a written charter that sets forth the purpose, composition, authority and responsibility of enGene's 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 Gerry Brunk, Chair, and Richard Glickman.

Nominating and Corporate Governance Committee

The members of the nominating and governance committee are independent for purposes of NI 58-101.

enGene's Board of Directors 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 enGene's Board of Directors in:

- identifying individuals qualified to become members of enGene's Board of Directors;
- selecting or recommending that enGene's Board of Directors select director nominees for the next annual meeting of shareholders and determining the composition of its Board of Directors and its committees;
- developing and overseeing a process to assess enGene's Board of Directors, the Chair of the board, the committees of the board, the chairs of the committees, individual directors and management; and
- developing and implementing enGene's corporate governance guidelines.

In identifying new candidates for enGene's Board of Directors, the nominating and corporate governance committee will consider what competencies and skills its board of directors, as a whole, should possess and assess what competencies and skills each existing director possesses, considering enGene's board of directors 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 of Directors 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 of Directors, each committee and each director regarding their or its effectiveness and contribution, and report evaluation results to its board of directors on a regular basis.

The Nominating and Corporate Governance Committee currently consists of Richard Glickman, Chair, and Gerry Brunk.

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 Form 10-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 guidelines 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 Annual Report on Form 10-K and is not incorporated by reference herein. If enGene makes any amendment to the Code of Conduct or grant any waivers, including any implicit waiver, from a provision of the code of ethics, 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 its board of directors for consideration. Additionally, the nominating and corporate governance committee assists enGene's Board of Directors 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 its board of directors as a whole).

Compensation Committee Interlocks and Insider Participation

None of the members of enGene's compensation committee at any time have been one of its officers or employees. None of the individuals who are enGene's executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on enGene's Board of Directors or compensation committee.

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 intends to comply 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 National Instrument 58-101 — *Disclosure of Corporate Governance Practices* ("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.

Item 11. Executive Compensation.

Unless otherwise indicated or the context otherwise requires, references in this section to "we," "us," "our," and other similar terms refer to enGene Holdings Inc. and its subsidiaries.

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, 2023 and 2022 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow this section.

For fiscal 2023, the "named executive officers" and their positions were as follows:

- Jason D. Hanson, our Chief Executive Officer;
- Alexander Nichols, our President and Chief Operating Officer; and
- James Sullivan, our Chief Scientific 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, 2023 and 2022.

Name and Principal Position	Fiscal Year	Base Salary ($)	Option Awards ($)[3]	Nonequity Incentive Plan Compensation[4]	All Other Compensation ($)[5]	Total ($)
Jason D. Hanson	2023	442,337	1,536,357	204,340	9,900	2,192,934
Chief Executive Officer	2022	446,419	—	193,638	9,150	649,207
Alexander Nichols						
President and Chief Operating Officer	2023	312,500 [1]	522,071	128,348	7,031	969,950
James Sullivan	2023	379,500	371,956	132,936	11,850	896,242
Chief Scientific Officer	2022	279,250 [2]	57,517	97,737	5,362	439,866

(1) Dr. Nichols began employment on December 27, 2022, and, as such, this number represents his prorated base salary.
(2) Dr. Sullivan began employment on February 15, 2022, and, as such, this number represents his prorated base salary.
(3) Mr. Hanson and Dr. Nichols did not receive any option grants in 2022 but Dr. Sullivan did receive an option grant in connection with his hiring. Mr. Hanson, Dr. Nichols and Dr. Sullivan all received options granted in 2023. The amount reported represents the aggregate grant date fair value of the stock options awarded to Mr. Hanson, Dr. Nichols and Dr. Sullivan during the 2023 and 2022 fiscal years, 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 12 to our consolidated financial statements as of and for the years ended October 31, 2023 and 2022 (the "Audited Financial Statements"). 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 Mr. Hanson, Dr. Nichols and Dr. Sullivan 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.
(4) The amounts in the "Nonequity incentive plan compensation" column represent annual bonus amounts awarded to the named executive officers by enGene's compensation committee, as detailed in "— Cash Incentive Compensation" below.
(5) This amount represents 401K employer contributions for each executive.

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 fiscal year ended October 31, 2023, the base salary for each of Mr. Hanson, Dr. Nichols and Dr. Sullivan was $442,337, $312,500, and $379,500, 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 set for the for each of the Company's named executive officers in the "Nonequity incentive plan compensation" column for 2023 and 2022 were awarded as a result of the achievement of certain performance measures over calendar years 2023 and 2022. The company performance criteria for calendar years 2023 and 2022 included operational goals in the

areas of the clinical development of EG-70, technology advances in the DDX platform, financing activity and building the corporate organization and corporate brand. For 2023, the Compensation Committee determined that overall corporate performance was achieved based on an assessment of the pre-established 2023 corporate goals. The target cash bonus for 2023 subject to the achievement of overall company performance criteria for Mr. Hanson, Dr. Sullivan and Dr. Nichols was 46%, 35% and 35% of their base salaries, respectively.

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. Executive grants are typically negotiated in connection with their hiring.

On October 31, 2023, upon completion of the Business Combination, the enGene Incentive Equity Plan (as defined below) became effective, which authorizes 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. Additionally, 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.

Employment Arrangements with our Named Executive Officers

Jason D. Hanson

On November 8, 2023, enGene USA, Inc., an indirect, wholly-owned subsidiary of the Company ("enGene USA"), and the Company's Chief Executive Officer, Jason Hanson, entered into an employment agreement (the "Hanson Employment Agreement") to be effective as of November 1, 2023. The Hanson Employment Agreement replaced the prior employment agreement between Mr. Hanson and enGene Inc., dated as of July 9, 2018, which agreement governed Mr. Hanson's compensation arrangements for fiscal year 2022.

The Hanson Employment Agreement has no fixed term and is terminable at will. Mr. Hanson is entitled under the Hanson Employment Agreement to an annual base salary of $590,000, to an annual 55% bonus opportunity, and to participate in enGene USA's employee benefit plans.

Pursuant to the Hanson Employment Agreement, (a) upon the termination of Mr. Hanson's employment by enGene USA without Cause (as defined in the Hanson Employment Agreement) or by Mr. Hanson for Good Reason (as defined in the Hanson Employment Agreement), Mr. Hanson 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. Hanson by enGene USA without Cause or by Mr. Hanson 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. Hanson is entitled to receive post-termination severance benefits from enGene USA consisting of (i) eighteen months' base salary, (ii) an amount equal to 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 time-based equity awards.

In addition, pursuant to the Hanson Employment Agreement, Mr. Hanson 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.

Alex Nichols

On November 8, 2023, enGene USA and the Company's President and Chief Operating Officer, Alex Nichols, entered into an employment agreement (the "Nichols Employment Agreement") to be effective as of November 1, 2023.

The Nichols Employment Agreement has no fixed term and is terminable at will. Mr. Nichols is entitled to, under the Nichols Employment Agreement, an annual base salary of $475,000, an annual 40% bonus opportunity, and eligibility to participate in enGene USA's employee benefit plans.

Pursuant to the Nichols Employment Agreement, (a) upon the termination of Mr. Nichols's employment by enGene USA without Cause (as defined in the Nichols Employment Agreement) or by Mr. Nichols for Good Reason (as defined in the Nichols Employment Agreement), Mr. Nichols 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. Nichols by enGene USA without Cause or by Mr. Nichols 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. Nichols 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 Nichols Employment Agreement, Mr. Nichols has agreed to standard restrictive covenant obligations, including a noncompete and nonsolicit obligation which runs while employed and for twelve months thereafter.

James Sullivan

On November 8, 2023, enGene USA and the Company's Chief Scientific Officer, James Sullivan, entered into an employment agreement (the "Sullivan Employment Agreement") to be effective as of November 1, 2023. The Sullivan Employment Agreement replaced the prior employment agreement between Mr. Sullivan and enGene Inc., dated as of February 14, 2022, which agreement governed Mr. Sullivan's compensation arrangements for fiscal year 2022.

The Sullivan Employment Agreement has no fixed term and is terminable at will. Mr. Sullivan is entitled to, under the Sullivan Employment Agreement, an annual base salary of $485,000, an annual 40% bonus opportunity, and eligibility to participate in enGene USA's employee benefit plans.

Pursuant to the Sullivan Employment Agreement, (a) upon the termination of Mr. Sullivan's employment by enGene USA without Cause (as defined in the Sullivan Employment Agreement) or by Mr. Sullivan for Good Reason (as defined in the Sullivan Employment Agreement), Mr. Sullivan 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. Sullivan by enGene USA without Cause or by Mr. Sullivan 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. Sullivan 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 Sullivan Employment Agreement, Mr. Sullivan 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 2023 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, 2023.

Name	Grant Date	Number Of Securities Underlying Unexercised Options (#) Exercisable	Number Of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)[1]	Option Expiration Date
Jason D. Hanson	7/9/2018	137,051 [2]	—	0.88	7/9/2028
	7/30/2019	30,939 [3]	—	0.88	7/30/2029
	8/20/2021	524,544 [4]	—	0.88	8/20/2031
	8/20/2021	10,906 [5]	—	0.88	8/20/2031
	7/7/2023	512,826 [6]	—	4.25	7/7/2033
Alexander Nichols	2/18/2023	177,935 [7]	—	1.52	2/18/2033
	7/7/2023	17,835 [8]	84,089 [8]	4.25	7/7/2033
James Sullivan	3/18/2022	88,901 [9]	—	0.88	3/18/2032
	7/7/2023	40,736 [10]	77,773 [10]	4.25	7/7/2033

(1) The amounts in the "Option Exercise Price" column are denominated in United States Dollars.
(2) This option is fully vested and exercisable. This option was received in the Business Combination in exchange for an option to purchase 759,374 enGene Common Shares.
(3) This option is fully vested and exercisable. This option was received in the Business Combination in exchange for an option to purchase 171,429 enGene Common Shares.

(4) This option is fully vested and exercisable. This option was received in the Business Combination in exchange for an option to purchase 2,906,386 enGene Common Shares.
(5) This option is fully vested and exercisable. This option was received in the Business Combination in exchange for an option to purchase 60,429 enGene Common Shares.
(6) This option was granted on July 7, 2023 on the condition it is not exercisable unless and until (i) the Business Combination Agreement has been completed and (ii) an effective registration statement for the New enGene shares underlying such granted options has been filed. This option was received in the Business Combination in exchange for an option to purchase 2,841,461 enGene Common Shares. This option is fully vested.
(7) This option is fully vested and exercisable. This option was received in the Business Combination in exchange for an option to purchase 985,899 enGene Common Shares.
(8) This option was granted on July 7, 2023 on the condition it is not exercisable unless and until (i) the Business Combination Agreement has been completed and (ii) an effective registration statement for the New enGene shares underlying such granted options has been filed. This option was received in the Business Combination in exchange for an option to purchase 564,739 enGene Common Shares. At the grant date, 12% of the option vested immediately, with the remaining portion to vest equally over 48 months.
(9) This option is fully vested and exercisable. This option was received in the Business Combination in exchange for an option to purchase 492,582 enGene Common Shares.
(10) This option was granted on July 7, 2023 on the condition it is not exercisable unless and until (i) the Business Combination Agreement has been completed and (ii) an effective registration statement for the New enGene shares underlying such granted options has been filed. This option was received in the Business Combination in exchange for an option to purchase 656,637 enGene Common Shares. At the grant date, 30% of the option vested immediately, with the remaining portion to vest equally over 48 months.

Employee Benefit and Equity Compensation Plans

Summary of the Equity Plans

For fiscal year ended October 31, 2023, executive compensation was under enGene Inc.'s employee stock option plan and equity incentive plan (together, the "enGene Inc. Plans"), Pursuant to the enGene Inc. Plans' options to purchase non-voting common shares of enGene Inc. stock were granted to directors, officers, employees, consultants and members of the scientific advisory board. The enGene Inc. Plans provided for the issuance of Common Share options up to a maximum of 15% of the aggregate issued and outstanding common shares and non-voting common shares of enGene Inc. calculated on an as converted and fully diluted basis. enGene Inc.'s Board of Directors administered the enGene Inc. Plans. It was enGene Inc.'s policy to establish the exercise price at an amount that approximates (and is no less than) the fair value of the underlying shares on the date of grant as determined by the Board of Directors.

Upon the Closing of the Business Combination, the enGene Inc. Plans have been superseded by the enGene Holdings Inc. 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 enGene Board or another committee appointed by the enGene Board to administer the Incentive Equity Plan; provided that any grants to members of the enGene Board must be authorized by a majority of the enGene Board (counting all the enGene Board members for purposes of a quorum, but only non-interested enGene Board members for purposes of such majority approval). The Committee (if other than the full enGene 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 enGene 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 enGene 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

Upon completion of the Business Combination, the number of enGene Common Shares subject to the Incentive Equity Plan was 5,314,884, inclusive of 2,607,943 Common Shares enGene is authorized to issue 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. The Incentive Equity Plan

contains an evergreen provision, pursuant to which, commencing with the first business day of each calendar year beginning in 2024, the aggregate number of enGene Common Shares that may be issued or transferred under the Incentive Equity Plan will be increased by a number of enGene Common Shares equal to the lesser of (x) 5% of the fully diluted capitalization of enGene after giving effect to the Business Combination, 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 enGene Common Shares subject to such awards will again be available for purposes of the Incentive Equity Plan. If enGene Common Shares are surrendered in payment of the exercise price of an option, the number of enGene Common Shares available for issuance under the Incentive Equity Plan will be reduced only by the net number of shares actually issued by enGene 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 enGene Common Shares available for issuance will be reduced only by the net number of shares actually issued by enGene upon such exercise.

If enGene Common Shares are withheld by enGene in satisfaction of the withholding taxes incurred in connection with the issuance, vesting or exercise of any grant or the issuance of enGene Common Shares under the Incentive Equity Plan, the number of enGene 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 enGene Common Shares, any enGene Common Shares subject to such awards will also be available for future awards. If enGene repurchases enGene Common Shares on the open market with the proceeds from the exercise price enGene 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 enGene 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 enGene Board, the maximum aggregate grant date value of enGene 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 enGene Common Shares, the Committee will make adjustments as it deems appropriate in: the maximum number of enGene 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 will be 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 enGene Common Shares subject to a particular grant and the vesting and exercisability terms of awards granted under the Incentive Equity Plan. As of the Closing Date, all employees and non-employee directors would be eligible to participate in 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 enGene 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 enGene 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 enGene 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 enGene 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; by, solely with respect to non-qualified stock options, enGene 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 enGene 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 enGene 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 enGene Common Shares. Share units become payable on terms and conditions determined by the Committee, including specified performance goals, and will be payable in cash, enGene 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 enGene 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 enGene 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 enGene 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 enGene Common Shares over the base amount of the SAR. The appreciation of a SAR will be paid in enGene 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 enGene Common Shares under enGene's 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, enGene 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, enGene 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 enGene 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 enGene experiences a change of control where enGene 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:

- 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;
- pay participants, in an amount and form determined by the Committee, in settlement of outstanding share units or dividend equivalents;
- require that participants surrender their outstanding stock options and SARs in exchange for a payment by us, in cash or enGene Common Shares, equal to the difference between the exercise price and the fair market value of the underlying enGene Common Shares; provided, however, if the per share fair market value of enGene 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
- 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:

- a person, entity or affiliated group, with certain exceptions, acquires more than 50% of the then-outstanding voting securities;
- enGene 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;
- enGene merges into, or consummates an amalgamation or arrangement with, another entity and the members of the enGene Board prior to such transaction would not constitute a majority of the board of the combined entity or its parent;
- enGene sells or disposes of all or substantially all of the assets of enGene;
- enGene consummates a complete liquidation or dissolution; or
- a majority of the members of the enGene 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 enGene 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. enGene 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 enGene may deduct from other wages and compensation paid by enGene 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 enGene 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 enGene Board may amend or terminate the Incentive Equity Plan at any time, except that enGene 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 enGene 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 enGene 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 enGene Common Shares underlying the grant) will be subject to any applicable policies implemented by the enGene 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 enGene Board adopted a Clawback Policy consistent with Nasdaq Listing Rule 5608, which requires enGene 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 enGene 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 enGene 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

enGene's non-employee directors did not receive any compensation, equity or non-equity awards in 2023. We reimburse non-employee members of our Board of Directors for reasonable travel expenses incurred in attending meetings of our Board of Directors and committees of our Board of Directors. See the "*Summary Compensation Table*" above for a discussion of our Chief Executive Officer's compensation and awards granted in 2023.

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

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 immediately following the consummation of the Business Combination on October 31, 2023 by:

- each person known to the Company to be the beneficial owner of more than 5% of outstanding Common Shares;
- each director and each of the Company's named executive officers; and
- all executive officers and directors of the Company as a group.

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 the Closing Date, 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.

Name and Address of Beneficial Owner	Number of Shares	Percent of Total Voting Power
enGene greater than 5% holders		
Forbion Growth [1]	8,169,004	31.9%
Lumira Ventures III, L.P. and affiliates [2]	3,381,853	14.4%
Forbion Capital Fund III Coöperarief U.A. [3]	3,369,275	14.2%
Fonds de solidarité des travailleurs du Québec [4]	3,088,682	13.1%
Biotechnology Value Fund, L.P. and affiliates [5]	3,196,439	13.2%
CHI IV Public Investments LP [6]	1,606,252	6.79%
Omega Fund VII, L.P. [7]	1,606,252	6.79%
enGene directors and named executive officers		
Jason D. Hanson [8]	1,216,266	5.0%
Dr. Anthony T. Cheung [9]	535,442	2.3%
Dr. James C. Sullivan [8]	133,797	*%
Dr. Gerald Brunk [10]	3,381,853	14.4%
Jasper Bos [11]	—	—%
Dr. Richard Glickman [12]	90,436	*%
enGene directors and executive officers as a group (9 persons)	5,557,303	21.7%

* Less than 1%.

Unless otherwise indicated, the address of each person named below is c/o enGene Holdings Inc., 4868 Rue Levy, Suite 220, Saint-Laurent, QC H4R 2P1, Canada.

(1) Forbion Growth Sponsor FEAC I B.V., or FEAC Sponsor, is the record holder of 3,765,932 of the enGene Shares reported herein. Forbion Growth Opportunities Fund I Cooperatief U.A. ("FGOF") is the record holder of 2,000,000 enGene Common Shares reported herein. The number of shares reported also includes warrants held by FEAC Sponsor that may be exercised to acquire 1,736,406 enGene Common Shares, and warrants held by FGOF that may be exercised to acquire 666,666 enGene Common Shares, in each case that are exercisable within 60 days following October 31, 2023. 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) Consists of 1,341,790 shares held by Lumira Ventures III, L.P. ("Lumira III"), 44,647 shares held by Lumira Ventures III (International), L.P. ("Lumira III Int'l"), 348,686 shares held by Lumira Ventures IV, L.P. ("Lumira IV"), 83,816 shares held by Lumira Ventures IV (International), L.P. ("Lumira IV Int'l"), 1,077,386 shares held by Merck Lumira Biosciences Fund, L.P. ("Merck-Lumira"), and 152,974 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 shares reported also includes warrants held by Lumira III that may be exercised to acquire 114,945 enGene Common Shares, warrants held by Lumira III Int'l that may be exercised to acquire 3,825 enGene Common Shares, warrants held by Lumira IV that may be exercised to acquire 38,301 enGene Common Shares, warrants held by Lumira IV Int'l that may be exercised to acquire 9,207 enGene Common Shares, warrants held by Merck-Lumira that may be exercised to acquire 145,603 enGene Common Shares, and warrants held by Merck-Lumira B that may be exercised to acquire 20,673 enGene Common Shares, in each case that are exercisable within 60 days following October 31, 2023. 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.

(3) The number of shares reported includes warrants that may be exercised to acquire 475,076 enGene Common Shares that are exercisable within 60 days following October 31, 2023. 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 currently a director of enGene, 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.

(4) The number of shares reported includes warrants that may be exercised to acquire 446,572 enGene Common Shares that are exercisable within 60 days following October 31, 2023. Fonds de solidarité des travailleurs du Québec (the "Fonds") is managed by a 19-member board of directors, which is majority independent and includes Mr. Claude Séguin, the chair of the board, and Ms. Janie C. Béïque, who is also the President and Chief Executive Officer of the Fonds. Investment power over the enGene shares held by the Fonds is exercised either by its board of directors or by a 9-member investment committee of the Fonds' board of directors, which is majority independent and includes Pierre-Maurice Vachon, who is also the Second Vice-Chair of the board of the Fonds, and Magali Picard, who is also first vice-chair of the board. None of the members of the Fonds' board of directors or investment committee have individual voting or investment power over the enGene shares held by the Fonds. Mr. Séguin, Ms. Béïque, Mr. Vachon and Ms. Picard each disclaim beneficial ownership of such shares except to the extent of their pecuniary interests therein. The business address of the Fonds is 545 Crémazie Blvd. East, Suite 200, Montréal, Québec, Canada H2M 2W4.

(5) Consists of 1,204,412 enGene Common Shares held by Biotechnology Value Fund, L.P. ("BVF"), 912,776 enGene Common Shares held by Biotechnology Value Fund II, L.P. ("BVF2"), 104,257 enGene Common Shares held by Biotechnology Value Trading Fund OS LP ("Trading Fund OS") and 29,592 enGene Common Shares held by MSI BVF SPV, LLC ("MSI BVF"). The number of shares reported also includes warrants held by BVF that may be exercised to acquire 505,835 enGene Common Shares, warrants held by BVF2 that may be exercised to acquire 383,352 enGene Common Shares, warrants held by Trading Fund OS that may be exercised to acquire 43,786 enGene Common Shares, and warrants held by MSI BVF that may be exercised to acquire 12,429 enGene Common Shares, in each case that are exercisable within 60 days following October 31, 2023.BVF I GP LLC ("BVF GP") is the general partner of BVF, and may be deemed to beneficially own the enGene Common Shares held by BVF; BVF II GP LLC ("BVF2 GP") is the general partner of BVF2, and may be deemed to beneficially own the enGene Common Shares held by BVF2; BVF Partners OS Ltd. ("Partners OS") is the general partner of Trading Fund OS, and may be deemed to beneficially own the enGene Common Shares held by Trading Fund OS. BVF GP Holdings LLC ("BVF GPH") is the sole member of each of BVF GP and BVF2 GP, and may be deemed to beneficially own the enGene Common Shares beneficially owned by BVF and BVF2. BVF Partners L.P. ("Partners") is the investment manager of BVF, BVF2, Trading Fund OS and MSI BVF and the sole member of Partners OS, and may be deemed to beneficially own the enGene Common Shares beneficially owned by BVF, BVF2, Trading Fund OS, and MSI BVF. BVF Inc. is the general partner of Partners, and may be deemed to beneficially own the enGene Common Shares beneficially owned by Partners. Mark N. Lampert is a director and officer of BVF Inc., and may be deemed to beneficially own the enGene Common Shares beneficially owned by BVF Inc. Each of BVF GP, BVF2 GP, Partners OS, BVF GPH, Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares beneficially owned by BVF, BVF2, Trading Fund OS and MSI BVF. The business address of BVF, BVF GP, BVF2, BVF2 GP, BVF GPH, MSI BVF, Partners, BVF Inc. and Mark N. Lampert is 44 Montgomery St., 40th Floor, San Francisco, California 94104. The business address of Trading Fund OS and Partners OS is PO Box 309 Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(6) The number of shares reported includes warrants that may be exercised to acquire 475,077 enGene Common Shares that are exercisable within 60 days following October 31, 2023. CHI Advisors LLC is the investment manager of CHI IV Public Investments LP and has sole voting control and investment discretion over securities owned by CHI IV Public Investments LP. The business address of CHI IV Public Investments LP and CHI Advisors LLC is 599 Lexington Avenue, 19th Floor, New York, NY 10022.

(7) The number of shares reported includes warrants that may be exercised to acquire 475,077 enGene Common Shares that are exercisable within 60 days following October 31, 2023. All of the securities are held by Omega Fund VII, L.P. ("Omega Fund"). Omega Fund VII GP Manager, Ltd. ("Omega Ltd.") is the sole general partner of Omega Fund VII GP, L.P. ("Omega GP"), which is the sole general partner of Omega Fund; and each of Omega Ltd. and Omega GP may be deemed to own beneficially the shares held by Omega Fund. Claudio Nessi and Otello Stampacchia are the directors of Omega Ltd. and, as a result, may be deemed to share voting and investment power over the shares held directly by Omega Fund. Each of Dr. Stampacchia, Dr. Nessi, Omega Ltd. and Omega GP disclaim beneficial ownership of the shares held by Omega Fund except to the extent of their pecuniary interest therein. The business address of the reporting entity is 888 Boylston Street, Suite 1111, Boston, MA 02199.

(8) Represents options to acquire enGene Common Shares that are exercisable within 60 days following October 31, 2023.

(9) Consists of 49,933 enGene Common Shares and options to acquire 485,509 enGene Common Shares that are exercisable within 60 days following October 31, 2023.

(10) Consists of enGene Common Shares and warrants to purchase enGene Common Shares held by the Lumira entities. See footnote (2) above. Mr. Brunk is an executive officer of certain entities controlling and/or managing the Lumira entities. Mr. Brunk disclaims beneficial ownership of the enGene Common Shares held by the Lumira entities, except to the extent of his pecuniary interest therein, if any.

(11) Mr. Bos is a director of FEAC Sponsor, and a member of the investment committee of Forbion Management. Mr. Bos disclaims beneficial ownership over the enGene Common Shares held by FEAC Sponsor and FGOF, except to the extent of his proportionate pecuniary interest therein.

(12) Consists of 24,555 enGene Common Shares and options to acquire 65,881 enGene Common Shares that are exercisable within 60 days following October 31, 2023.

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

The Business Combination closed on October 31, 2023. Therefore, the following discussion and analysis is being provided supplementally to give an understanding of FEAC's results of operations and financial position prior to the Business Combination.

FEAC

FEAC Class B Shares

On August 12, 2021, Forbion European Sponsor LLP paid $25,000, or approximately $0.009 per share, in consideration for 2,875,000 FEAC Class B Shares. On November 23, 2021, Forbion European Sponsor LLP transferred 2,875,000 FEAC Class B Shares to the FEAC Sponsor in exchange for $25,000, or approximately $0.009 per share. On December 9, 2021, FEAC issued an additional 287,500 FEAC Class B Shares to the FEAC Sponsor resulting from a 1.1 for 1 share dividend. As a result, the FEAC Sponsor owned 3,162,500 FEAC Class B Shares as of the date of the Business Combination Agreement. The FEAC Class B Shares will be exchanged for FEAC Class A Shares, on a one-for-one basis, on the day that is two business days prior to the Closing of the Business Combination. The number of FEAC Class B Shares issued was determined based on the expectation that the FEAC Class B Shares would represent 20% of the issued and outstanding ordinary shares of FEAC upon completion of the IPO. Such FEAC Class B Shares were issued pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act.

Private Placement Warrants

Simultaneously with the closing of the IPO, the FEAC Sponsor purchased in a private placement 4,700,000 FEAC Private Placement Warrants (5,195,000 FEAC Private Placement Warrants when the underwriters' over-allotment option was fully exercised on December 15, 2021), each exercisable to purchase one FEAC Class A Share at $11.50 per share, at a price of $1.50 per FEAC Private Placement Warrants. The sale of the FEAC Private Placement Warrants in connection with the IPO and subsequent over-allotment option exercise generated gross proceeds of $7,792,500. Except as described below, the FEAC Private Placement Warrants had terms and provisions that are identical to those of the FEAC Warrants. The FEAC Private Placement Warrants were not transferable, assignable or salable (and the FEAC Class A Shares issuable upon exercise of the FEAC Private Placement Warrants are not transferable, assignable or salable until 30 days after the completion of the Business Combination), except pursuant to limited exceptions, and they are not redeemable by FEAC. The FEAC Sponsor, or its permitted transferees, have the option to exercise the FEAC Private Placement Warrants on a cashless basis.

There were no redemption rights or liquidating distributions with respect to the FEAC Class B Shares or FEAC Private Placement Warrants.

Working Capital Loans

In order to finance transaction costs in connection with the Business Combination, the FEAC Sponsor or an affiliate of the FEAC Sponsor, or certain of FEAC's officers and directors were permitted, but not obligated to, loan to FEAC funds as deemed required ("Working Capital Loans"). FEAC repaid the Working Capital Loans out of the proceeds of the Trust Account released to FEAC in connection with the completion of the Business Combination. An aggregate amount of $1,500,000 in Working Capital Loans and Extension Loans was converted, at the election of the FEAC Sponsor, into additional FEAC Warrants at a price of $1.50 per warrant on terms identical to the FEAC Private Placement Warrants, concurrently with the consummation of the Business Combination.

On March 24, 2023, the FEAC Sponsor and FEAC entered into an unsecured promissory note (the "First Loan Note") under which the FEAC Sponsor agreed to extend to FEAC a loan of up to $900,000, to be used for FEAC's general corporate purposes. The FEAC Sponsor funded the initial principal amount of $450,000 under the First Loan Note on March 24, 2023 and an additional $450,000 under the First Loan Note on April 26, 2023. The First Loan Note bears no interest became due and payable on the date of the Business Combination (the "Loan Note Maturity Date"). In connection with the completion of the Business Combination, the FEAC Sponsor elected to convert the total principal amount of the First Loan Note into additional warrants of FEAC at a price of $1.50 per warrant and on terms identical to the FEAC Private Placement Warrants (see also "*The Business Combination Agreement — Repayment of the First Loan Note and the First Extension Loan Note*"). The issuance of the First Loan Note was made pursuant to the exemption from registration contained in Section 4(a)(2) of the Securities Act.

On June 6, 2023, FEAC issued an additional unsecured promissory note (the "Second Loan Note") under which the FEAC Sponsor agreed to extend to FEAC a loan in the total principal amount of $300,000 to the FEAC Sponsor. The proceeds of the Second Loan Note were used by FEAC for general corporate purposes. The FEAC Sponsor funded the principal amount of $300,000 on June 6, 2023. The Second Loan Note bears no interest and became due and payable on the Loan Note Maturity Date. In connection with the completion of the Business Combination FEAC repaid the Second Loan Note out of the proceeds of the Trust Account released to FEAC.

On September 13, 2023, FEAC issued an additional unsecured promissory note (the "Third Loan Note") under which the FEAC Sponsor agreed to extend to FEAC a loan in the total principal amount of $450,000 to the FEAC Sponsor. The proceeds of the Third Loan Note were used by FEAC for general corporate purposes. The FEAC Sponsor funded the principal amount of $450,000 on September 13, 2023. The Third Loan Note bears no interest and became due and payable on the Loan Note Maturity Date. In connection with the completion of the Business Combination FEAC repaid the Third Loan Note out of the proceeds of the Trust Account released to FEAC.

Extension Loans; Business Combination Deadline Extensions

FEAC was permitted to extend the period of time to consummate the business combination by up to two additional three-month periods (for a total of 24 months to complete the initial business combination). In order to extend the time available for FEAC to consummate an initial business combination, the FEAC Sponsor or its affiliates or designees were required to deposit into the Trust Account, for each additional three-month period, $1,265,000 ($0.10 per FEAC Class A Shares in either case), on or prior to the date of the applicable deadline, the first of which was on June 14, 2023. Any such payments were required to be made in the form of a non-interest bearing, unsecured promissory note (each such note, an "Extension Loan").

On June 6, 2023, FEAC extended the time available to consummate the initial business combination from June 14, 2023 to September 14, 2023 by borrowing from FEAC Sponsor, and having FEAC Sponsor deposit on FEAC's behalf an additional $1,265,000, or $0.10 per FEAC Class A Share, into the Trust Account (the "First Extension Funding"), in accordance with FEAC's Current Articles and the Investment Management Trust Agreement by and between the Company and Continental Stock Transfer & Trust Company, dated as of December 9, 2021. In connection with the First Extension Funding, on June 6, 2023, FEAC issued an unsecured promissory note (the "First Extension Loan Note") in the total principal amount of $1,265,000 to the FEAC Sponsor. The FEAC Sponsor funded the principal amount of $1,265,000 by depositing such amount into the Trust Account on June 6, 2023. The First Extension Loan Note did not bear interest and became due and payable on the Loan Note Maturity Date.

Concurrently with the consummation of the initial business combination, the FEAC Sponsor elected to convert up to $600,000 total principal amount of the First Extension Loan Note into additional warrants of FEAC at a price of $1.50 per warrant, each warrant exercisable for one FEAC Class A Share. The warrants were to be identical to the FEAC Private Placement Warrants (see also "*The Business Combination Agreement — Repayment of the First Loan Note and the First Extension Loan Note*").

On September 13, 2023, FEAC further extended the time available to consummate the initial business combination from September 14, 2023 to December 14, 2023 by borrowing from FEAC Sponsor, and having FEAC Sponsor deposit on FEAC's behalf an additional $1,265,000, or $0.10 per FEAC Class A Share, into the Trust Account (the "Second Extension Funding"), in accordance with FEAC's then existing Articles and the Investment Management Trust Agreement by and between the Company and Continental Stock Transfer & Trust Company, dated as of December 9, 2021. In connection with the Second Extension Funding, on September 13, 2023, FEAC issued an unsecured promissory note (the "Second Extension Loan Note") in the total principal amount of $1,265,000 to the FEAC Sponsor. The FEAC Sponsor funded the principal amount of $1,265,000 by depositing such amount into the Trust Account on September 13, 2023. The Second Extension Loan Note did not bear interest and became due and payable on the Loan Note Maturity Date.

Sponsor and Insiders Letter Agreement; Surrender; Sponsor Loans Conversion

On May 16, 2023, concurrently with the execution of the Business Combination Agreement, FEAC, the FEAC Sponsor, FGOF and the other holders of FEAC Class B Shares, enGene Inc., enGene Holdings Inc. and the other parties named therein (collectively, other than enGene Inc. and enGene Holdings Inc., the "FEAC Sponsor Parties") entered into the Sponsor and Insiders Letter Agreement, pursuant to which the FEAC Sponsor agreed to surrender, after giving effect to the conversion of all or part of the principal amount outstanding under loans made by the FEAC Sponsor to FEAC into FEAC Private Placement Warrants, 1,789,004 FEAC Class B Shares and 5,463,381 FEAC Private Placement Warrants, as a contribution to the capital of FEAC and for no consideration, effective immediately prior to the Class B Conversion on the date which was two business days prior to the Closing Date (the "Surrender").

In addition, the FEAC Sponsor Parties agreed to (i) be bound by certain other covenants and agreements related to the Business Combination, (ii) waive the anti-dilution protection with respect to the FEAC Class B Shares (whether resulting from the PIPE Financing or otherwise) and (iii) be bound by certain transfer restrictions with respect to the FEAC Shares and the FEAC Private Placement Warrants held by them (including the enGene Common Shares and Warrants received in exchange therefore in connection with the Business Combination and the Transactions), in each case, on the terms and subject to the conditions set forth in the Sponsor and Insiders Letter Agreement.

Also, FEAC, the FEAC Sponsor and each Insider that was a Lender under the Sponsor Loans (each such term as defined in the Sponsor and Insiders Letter Agreement), each on its own behalf and on behalf of its affiliates (including the officers and directors of FEAC and each Lender), assuming that the aggregate principal amount outstanding under the Sponsor Loans exceeded $1,500,000 on the day which was two business days prior to the Closing Date, agreed to elect to convert, and to take such necessary or appropriate actions so as to ensure the conversion of, an amount equal to $1,500,000 of the aggregate principal amount outstanding under the Sponsor Loans, taken together, into additional FEAC Private Placement Warrants immediately prior to the Surrender on the date that was two business days prior to the Closing Date, in each case in accordance with the FEAC Warrant Agreement and the relevant promissory note governing each such Sponsor Loan (the "FEAC Sponsor Loans Conversion").

FEAC Voting Agreement

Concurrently with the execution and delivery of the Business Combination Agreement, enGene Inc., enGene Holdings Inc. and the FEAC Sponsor Parties entered into the FEAC Voting Agreement, pursuant to which the FEAC Sponsor Parties agreed to, among other things, (i) vote or cause to be voted all of their FEAC Shares in favor of the Transaction Proposals; (ii) be bound by certain other covenants and agreements related to the Business Combination, and (iii) be bound by certain transfer restrictions with respect to the FEAC Shares, in each case, on the terms and subject to the conditions set forth in the FEAC Voting Agreement.

Registration Rights Agreement

In connection with the Business Combination, on October 31, 2023, enGene Holdings Inc., FEAC, the Sponsor Holders and the enGene Holders (each as defined in the Registration Rights Agreement) entered into a Registration Rights Agreement. Pursuant to the terms of the Registration Rights Agreement, among other things, the Sponsor Holders and the enGene Holders were granted certain customary registration rights with respect to their respective equity securities of enGene Holdings Inc., in each case, on the terms and subject to the conditions therein.

Office Space, Secretarial and Administrative Services

Commencing on the date of the IPO and through Closing Date, FEAC agreed to pay the FEAC Sponsor a total of $10,000 per month for office space, utilities, secretarial and administrative support and to reimburse the FEAC Sponsor for any out-of-pocket expenses related to identifying, investigating and completing an initial business combination. FEAC maintained its executive offices at 4001 Kennett Pike, Suite 302 Wilmington, Delaware 19807. The cost for the use of this space was included in the $10,000 per month fee FEAC paid to the FEAC Sponsor for office space, administrative and support services.

Additionally, the FEAC Sponsor agreed to pay an annual salary of $25,000 to each of the independent board members of FEAC for services rendered prior to or in connection with the completion of the Business Combination. Board members were also entitled to reimbursement for any out-of-pocket expenses related to identifying, investigating, negotiating and completing the Business Combination as well.

FEAC's audit committee reviewed on a quarterly basis all payments that were made to the FEAC Sponsor, FEAC's officers, directors or its or their affiliates.

enGene

Throughout this subsection, unless otherwise noted, we, "our", "us," "enGene" and the "Company" refer to enGene Holdings Inc. and all of its subsidiaries post the consummation of the Reverse Recapitalization, and "Old enGene" refers to enGene Inc.

Closing Transactions

On October 31, 2023, upon the consummation of the Business Combination, all of Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close were exchanged for enGene Common Shares, with no dividends or distributions being declared or paid on the redeemable convertible preferred shares. Further, certain of Old enGene's existing convertible notes were converted into enGene Common Shares at the conversion ratio in place at the time of conversion, and all of Old enGene's common shares were exchanged for enGene Common Shares at the Exchange Ratio. A total of 13,091,608 enGene Common Shares were issued to enGene's equity and convertible note holders upon the close of the Business Combination. Each of Old enGene's outstanding warrants to purchase Common Shares were exchanged for 2,679,432 Warrants based on the Exchange Ratio. All of Old enGene's existing outstanding Class C Warrants outstanding at the time of the Business Combination were terminated. Additionally, there were 3,670,927 enGene Common Shares issued to FEAC and its shareholders as part of the Business Combination, along with 5,029,444 Warrants to purchase enGene Common Shares.

2022 Convertible Notes

On October 20, 2022, Old enGene entered into a note purchase agreement with, and issued the 2022 Convertible Notes to, existing shareholders, including the 2022 Noteholders.

Prior to the execution and delivery of the Business Combination Agreement, Old enGene and the 2022 Noteholders entered into the Amended 2022 Convertible Notes to amend and restate the 2022 Convertible Notes, pursuant to which (i) the Amended 2022 Convertible Notes are, among other things, convertible into that number of Old enGene common shares that, when exchanged at the enGene Exchange Ratio, shall equal that number of FEAC Class A Shares (or after the Assumption, enGene Common Shares) that the holders of the Amended 2022 Convertible Notes would have received if they had subscribed for FEAC Class A Shares (or after the Assumption, enGene Common Shares) on the same terms as the PIPE Financing, and (ii) each 2022 Noteholder received warrants of enGene in consideration of certain amendments set forth in each Amended 2022 Convertible Note.

2023 Convertible Notes

On April 4, 2023, Old enGene entered into a Note Purchase Agreement with, and issued the 2023 Subordinated Notes to, existing shareholders, including, the 2023 Noteholders.

Concurrently with the execution and delivery of the Business Combination Agreement, Old enGene and the 2023 Noteholders entered into agreements, pursuant to which Old enGene repaid the 2023 Subordinated Notes by issuing to each 2023 Noteholder (i) an amount of convertible promissory notes of Old enGene substantially in the same form and on the same terms as certain convertible promissory notes issued concurrently to the FEAC Sponsor and Investissement Québec ("IQ"), and (ii) a number of warrants to acquire Old enGene common shares substantially in the same form and on the same terms as certain warrants issued concurrently with the FEAC Sponsor and IQ, corresponding, in the aggregate, to the principal amount of 2023 Subordinated Notes held by such 2023 Noteholder.

On May 17, 2023 pursuant to the agreements described immediately above, Old enGene issued an aggregate amount of $38.0 million convertible debentures and warrants to the 2023 Noteholders, the FEAC Sponsor and IQ. This financing was completed in two tranches, with the second tranche closing on June 15, 2023.

Registration Rights Agreement

In connection with the Business Combination, on October 31, 2023, enGene, FEAC, the Sponsor Holders and the enGene Holders (each as defined in the Registration Rights Agreement) entered into a Registration Rights Agreement. Pursuant to the terms of the Registration Rights Agreement, among other things, the Sponsor Holders and the enGene Holders were granted certain customary registration rights with respect to their respective equity securities of enGene, in each case, on the terms and subject to the conditions therein.

Director Indemnification

enGene has entered into indemnification agreements with each of its directors, 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 Canada Business Corporations Act 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.

enGene has entered into indemnification agreements with its directors and certain of its executive officers. The indemnification agreements require enGene to indemnify its directors and officers to the fullest extent permitted under Canadian law and the Canada Business Corporations Act.

Policies and Procedures for Related Party Transactions

enGene will implement policies and procedures with respect to the approval of related party transactions following the closing of the Transactions.

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 1.3487 for fiscal 2023 and 1.2878 for fiscal 2022.

	2023	2022
Audit fees [1]	1,983,000	737,000
Audit-related fees [2]	—	—
Tax fees [3]	744,000	64,000
All other fees [2]	—	—
Total	2,727,000	801,000

(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 2023 or 2022.

(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 2023 and 2022 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.

(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 on Form 10-K, 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.
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	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 Form 8-K filed with the SEC on December 28, 2023). †+
10.8	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). +†
10.9	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). +†
10.10	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). +†

10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17	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).
10.18	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).
10.19	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). -
10.20	Employment Agreement, dated November 8, 2023, by and between EnGene USA, Inc. and Alex Nichols (incorporated herein by reference to Exhibit 10.02 of enGene's Current Report on Form 8-K filed with the SEC on November 9, 2023). -
10.21	Employment Agreement, dated November 8, 2023, by and between EnGene USA, Inc. and James C. Sullivan (incorporated herein by reference to Exhibit 10.03 of enGene's Current Report on Form 8-K filed with the SEC on November 9, 2023). -
10.22	Employment Agreement, dated November 8, 2023, by and between enGene Inc. and Anthony T. Cheung (incorporated herein by reference to Exhibit 10.04 of enGene's Current Report on Form 8-K filed with the SEC on November 9, 2023). -
10.23	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).-
10.24	Employment Agreement, dated November 29, 2023, by and between enGene USA, Inc. and Richard Bryce (incorporated herein by reference to Exhibit 10.2 of enGene's Current Report on Form 8-K filed with the SEC on November 29, 2023). -
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).
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.
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: January 29, 2024

By: /s/ Jason D. Hanson
Name: Jason D. Hanson
Title: Chief Executive Officer

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/ Jason D. Hanson Jason D. Hanson	Chief Executive Officer and Director *(Principal Executive Officer)*	January 29, 2024
/s/ Ryan Daws Ryan Daws	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	January 29, 2024
/s/ Jasper Bos Jasper Bos	Director	January 29, 2024
/s/ Gerry Brunk Gerry Brunk	Director	January 29, 2024
/s/ Dr. Richard Glickman Dr. Richard Glickman	Director	January 29, 2024
/s/ Lota Zoth Lota Zoth	Director	January 29, 2024

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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principle
As discussed in Note 2 to the consolidated financial statements, the Company has elected to apply the fair value option to account for convertible debt instruments issued in the year ended October 31, 2023, rather than the amortized cost method used for previously issued convertible debt instruments.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred a net loss and negative cash flows from operating activities for the year ended October 31, 2023, has an accumulated deficit at October 31, 2023, and will require additional financing in order to fund its future expected negative cash flows, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. 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
January 29, 2024

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

	October 31, 2023	October 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 81,521	$ 20,434
Restricted investments	76	74
Investment tax credits receivable	2,343	1,336
Prepaid and other current assets	1,500	739
Total current assets	85,440	22,583
Property and equipment, net	589	387
Other assets	930	939
Total assets	$ 86,959	$ 23,909
Liabilities, redeemable convertible preferred shares and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,156	$ 723
Accrued expenses and other current liabilities	3,539	3,116
Current portion of notes payable	562	1,265
Total current liabilities	5,257	5,104
Note payable, net of current portion	9,216	9,649
Convertible debentures	—	17,405
Convertible debenture embedded derivative liabilities	—	3,791
Warrant liabilities	—	11,456
Total liabilities	14,473	47,405
Class A redeemable convertible preferred shares, no par value; zero shares authorized, issued and outstanding as of October 31, 2023; unlimited shares authorized and 266,696 (restated to reflect Reverse Recapitalization – see Notes 1 and 3) shares issued and outstanding as of October 31, 2022. Redemption amount of zero and $3,634 as of October 31, 2023 and 2022, respectively.	—	1,899
Class B redeemable convertible preferred shares, no par value; zero shares authorized, issued and outstanding as of October 31, 2023; unlimited shares authorized and 156,036 (restated to reflect Reverse Recapitalization – see Notes 1 and 3) shares issued and outstanding as of October 31, 2022. Redemption amount of zero and $1,533 as of October 31, 2023 and 2022, respectively.	—	1,554
Class C redeemable convertible preferred shares, no par value; zero shares authorized, issued and outstanding as of October 31, 2023; unlimited shares authorized, 5,560,607 (restated to reflect Reverse Recapitalization – see Notes 1 and 3) shares issued and outstanding as of October 31, 2022. Redemption amount of zero and $107,462 as of October 31, 2023 and 2022, respectively.	—	49,665
Shareholders' equity (deficit):		
Preferred shares, no par value; unlimited shares authorized, zero shares issued and outstanding as of October 31, 2023 and 2022.	—	—
Common shares, no par value; unlimited shares authorized, 23,197,976 and 665,767 (restated to reflect Reverse Recapitalization – see Notes 1 and 3) shares issued and outstanding as of October 31, 2023 and 2022, respectively.	259,373	16,390
Additional paid-in capital	13,717	7,683
Accumulated other comprehensive loss	(1,016)	(1,016)
Accumulated deficit	(199,588)	(99,671)
Total shareholders' equity (deficit)	72,486	(76,614)
Total liabilities, redeemable convertible preferred shares and shareholders' equity	$ 86,959	$ 23,909

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,	
	2023	2022
Operating expenses:		
Research and development	$ 16,458	$ 15,467
General and administrative	9,602	3,960
Total operating expenses	26,060	19,427
Loss from operations	26,060	19,427
Other (income) expense, net:		
Change in fair value of convertible debentures embedded derivative liabilities	21,421	(269)
Change in fair value of warrant liabilities	(10,849)	3,326
Change in fair value of convertible debentures	56,212	—
Interest income	(1,117)	(129)
Interest expense	4,953	1,423
Loss on extinguishment of convertible debentures	3,091	—
Other expense, net	129	662
Total other (income) expense, net	73,840	5,013
Net loss before provision for income taxes	99,900	24,440
Provision for income taxes	17	22
Net loss	$ 99,917	$ 24,462
Deemed dividend attributable to redeemable convertible preferred shareholders	4,822	4,562
Net loss attributable to common shareholders, basic and diluted	$ 104,739	$ 29,024
Other comprehensive loss (gain):		
Foreign currency translation adjustment	—	(1,167)
Total comprehensive loss	$ 99,917	$ 23,295
Net loss per share of common shares, basic and diluted (restated to reflect Reverse Recapitalization – see notes 1 and 3)	$ 151.22	$ 44.30
Weighted-average common shares outstanding, basic and diluted (restated to reflect Reverse Recapitalization – see notes 1 and 3)	692,609	655,153

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

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

	Class A Redeemable Convertible Preferred Shares		Class B Redeemable Convertible Preferred Shares		Class C Redeemable Convertible Preferred Shares		Common Shares		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares*	Amount	Shares*	Amount	Shares*	Amount	Shares*	Amount				
Balance at October 31, 2021	266,696	$ 1,899	156,036	$ 1,554	5,560,607	$ 49,665	650,858	$ 16,363	$ 7,587	$ (2,183)	$ (75,209)	$ (53,442)
Exercise of stock options	—	—	—	—	—	—	14,909	27	(20)	—	—	7
Share-based compensation expense	—	—	—	—	—	—	—	—	116	—	—	116
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	1,167	—	1,167
Net loss	—	—	—	—	—	—	—	—	—	—	(24,462)	(24,462)
Balance at October 31, 2022	266,696	1,899	156,036	1,554	5,560,607	49,665	665,767	$ 16,390	$ 7,683	$ (1,016)	$ (99,671)	$ (76,614)
Exercise of stock options	—	—	—	—	—	—	47,186	79	(35)	—	—	44
Issuance of common shares upon cashless exercise of options	—	—	—	—	—	—	15,494	11	(11)	—	—	—
Conversion and exchange of Old enGene convertible debentures and common share warrants into enGene Holdings common shares and common share warrants in connection with the Reverse Recapitalization	—	—	—	—	—	—	6,379,822	138,410	1,983	—	—	140,393
Conversion and exchange of redeemable convertible preferred shares into common shares in connection with the Reverse Recapitalization	(266,696)	(1,899)	(156,036)	(1,554)	(5,560,607)	(49,665)	5,983,339	53,118	—	—	—	53,118
Common shares and common share warrants issued upon Reverse Recapitalization and PIPE Financing, net of issuance costs of $11.1 million	—	—	—	—	—	—	10,106,368	51,365	647	—	—	52,012
Share-based compensation expense	—	—	—	—	—	—	—	—	3,450	—	—	3,450
Net loss	—	—	—	—	—	—	—	—	—	—	(99,917)	(99,917)
Balance at October 31, 2023	—	—	—	—	—	—	23,197,976	$ 259,373	$ 13,717	$ (1,016)	$ (199,588)	$ 72,486

*- The shares have been retrospectively restated to reflect exchange of shares upon the close of Reverse Recapitalization. See notes 1 and 3.

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,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (99,917)	$ (24,462)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	778	644
Loss on extinguishment of convertible debentures	3,091	—
Change in fair value of warrant liabilities	(10,849)	3,326
Change in fair value of convertible debenture embedded derivative liabilities	21,421	(269)
Change in fair value of convertible debentures	56,212	—
Debt issuance costs expensed upon issuance of convertible debentures recorded using the fair value option	924	—
Non-cash lease expense	—	(5)
Foreign currency adjustments	489	646
Share-based compensation expense	3,450	116
Depreciation of property and equipment	175	238
Changes in operating assets and liabilities:		
Investment tax credit receivable	(1,007)	143
Prepaid expenses and other assets	(751)	(113)
Accounts payable	373	(197)
Accrued expenses and other liabilities	868	2,341
Net cash used in operating activities	(24,743)	(17,592)
Cash flows from investing activities		
Purchases of property and equipment	(318)	(153)
Net cash used in investing activities	(318)	(153)
Cash flows from financing activities		
Proceeds from PIPE financing	56,892	—
Proceeds from FEAC trust account in connection with Reverse Recapitalization	7,363	—
Payment of transaction costs in connection with the Reverse Recapitalization and PIPE Financing	(10,497)	—
Proceeds from issuance of convertible notes	38,000	18,400
Payment of issuance costs associated with convertible debentures	(924)	(44)
Repayment of convertible debentures	(3,176)	—
Proceeds from issuance of common shares upon the exercise of stock options	44	12
Repayments of term loan principal	(1,555)	—
Proceeds from issuance of term loan	—	11,000
Payments of debt issuance costs associated with the term loan	—	(391)
Repayment of debt	—	(1,010)
Net cash provided by financing activities	86,147	27,967
Effect of exchange rate changes on cash	1	(805)
Net increase in cash and cash equivalents	61,087	9,417
Cash and cash equivalents at beginning of period	20,434	11,017
Cash and cash equivalents at end of period	$ 81,521	$ 20,434
Supplemental cash flow information:		
Cash paid for interest	$ 1,398	$ 615
Supplemental disclosure of non-cash investing and financing activities		
Reverse Recapitalization and PIPE financing transaction costs included within accrued expenses and accounts payable	$ 613	$ —
Conversion of Preferred Shares upon Reverse Recapitalization	53,118	—
Derivative liability recognized upon issuance and modification of convertible debentures	—	3,531
Conversion of Convertible Debentures upon Reverse Recapitalization	113,627	—
Reclassification of warrant liability to equity upon Reverse Recapitalization	1,983	—
Liabilities assumed upon Reverse Recapitalization	1,130	—
Warrant liability recognized upon issuance of term loan	1,420	90
Settlement of derivative liability upon repayment and conversion of convertible debentures	25,217	—
Fixed assets included in accrued expenses and accounts payable	58	—
Settlement of April 2023 Notes through the issuance of May 2023 Notes and warrants	8,000	—

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" 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. enGene Inc., its wholly owned subsidiary since October 31, 2023 (now known as "enGene Inc." or "Old enGene"), is a biopharmaceutical company located in Montreal, Quebec, Canada, and incorporated pursuant to the Canada Business Corporations Act on November 9, 1999. a Cayman Island exempted company on August 9, 2021.

The Company is a clinical-stage biotechnology company focused on developing gene therapies to improve the lives of patients with its head office located in Montreal, Quebec, Canada. The Company is developing non-viral gene therapies based on its novel and proprietary dually derived chitosan, or "DDX", gene delivery platform, which allows localized delivery of multiple gene cargos directly to mucosal tissues and other organs.

Merger with Forbion European Acquisition Corp.

Forbion European Acquisition Corporation ("FEAC") was a Special Purpose Acquisition Company ("SPAC"), incorporate 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, enGene Inc., consummated the merger (the "Reverse Recapitalization") pursuant to a business combination agreement, dated as of May 16, 2023 (the "Merger Agreement").

The transaction was accounted for as a "reverse recapitalization" in accordance with accounting principles generally accepted in the United States ("GAAP"). Under this method of accounting, FEAC was treated as the "acquired" company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Reverse Recapitalization, senior management of Old enGene continues as senior management of the combined company; Old enGene identifies a majority of the members of the board of directors of the combined company; the name of the combined company is enGene Holdings Inc. and it utilizes Old enGene's current headquarters, and Old enGene's operations comprise the ongoing operations of the combined company. Accordingly, for accounting purposes, the Company is considered to be a continuation of Old enGene, with the net identifiable assets of FEAC deemed to have been acquired by Old enGene in exchange for Old enGene common shares accompanied by a recapitalization, with no goodwill or intangible assets recorded. The number of redeemable convertible preferred shares, number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization, have been retrospectively restated to reflect an exchange ratio of approximately 0.18048 (the "Exchange Ratio") established in the Merger Agreement. Operations prior to the Reverse Recapitalization are those of Old enGene.

The Reverse Recapitalization was effected in the following steps: (i) two entities were incorporated to effect the transaction, Can Merger Sub, a Canadian corporation and a wholly owned subsidiary of FEAC and Cayman Merger Sub, a Cayman Islands exempt company and a direct wholly owned subsidiary of the Company; (ii) immediately prior to the Closing Date, Cayman Merger Sub was merged with and into FEAC with FEAC as the surviving entity, resulting in FEAC becoming a wholly owned subsidiary of the Company (the "Cayman Merger"); (iii) on the Closing Date, Can Merger Sub and Old enGene amalgamated pursuant to a plan of arrangement (the "Amalgamation"), resulting in Old enGene becoming a wholly owned subsidiary of the Company. As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its ordinary shares and warrants on the Nasdaq Global Market under the symbols "ENGN" and "ENGNW," respectively, commencing trading on November 1, 2023, with Old enGene, a subsidiary of the Company continuing the existing business operations.

Upon the consummation of the Reverse Recapitalization, each FEAC Class A share and FEAC Class B share (collectively, the "FEAC Shares") issued and outstanding immediately prior to the effective time of the Cayman Merger (including Forbion Growth Sponsor FEAC I B.V.'s, the ("FEAC Sponsor") shares but excluding any dissenting FEAC Shares), was transferred to the Company and (i) for each FEAC Share, the Company issued to each shareholder one validly issued share of the Company's common share; (ii) each warrant to purchase one FEAC share was assumed by the Company and converted into a warrant to purchase one share of the Company's common share at an exercise price of $11.50 per share, with all fractional shares rounded down to the nearest whole share. Concurrently with the Cayman Merger, the Company redeemed its 10 Class B common shares held by its sole shareholder for $1 CAD per share, which was equal to the amount of capital that the sole shareholder of the Company contributed. As a result of the Reverse Recapitalization, all outstanding FEAC Shares of 3,670,927 held by FEAC Sponsor and shareholders were converted into the same

number of the Company's common shares and outstanding FEAC warrants of 5,029,444 held by FEAC warrant holders were converted into the same number of warrants to purchase one share of the Company's common shares.

On the Closing Date, each share of Old enGene common shares was cancelled and in exchange the holders thereof received approximately 0.18048 newly issued shares of the Company's common share. In addition, each share of Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close of the Reverse Recapitalization was exchanged for shares of the Company's common shares based on the same Exchange Ratio, with no dividends or distributions being declared or paid on Old enGene's redeemable convertible preferred shares. Further, certain of Old enGene's existing convertible notes outstanding immediately prior to the close of the Reverse Recapitalization were converted to Old enGene common shares at the conversion ratio in place at the time of conversion. In addition, all of Old enGene's existing outstanding Class C warrants outstanding at the time of the Reverse Recapitalization were terminated and all outstanding warrants exercisable for common shares in Old enGene were exchanged for warrants exercisable for the Company's common shares at the Exchange Ratio. No other terms and conditions underlying the warrant changed. At the closing of the Reverse Recapitalization, each share option of Old enGene common share was cancelled, and the holders thereof received in exchange newly issued share options of the Company's common share based on the same Exchange Ratio. The modification of the share options did not result in any incremental compensation expense upon closing of the Reverse Recapitalization. Upon the close of the Reverse Recapitalization, 13,091,608 common shares of the Company were issued to the Old enGene's equity and convertible note holders, 2,679,432 common share warrants of the Company were issued to Old enGene's warrant holders (which are inclusive of the shares and warrants issued to the FEAC Sponsor), and 2,706,941 common share options of the Company were issued to Old enGene's share option holders.

As part of the Reverse Recapitalization, the Company received net proceeds of $7.4 million from the FEAC trust account, net of the redemption payment to FEAC's public shareholders and FEAC expenses.

PIPE Financing

In connection with the Merger Agreement, FEAC, the Company, and certain investors (the "PIPE Investors") entered into subscription agreements (the "Subscription Agreements") pursuant to which, the PIPE Investors agreed to purchase FEAC Class A Shares and FEAC Warrants (or the Company's shares and warrants when such obligation was assumed (the "Assumption") by the Company after the completion of the Cayman Merger and prior to the consummation of the PIPE Financing), for an aggregate commitment amount of $56.9 million. Concurrent with the execution of the Merger Agreement, FEAC, the FEAC Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A. and the other holders of FEAC Class B Shares, Old enGene, the Company and the other parties named therein entered into the sponsor and insiders letter agreements (the "Side Letter Agreements"), pursuant to which the FEAC Sponsor agreed to surrender and in effect issue to PIPE Investors, 1,789,004 FEAC Class B shares and 5,463,381 FEAC private placement warrants, immediately prior to the closing of the Reverse Recapitalization. Pursuant to the Subscription Agreements and Side Letter Agreements, the Company issued 6,435,441 shares of the Company's common share and 2,702,791 warrants to purchase the Company's common share for an aggregate purchase price equal to $56.9 million.

Convertible Bridge Financing

Prior to the execution and delivery of the Reverse Recapitalization Agreement, Old enGene agreed to certain modifications of existing convertible indebtedness in an aggregate principal amount of $18.4 million (the "2022 Convertible Notes" and, together with the Old enGene warrants to be issued by Old enGene as consideration for such modifications, the "Amended 2022 Financing"). Concurrently with the execution of the Merger Agreement, Old enGene also entered into agreements pursuant to which it issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in settlement of the April 2023 Notes in an aggregate principal amount of $8.0 million (collectively, the "May 2023 Notes" and, together with the warrants purchased concurrently, the "2023 Financing"; the 2023 Financing together with the Amended 2022 Financing, the "Convertible Bridge Financing"). In connection with the Reverse Recapitalization, the Convertible Bridge Financing indebtedness was converted into 35,349,238 of Old enGene common at the conversion ratio in place at the time of conversion, which was exchanged to 6,379,822 of the Company's common shares based on the aforementioned exchange ratio (see Note 9 for further detail).

In relation to the Amended 2022 Financing, the holders of the 2022 Convertible Notes received warrants to purchase Old enGene common shares and the holders of the 2023 Convertible Notes were issued warrants in connection with the issuance of the 2023 Convertible Notes. On the closing of the Reverse Recapitalization, these warrants converted through the transaction to 2,679,432 warrants to purchase common shares of the Company based on the aforementioned exchange ratio.

Immediately after giving effect to the Reverse Recapitalization and the PIPE Financing, the Company has 23,197,976 common shares and 10,411,641 warrants outstanding.

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 gene therapies 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 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 has incurred a net loss of $99.9 million and negative cash flows from operating activities of $24.7 million for year ended October 31, 2023, and, as of that date, has an accumulated deficit of $199.6 million. To date, the Company has not generated any revenues and has financed its liquidity needs primarily through the Reverse Recapitalization, PIPE Financing, debt and convertible debentures, and issuance of redeemable convertible Preferred Shares and warrants.

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 (see note 18). The Company will require additional financing in order to fund its future expected negative cash flows and Management's plans are to raise additional financing. While the Company has historically been successful in securing financing, raising additional funds is dependent on a number of factors outside of the Company's control, and as such there is no assurance that it will be able to do so in the future. These conditions indicate the existence of a material uncertainty that raise substantial doubt about the Company's ability to continue as a going concern and, therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business.

These consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that results from the outcome of this uncertainty. Such adjustments could be material.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("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.

As the merger with FEAC has been accounted for as a reverse recapitalization, the historical operations of the Company represent that of Old enGene which is the accounting predecessor. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization have been retrospectively restated to reflect the Exchange Ratio of approximately 0.18048 established in the Merger Agreement. For additional information on the Reverse Recapitalization, please refer to Note 3.

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, the recoverability of investment tax credits receivable and the valuations of common shares, redeemable convertible preferred shares, warrants to purchase redeemable convertible preferred shares, convertible debentures, embedded derivatives on convertible debt and share-based compensation. 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

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates as a single business segment focused on research, discovery, and clinical development of human gene therapy products. The majority of the Company's tangible assets are held in Canada.

Functional Currency Change

Prior to November 1, 2022, Old enGene's functional currency was the Canadian dollar ("CAD"), and its reporting currency was the U.S. dollar ("USD"). During the period, Old enGene reassessed its functional currency and determined that its functional currency changed from the Canadian dollar to the USD based on management's analysis as a result of evaluating criteria within ASC 830. The change in functional currency is accounted for prospectively from November 1, 2022, and prior year financial statements have not been restated for the change in functional currency. All assets and liabilities were reported using the same USD values as previously reported under the USD reporting currency described above. As a result, the cumulative translation adjustment balance as of October 31, 2022, is carried forward and will remain unchanged.

The Company reported net realized and unrealized foreign currency transaction losses of $0.1 million and $0.7 million for the years ended October 31, 2023 and 2022, respectively. These gains and losses are reflected within other expense (income), net in the Company's consolidated statements of operations and comprehensive loss.

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. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits.

As of October 31, 2023, the Company held cash deposits at Silicon Valley Bank, or SVB, in excess of Federal Deposit Insurance Corporation (FDIC) insured limits. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the FDIC, was appointed as receiver. No losses were incurred by the Company on deposits that were held at SVB. 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 is dependent on third-party Contract Development and Manufacturing Organization ("CDMOs") and Contract Research Organization ("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. Cash and cash equivalents have been measured at amortized cost. The Company had no cash equivalents as of the years ended October 31, 2023 and 2022.

Restricted Investments

Restricted investments consist of temporary holdings of highly liquid Canadian guaranteed investment certificates held with a bank and is used as a guarantee of the Company's short term borrowings and security deposits for it's lease agreements. As of October 31, 2023, the Company classified $70 thousand of restricted investments within other assets on the Consolidated Balance Sheet associated with its lease agreement that has a term longer than twelve months.

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 adopted FASB ASC 842 with an effective date of November 1, 2019, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, 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 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. The Company's convertible debentures embedded derivative, certain of its convertible debentures and warrant liabilities were carried at fair value, and were determined according to Level 3 inputs in the fair value hierarchy described above.

Fair Value Option

The Company elected the fair value option of accounting of ASC 825 for all convertible debentures issued in fiscal 2023 from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, the Company did not record any changes in fair value related to instrument-specific credit risk. All costs associated with the issuance of the convertible debentures accounted for using the fair value option were expensed upon issuance.

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.

Convertible Debenture Embedded Derivative Liabilities

The Company's convertible debentures contained certain features that meet the definition of embedded derivatives requiring bifurcation from the convertible debenture instrument, for which the fair value option was not elected, as a separate compound derivative. The convertible debenture embedded derivative liabilities are initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss.

Common Share and Preferred Share Warrants

The Company accounts for its common share warrants and redeemable convertible preferred shares warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the consolidated statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants were no longer considered liability.

Convertible Debentures

The Company's 2022 Notes (as defined in Note 9) are convertible debentures that consist of a debt instrument, a minimum interest obligation, and a share conversion feature. Certain of the convertible debentures issued by the Company also included warrants to purchase redeemable convertible preferred shares, which were classified as liabilities. The Company identified embedded derivatives related to certain share conversion and repayment features within the convertible notes that required bifurcation as a single compound derivative instrument. At inception, the Company utilized the residual method to determine the value of the debt instrument based on the difference between gross proceeds and the estimated fair value of the embedded derivative and any warrants that were issued. The debt instrument is accounted for using the amortized cost method. The discounts on debt resulting from any issuance costs, embedded derivatives and warrants are amortized over the life of the debt using the effective interest method. The issuance costs allocated to the embedded derivatives and warrants are expensed at inception.

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 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded Old enGene's employee stock option plan (the "ESOP") and equity incentive plan (the "EIP") (collectively, the "Old 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 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 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 stock 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 Old enGene 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 stock 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. The Company's comprehensive loss includes foreign currency translation.

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. Net loss per share attributable to common shareholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. Net loss attributable to common shareholders is allocated first based on dividend rights and then to common and preferred shareholders based on ownership interests on an as-converted basis as if all the earnings for the period had been distributed.

When considering the impact of the convertible equity instruments, diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred shareholders and warrant holders based on dividend rights and then to common and preferred shareholders and warrant holders based on ownership interests. 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, warrants, and the potential issuance of common shares upon the conversion of the convertible notes. 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 13, Net Loss per Share, for further detail.

Deferred Transaction Costs

The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Reverse Recapitalization and PIPE Financing as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs were recorded within equity as a reduction of the common share and warrants value within additional paid in capital, for both instruments issued and assumed to shareholders of FEAC and to PIPE financing investors, were allocated to each on a relative fair value basis. The Company incurred a total of $11.3 million of transaction costs as part of the Reverse Recapitalization and PIPE Financing. The Company did not have any deferred transaction costs recorded on the balance sheet as of October 31, 2023 and 2022. In addition, transaction costs of $0.8 million related to the issuance of the April 2023 Notes and the May 2023 Notes for which the fair value option of accounting was elected and those allocated to the liability classified warrants issued as part of the 2023 Financing are not deferred and are included in general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

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 research and development 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 by the tax authorities, 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 eligible research and development expenditures 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 research and development, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible research and development 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, 2023 and 2022, the Company recorded $1.1 million and $1.4 million, respectively, as a reduction of research and development expense associated with research and development investment tax credits.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, or ASU-2019-12, Simplifying the Accounting for Income Tax, which contains several provisions that reduce financial statement complexity including removing the exception to the incremental approach for intra-period tax expense allocation when a company has a loss from continuing operations and income from other items not included in continuing operations. The Company adopted this accounting standard as of November 1, 2021 with no material impact on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies and clarifies certain calculation and presentation matters related to convertible and equity and debt instruments. Specifically, ASU2020-06 removes requirements to separately account for conversion features as a derivative under ASC Topic 815 and removing the requirement to account for beneficial conversion features on such instruments. ASU 2020-06 also provides clearer guidance surrounding disclosure of such instruments and provides specific guidance for how such instruments are to be incorporated in the calculation of Diluted EPS. The Company adopted this standard on November 1, 2020 and the adoption did not have a material impact on the consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832): Disclosure by Business Entities about Government Assistance ("ASU 2021-10"), which improves the transparency of government assistance received by most business entities by requiring the disclosure of: (1) the types of government assistance received; (2) the accounting for such assistance; and (3) the effect of the assistance on a business entity's financial statements. This guidance is effective for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted ASU 2021-10 effective November 1, 2021 and included incremental financial statement disclosures, and the adoption did not have a material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements – Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). This new standard changes the impairment model for most financial assets and certain other instruments. Entities will be required to use a model that will result in the earlier recognition of allowances for losses for trade and other receivables, held-to-maturity debt securities, loans, and other instruments. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) ("ASC 2019-10"), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for entities meeting the definition of a smaller reporting company. The Company will adopt ASU 2016-13 effective November 1, 2023. The Company does not expect the adoption of ASU 2016-13 will have a material impact on the consolidated financial statements.

In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which amends guidance in ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for

public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the impact of the guidance on the financial statements disclosures.

3. Reverse Recapitalization

On October 31, 2023 (the "Closing Date"), FEAC, Old enGene, and the Company consummated the merger pursuant to the Merger Agreement, dated as of May 16, 2023. As a result of the Reverse Recapitalization, the Company became a publicly traded company, with old enGene, a subsidiary of the Company, continuing the existing business operations.

At the effective time of the Reverse Recapitalization:

- each outstanding share of Old enGene common stock was exchanged for shares of the Company's common stock at the Exchange Ratio;
- each share of Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close of the Reverse Recapitalization was exchanged for shares of the Company's common shares based on the same Exchange Ratio, with no dividends or distributions being declared or paid on Old enGene's redeemable convertible preferred shares;
- the 2022 Notes and May 2023 Notes (each as defined in Note 9) of Old enGene's existing convertible notes outstanding immediately prior to the close of the Reverse Recapitalization were converted to Old enGene common shares at the conversion ratio in place at the time of conversion and were exchanged for shares of the Company at the Exchange Ratio; and
- each outstanding option to purchase old enGene common stock became fully vested and converted into an option to purchase a number of shares of the Company's common stock equal to the number of shares of old enGene common stock subject to such option multiplied by the Exchange Ratio, rounded down to the nearest whole share, at an exercise price per share equal to the current exercise price per share for such option divided by the Exchange Ratio, rounded up to the nearest whole cent;
- all of Old enGene's outstanding warrants exercisable for common shares in Old enGene were exchanged for warrants exercisable for the Company's common shares using the Exchange Ratio, with the warrants maintaining the same terms and conditions;
- all of Old enGene's existing outstanding Class C warrants outstanding at the time of the Reverse Recapitalization were terminated; and
- all outstanding FEAC Shares of 3,670,927 held by FEAC Sponsor and shareholders were converted into the same number of the Company's common shares, and outstanding FEAC warrants of 5,029,444 held by FEAC warrant holders were converted into the same number of warrants to purchase one share of the Company's common shares.

Upon the close of the Reverse Recapitalization, 13,091,608 common shares of the Company were issued to the Old enGene's equity and convertible note holders, 2,679,432 common share warrants of the Company were issued to Old enGene's warrant holders, and 2,706,941 common share options of the Company were issued to Old enGene's share option holders.

In connection with the Merger Agreement, FEAC, the Company, and PIPE Investors entered into Subscription Agreements pursuant to which, the PIPE Investors have agreed to purchase the Company's shares and warrants for an aggregate commitment amount of $56.9 million. As part of the PIPE Financing, the Company issued 6,435,441 shares of the Company's common shares and 2,702,791 warrants to purchase the Company's common shares for an aggregate purchase price equal to $56.9 million on October 31, 2023. The common shares and warrants issued as part of the PIPE Financing were determined to be equity classified. The proceeds were allocated between the common shares and warrants on a relative fair value basis, taking into consideration the quoted market price of the FEAC common shares and warrants on the close of the market on October 31, 2023, resulting in $56.1 million being allocated to the common shares and $0.8 million being allocated to the warrants. In connection with the Merger Agreement, FEAC, the FEAC Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A. and the other holders of FEAC Class B Shares, Old enGene, the Company and the other parties named therein entered into the Side Letter Agreements, pursuant to which the FEAC Sponsor agreed to surrender and in effect issue to PIPE Investors FEAC Class B shares and FEAC private placement warrants, immediately prior to the closing of the Reverse Recapitalization. Immediately following the Reverse Recapitalization and the PIPE Financing, the Company has 23,197,976 common shares and 10,411,641 warrants outstanding.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

On October 31, 2023, as part of the close of Reverse Recapitalization, the Company received proceeds of $7.4 million, from the FEAC trust account, net of the redemption payment to FEAC's public shareholders and cash paid from the trust for FEAC expenses. Additionally, the Company received proceeds of approximately $56.9 million from the PIPE Financing. Upon the closing of the Reverse Recapitalization and PIPE Financing, the Company incurred $6.0 million in transaction costs, which was withheld from the proceeds received. The Company incurred a total of $11.1 million of transaction costs associated with the Reverse Recapitalization and PIPE Financing, of which $5.1 million was previously deferred by the Company and netted against the proceeds upon close. The transaction costs were allocated to the common shares and warrants on a relative fair value basis and netted against the proceeds upon close.

The following table summarizes the elements of the net proceeds from the Reverse Recapitalization and PIPE Financing transaction as of October 31, 2023:

	Recapitalization
Cash – FEAC's Trust Account and Cash (net of redemptions and cash paid for FEAC expenses prior to close)	$ 7,363
Cash – PIPE Financing	56,892
Less transaction costs withheld from cash proceeds on Closing Date	(6,024)
Cash proceeds received from the Reverse Recapitalization and PIPE Financing on Closing Date	$ 58,231
Less transaction costs previously deferred and netted against proceeds	(5,086)
Net cash proceeds from the Reverse Recapitalization and PIPE Financing	53,145

The total transaction costs of $11.1 million were related to third-party legal, accounting services and other professional services to consummate the Reverse Recapitalization and the PIPE Financing incurred by Old enGene. These transaction costs are allocated between common shares and additional paid-in capital, based on the relative fair value of the common shares and warrants issued upon the close of the Reverse Recapitalization, on the Company's consolidated balance sheet as the Company's common shares have no par value.

The following table summarizes the number of shares of common stock outstanding immediately following the consummation of the Reverse Recapitalization and PIPE Financing transaction:

	Number of Shares
Old enGene Shareholders (Excluding Convertible Notes)	6,711,786
FEAC Shareholders, including sponsor's and shareholder with non-redemption agreement	3,670,927
Convertible Notes - Common Shares Issued	6,379,822
Common shares issued to PIPE Investors	6,435,441
Total common shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	23,197,976

4. Fair Value Measurements

The Company did not have any financial assets or liabilities that required fair value measurement on a recurring basis as of October 31, 2023.

The following table presents the Company's fair value hierarchy for financial liabilities measured at fair value as of October 31, 2022:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	October 31, 2022			
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Liabilities				
Convertible debenture embedded derivative liabilities	$ 3,791	$ —	$ —	$ 3,791
Warrant liabilities	11,456	—	—	11,456
Total financial liabilities	$ 15,247	$ —	$ —	$ 15,247

As of October 31, 2022, the Company had no financial assets that required fair value measurement on a recurring basis.

As of October 31, 2022, the Company had Level 3 financial liabilities that were measured at fair value on a recurring basis. The Company's convertible debenture embedded derivative liabilities and warrant liabilities were carried at fair value determined using Level 3 inputs in the fair value hierarchy. 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 the warrants could have been materially different.

During the year ended October 31, 2023 and 2022, there were no transfers or reclassifications between fair value measure levels of liabilities. The carrying values of all financial current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Convertible Debentures Embedded Derivative Liabilities

The Company's convertible debentures contained equity conversion options, and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the host contract for the convertible debentures for which the fair value has not been elected. The Company estimated the fair value of the convertible debenture embedded derivative liabilities on issuance using a probability weighted scenario expected return model. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features and probability of exercise of the extension features within the convertible debentures as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the embedded derivative.

The assumptions ranges that the Company used to determine the fair value of the convertible debentures embedded derivative liabilities for the 2022 Notes and BDC Notes that were outstanding as of each respective period (refer to Note 9 for description of notes) were as follows:

	Immediately prior to settlement on October 31, 2023	As of October 31, 2022
Probability of qualified financing*	100%	60%
Volatility**	n/a	85%
Class C Preferred Share price (CAD)**	n/a	$ 2.20
Liquidity price at conversion of listing event***	$ 8.84	n/a
Fair value of common share at conversion of listing event***	$ 21.70	$ n/a
Discount rate****	18.4%	10.4-18.4%
Expected time to respective scenarios	0.0 years	0.4 years

* The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2022 Notes and to a liquidity event for the BDC Notes).

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

** Volatility and Class C Preferred share price is not applicable and expected time to scenario is 0.0 years as of October 31, 2023 as the 2022 Notes converted to shares upon the Reverse Recapitalization and the BDC Notes were repaid in full.
*** The liquidity price at the conversion of a listing event represents the conversion price of the 2022 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the quoted market price of the FEAC common shares on the close of the market on October 31, 2023, immediately prior to the settlement upon the completion of the Reverse Recapitalization.
**** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.

Upon the close of the Reverse Recapitalization the 2022 Notes were converted and exchanged for common shares of the Company, resulting in an extinguishment of the 2022 Notes and related embedded derivative liability. Further the BDC Note was repaid in full and the related embedded derivative liability was extinguished. Refer to Note 3 and Note 9. Immediately prior to the conversion and exchange of the 2022 Notes as part of the Reverse Recapitalization, the embedded derivative was measured to a fair value of $24.8 million. Further immediately prior to the repayment of the BDC Note, the embedded derivative liability was measured to a fair value of $0.4 million.

The following table provides a summary of the change in the estimated fair value of the Company's convertible debentures embedded derivative liabilities for the year ended October 31, 2023, and 2022.

	Total
Balance as of October 31, 2021	$ 602
Fair value of convertible debenture embedded derivative liabilities recognized upon issuance	3,500
Change in fair value of convertible debenture embedded derivative liabilities	(269)
Foreign exchange rate translation adjustment	(42)
Balance as of October 31, 2022	3,791
Change in fair value of convertible debenture embedded derivative liabilities	21,421
Foreign exchange rate translation adjustment	5
Settlement of derivative liability in accordance with repayment and conversion of convertible debentures upon the consummation of the Reverse Recapitalization	(25,217)
Balance as of October 31, 2023	$ —

April 2023 Notes

The Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be the total cash proceeds received of $8.0 million and was considered a Level 3 measurement within the fair value hierarchy. The April 2023 Notes were repaid through the issuance of $8.0 million in aggregate amount of convertible notes and warrants issued as part of the 2023 Financing. No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, given the close proximity between the issuance date of the notes and the repayment date. As of October 31, 2023, the April 2023 Notes are no longer outstanding.

May 2023 Notes

The Company elected the fair value option of accounting for the May 2023 Notes. At issuance and for periods prior to the settlement of the May 2023 Notes, the Company estimated the fair value of the May 2023 Notes using a probability weighted scenario expected return model and was considered a Level 3 measurement per the fair value hierarchy. As part of the issuance of the May 2023 Notes, the Company also issued warrants which were determined to be freestanding, liability classified and measured at fair value. Refer below. The Company recorded both the May 2023 Notes and warrants issued as part of the 2023 Financing at fair value upon issuance, which totaled the amount of proceeds received on an aggregate basis, and subsequently remeasured the financial instruments to fair value at each reporting date.

The assumptions that the Company used to determine the fair value of the May 2023 Notes as of the issuance date are as follows:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	As of Issuance Date
Probability of qualified financing*	60%
Volatility	85%
Class C Preferred Share Price (CAD)	$ 2.074
Liquidity price at conversion of listing event**	$ 8.42
Fair value of common share at conversion of listing event**	$ 10.25
Discount rate***	40.8%
Expected time to respective scenarios	0.3 years

* The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2023 Notes).
** The liquidity price at the conversion of a listing event represents the conversion price of the 2023 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the price per share of the Newco upon the merger with FEAC, as set forth in the Business Combination Agreement.
*** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.

Immediately prior to the conversion and exchange of the May 2023 Notes as part of the Reverse Recapitalization, the notes were remeasured to a fair value of $93.3 million. The fair value immediately prior to the settlement was determined using the quoted market price of $21.70 per share for the FEAC common shares on the close of business on October 31, 2023, which was determined to be fair value of the common share on settlement, and considering the 4,298,463 shares of the Company issued to the holders of the May 2023 Notes upon the consummation of the Reverse Recapitalization.

The following table provides a summary of the change in the estimated fair value of the Company's 2023 Notes for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the 2023 Notes were exchanged for common shares of the Company, resulting in an extinguishment of the 2023 Notes. Refer to Note 3 and Note 9.

	Total
Balance as of October 31, 2022	$ —
Issuance of May 2023 Notes	37,043
Change in fair value of May 2023 Notes	56,212
Settlement of 2023 Notes upon the consummation of the Reverse Recapitalization	(93,255)
Balance as of October 31, 2023	$ —

Warrant Liabilities

Prior to the consummation of the Reverse Recapitalization, Old enGene issued warrants to purchase redeemable convertible preferred shares as part of the issuance of certain redeemable convertible preferred shares, convertible debentures, and term loan (the "Preferred Share Warrants"). Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration and the fair value was determined to be zero. The Company estimated the fair value of its Preferred Share Warrant liabilities using a Modified Black-Scholes option-pricing model, which included assumptions that are based on the individual characteristics of the Preferred Share Warrants on the valuation date, and assumptions related to the fair value of the underlying redeemable convertible preferred shares, expected volatility, expected life, dividends, risk-free interest rate and discount for lack of marketability ("DLOM"). Due to the nature of these inputs, the Preferred Share Warrants are considered a Level 3 liability.

The weighted average expected life of the Preferred Share Warrants was estimated based on the weighting of scenarios considering the probability of different terms up to the contractual term of 10 years in light of the expected timing of a future exit event, which includes a SPAC transaction. The Company determines the expected volatility based on an analysis of reported data for a group of guideline companies that have issued instruments 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 risk-free interest rate is determined by reference to the Canadian treasury yield curve in effect at the time of measurement of the warrant liabilities for time periods approximately equal to the weighted average expected life of the warrants. The Company has not paid, and did not anticipate paying, cash dividends on its redeemable convertible preferred shares; therefore, the expected dividend yield is assumed to be zero.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

Because there was no public market for the underlying redeemable convertible preferred shares, the Company determined their fair value based on third-party valuations. 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 redeemable convertible preferred shares include volatility, DLOM, and the expected timing of a future liquidity event such as an IPO, SPAC transaction 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 to considering the results of these valuations, the Company considered various objective and subjective factors to determine the fair value of the Company's preferred shares as of each valuation date, including the prices at which the Company sold redeemable convertible preferred in the most recent transactions, 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 redeemable convertible preferred shares, among other factors.

The assumptions that the Company used to determine the fair value of the Preferred Share Warrant liabilities as of October 31, 2022 were as follows:

	As of October 31, 2022
Weighted average expected life (in years)	3.0
Expected volatility	78.0%
Risk-free interest rate	3.92%
Expected dividend yield	—
Preferred share price – Class C (CAD)	$ 2.20
Exercise price – Class C (CAD)	$ 2.632

The warrants issued by Old enGene as part of the 2023 Financing (the "2023 Warrants") were concluded to be freestanding, liability classified instruments upon issuance, which were subsequently reclassified to equity upon the consummation of the Reverse Recapitalization. See Note 9. The Company estimated the fair value of the 2023 Warrants based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they are substantially similar to FEAC public warrants. The price used to value the 2023 Warrants as of the issuance date and immediately prior to the consummation of the Reverse Recapitalization was $0.53 and $0.74, per warrant, respectively, which represented the quoted market price of the FEAC public warrants on each date.

The following table provides a summary of the change in the estimated fair value of the Company's warrant liabilities for the year ended October 31, 2023:

	Total
Balance as of October 31, 2021	$ 9,088
Warrant liabilities recognized upon issuance of term loan	90
Change in fair value of warrant liabilities	3,326
Foreign exchange rate translation adjustment	(1,048)
Balance as of October 31, 2022	11,456
Warrant liability recognized upon issuance of May 2023 Notes	1,420
Change in fair value of warrant liabilities	(10,849)
Foreign exchange rate translation adjustment	(44)
Reclassification of 2023 Warrants to equity upon consummation of the Reverse Recapitalization	(1,983)
Balance as of October 31, 2023	$ —

5. Property and Equipment, Net

As of October 31, 2023, and 2022, property and equipment, consisted of the following:

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

	October 31, 2023	October 31, 2022
Lab equipment	$ 1,779	$ 1,472
Computer equipment	269	221
Computer software	70	70
Office furniture	69	55
Leasehold improvements	129	122
Property and equipment	2,316	1,940
Less: Accumulated depreciation and amortization	1,727	1,553
Property and equipment, net	$ 589	$ 387

Depreciation and amortization expense related to property and equipment was $0.2 million and $0.2 million for the year ended October 31, 2023 and 2022, respectively.

6. Accrued Expenses and Other Current Liabilities

As of October 31, 2023 and 2022, accrued expenses and other current liabilities consisted of the following:

	October 31, 2023	October 31, 2022
Accrued research and development expenses	$ 759	$ 1,845
Professional fees	1,708	573
Employee compensation and related benefits	814	676
Accrued income tax payable	39	22
Other	219	—
Total accrued expenses and other current liabilities	$ 3,539	$ 3,116

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 the technology of radiopharmaceutical products 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 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 annual maintenance fee. The Company is also required to make a payment to NTC of $50 upon assigning the License Agreement to a third party.

The License Agreement provides for a one-time payment of $50 for the first dose of a milestone product, as defined in the License Agreement, in the first patient in a Phase I clinical trial or, if there is no Phase I clinical trial, in a Phase II clinical trial, as well as a one-time payment of $450 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 been achieved as of the year ended October 31, 2023. 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

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

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, 2023 and 2022, the Company incurred $50 of expenses related to the annual maintenance fee under the License Agreement which is recorded within research and development expenses.

8. Notes Payable

2021 Loan and Security Agreement

On December 30, 2021, the Company entered into a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules" or the "Lender") for the issuance of a term loan facility of up to an aggregate principal amount of up to $20.0 million (the "Term Loans"). The Loan Agreement provides for (i) an initial term loan advance of $7.0 million, which closed on December 30, 2021, (ii) subject to the achievement of certain Clinical Milestones ("Clinical Milestone"), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $4.0 million from the achievement of the Clinical Milestone through June 15, 2022, which was drawn in June 2022, and (iii) subject to the achievement of certain financial milestones ("Financial Milestone"), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $9.0 million from achievement of the Financial Milestone through December 15, 2022, which was not achieved. The Company is required to pay an end of term fee ("End of Term Charge") equal to 6.35% of the aggregate principal amount of the Term Loans advances upon repayment.

The Term Loans mature on July 1, 2025, with no option for extension (the "Maturity Date").

The Term Loan bears interest at an annual rate equal to the greater of (i) 8.25% plus the prime rate of interest as reported in the Wall Street Journal minus 3.25% and (ii) 8.25% provided, that, from and after the date the Company achieves the financial milestone, as defined within the agreement, the reference to 8.25% in clauses (i) and (ii) is reduced to 8.15%. Borrowings under the Loan and Security Agreement are repayable in monthly interest-only payments through June 2023. After the interest-only payment period, borrowings under the Loan and Security Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. 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 of the last draw down; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the closing date of the last draw down, but on or prior to twenty-four months following the closing date of the last draw down; and 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date.

In connection with the Loan Agreement, 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 Company's property and other assets, and certain equity interests and accounts of enGene, subject to limited exceptions including the Company's intellectual property. The Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company.

The debt discount and issuance costs are being accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Loan Agreement is approximately 18.3% and 15.9% as of October 31, 2023 and 2022, respectively.

As of October 31, 2023 and 2022, the carrying value of the Term Loan consists of the following:

	October 31, 2023	October 31, 2022
Note payable, including End of Term Charge	$ 10,144	$ 11,699
Debt discount, net of accretion	(474)	(891)
Accrued interest	108	106
Note payable, net of discount	$ 9,778	$ 10,914

As of October 31, 2023, the Company classified $0.6 million of the note payable as current, which represents the principal payments due and amortization of the debt discount between October 31, 2023 and the date the Term Loan was amended in December

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2023, as the debt was refinanced on a long-term basis in the subsequent event period (see Note 18). As of October 31, 2022, the Company classified $1.3 million of the note payable as current which represents the principal payments due and amortization of the debt discount to be recorded within twelve months from the balance sheet date. During the years ended October 31, 2023 and 2022, the Company recognized $1.8 million and $1.0 million of interest expense related to the Loan Agreement, respectively, of which $0.4 million and $0.3 million was related to the amortization of the debt discount, respectively.

Through October 31, 2023, the Company borrowed $11.0 million under the Loan Agreement and incurred $1.1 million of debt discount and issuance costs inclusive of facility fees, legal fees, End of Term Charge and initial fair value of the warrants.

As of October 31, 2023, and prior to the amendment of the Term Loan (see Note 18), the estimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge, are as follows:

	Note Principal Payments
2024	$ 5,106
2025	5,038
Total principal payments, including End of Term Charge	10,144

As of October 31, 2023, based on borrowing rates available to the Company for loans with similar terms and consideration of the Company's credit risk, the carrying value of the Company's variable interest rate debt, excluding unamortized debt issuance costs, approximates fair value.

Hercules Warrants

Under the Loan and Security Agreement, the Company agreed to issue to Hercules warrants (the "Hercules Warrants") to purchase a number of shares of Old enGene's redeemable convertible preferred shares at the exercise price equal to 2.5% of the aggregate amount of the Term Loans that are funded, as such amounts are funded. On the Closing Date, the Company issued a warrant to purchase 84,714 Class C Preferred Shares which were determined to have a fair value of $34 upon issuance. On the second tranche closing, in June 2022, the Company issued an additional warrant to purchase 48,978 Class C Preferred Shares which were determined to have a fair value of $23 upon issuance. The initial Hercules Warrant values are recorded as a discount to the term loan and are being amortized to interest expense using the effective interest method over the life of the Term Loans. The Company remeasured the fair value of the warrants at each reporting date with changes being recorded as a change in the fair value of the warrant liabilities.

The Hercules Warrants were initially exercisable for a period of ten years from the date of the issuance of each warrant at a per-share exercise price equal to $2.632 Canadian Dollars, subject to certain adjustments as specified in the warrants. In addition, the Company has granted to the holders of the Hercules Warrants certain registration rights on a pari passu basis with the holders of outstanding Preferred Shares and warrants to purchase Preferred Shares. Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration.

The Company accounted for the warrants as a liability prior to the consummation of the Reverse Recapitalization since they were indexed to Old enGene's redeemable convertible preferred shares that were classified as temporary equity.

April 2023 Notes

On April 4, 2023, the Company entered into a note purchase agreement (the "April 2023 Notes") for a principal amount of $8.0 million with Merck Lumira Biosciences Fund, L.P., Merck Lumira Biosciences Fund (Quebec), L.P., Lumira Ventures III, L.P., Lumira Ventures III (International), L.P., Lumira Ventures IV, L.P., Lumira Ventures IV (International), L.P., Fond de solidarité des travailleurs du Québec (F.T.Q.), and Forbion Capital Fund III Cooperatief U.A. (collectively the "April 2023 Investors"). The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, is to accrue interest at a rate of 15% per annum. The April 2023 Notes are classified as current as they mature on the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing in May 2023, the Company issued convertible debentures and warrants of the Company to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, as repayment of the April 2023 Notes.

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The Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be $8.0 million. As part the 2023 Financing, the terms of the April 2023 Notes were modified, in which the repayment of the April 2023 Notes resulted in the Company issuing convertible debentures and warrants of the Company to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing. Upon the completion of the 2023 Financing in May 2023, the Company issued $8.0 million in convertible notes and warrants in repayment for the April 2023 Notes. No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, and prior to the extinguishment of the April 2023 Notes in May 2023 given the short period of time that the April 2023 Notes were outstanding. No gain or loss was recorded as a result of the extinguishment of the April 2023 Notes as the fair value of the notes upon extinguishment was determined to be equal to the fair value of the repayment amount.

9. Convertible Debentures

The Company has issued convertible debentures to various investors. The outstanding principal, accrued interest, and unamortized deferred financing costs of the convertible debentures recorded on the balance sheet as of each period end are as follows:

	October 31, 2023	October 31, 2022
BDC Notes	$ —	$ 2,497
2022 Notes	—	14,908
Total Convertible debentures	$ —	$ 17,405

BDC Notes

In September 2020, the Company issued a convertible debenture to the Business Development Bank of Canada ("BDC") in the amount of $2.2 million (the "BDC Notes"). The debt bears interest at rate of 8% per annum and had an initial maturity date of September 28, 2023. In December 2021 the Company amended the agreement which resulted in the maturity date extending to September 29, 2025. The BDC Notes are convertible at the option of the Holder into the Company's Class B redeemable convertible preferred shares at a price of 80% of the price paid per share in qualified financing, as defined within the BDC convertible debenture agreement. The issuance of the Term Loan in 2021 met the definition of a qualified financing per the BDC convertible debenture agreement. As the conversion option was not exercised upon the issuance of the Term Loan, the conversion rights upon a qualified financing were waived. There are optional conversion options that still exist if the Company is in default, as defined under the terms of the BDC Notes, or in the event of certain liquidation events, as defined within the BDC Notes, which allow for conversion of the BDC Note into the most senior share outstanding at the time of the event. If a liquidation event, as defined within the BDC Note agreement, and which includes a SPAC transaction, is consummated after a qualified financing, and optional conversion is not elected, the Company is required to pay the investor in cash, the outstanding principal and the accrued but unpaid interest and in addition an amount equal to 20% of the principal.

Upon issuance of the BDC Notes, the Company identified embedded derivatives related to the equity conversion features and liquidity event repayment features which required bifurcation as a single compound derivative instrument. The Company estimated the fair value of the embedded derivative liabilities upon issuance at $0.2 million. The Company remeasured the fair value of the embedded derivatives in effect at each reporting period, with the subsequent changes in the fair value of the derivative being recognized in changes in fair value of derivatives within the Company's consolidated statements of operations and comprehensive loss. During the year ended October 31, 2023, the Company recorded a change in fair value of the convertible debentures embedded derivative liability associated with the BDC Note of $0.3 million. Total interest expense, including the amortization of debt discounts, of $0.3 million was recorded for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the Company repaid the BDC Note, including the liquidity event repayment amount, resulting in full settlement of the note and extinguishment of the embedded derivative liability. The estimated fair value of the embedded derivative liabilities at October 31, 2022 was $0.3 million, resulting in $0.3 million of expense recorded as change in fair value of convertible debentures embedded derivative liabilities in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2022. Total interest expense, including the amortization of debt discounts, was $0.4 million for the year ended October 31, 2022. As part of the issuance of the BDC Notes, the Company incurred an aggregate of $36 of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the BDC Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred.

On May 12, 2023, the Company consented to certain modifications of the BDC Notes pursuant to which the Company will be required on the Closing Date to repay in cash (i) the outstanding principal and the accrued but unpaid interest; and (ii) an amount equal to 20% of the principal.

Upon the close of the Reverse Recapitalization, the Company repaid the BDC Note in full, resulting in a loss on extinguishment of $9 thousand due to the difference between the repayment amount and the carrying amount of the debenture and fair value of the embedded derivative lability at the time of repayment.

2022 Notes

During the year ended October 31, 2022, the Company issued convertible debentures for an aggregate amount of $18.4 million on October 20, 2022 (the "2022 Notes"). The 2022 Notes had an initial maturity that is the later of (i) three years from the date of issuance; or (ii) the maturity date of the Term Loan (see Note 9). The 2022 Notes bear interest at 10% per annum commencing on the date of issuance. The 2022 Notes are automatically convertible into common shares or redeemable convertible preferred shares ("Capital Shares") of the Company, whichever is issued by the Company in a qualified financing of Capital Shares that is not a listing event with an aggregate consideration of $50.0 million. The outstanding principal and accrued interest will convert at a price of 85% of the price paid in such qualified financing. In the event of a non-qualified financing, the noteholder majority has the option to convert the debentures to Capital Shares issued in the non-qualified financing event, at a price equal to 85% of the price paid per share in the non-qualified financing. Additionally, prior to the amendment of the 2022 Notes in May 2023 (as further described below), upon a listing event such as an initial public offering, the 2022 Notes would be automatically converted into the number of common shares equal to the quotient by dividing the outstanding principal and interest by the listing price, except if the listing event is a SPAC business combination, following which the 2022 Notes will be automatically converted into common shares based on the outstanding principal excluding interest. As part of amendment in May 2023, the conversion terms of the 2022 Notes associated with a listing event were amended to remove conversion upon an initial public offering and to fix the conversion price at $8.84. Further, given that the Company entered into a SPAC transaction agreement, as defined in the Notes agreement, before July 31, 2023, in the event that the SPAC transaction agreement was to terminate in accordance with its terms, the Company could be required, at the election of the noteholder majority, to repay the principal amount and accrued and unpaid interest or to convert this amount into the number of the then most senior share class of the Company. In the event of default, the noteholder majority has the option to require payment of the principal and accrued interest amounts or to convert the outstanding principal and accrued interest into the number of the then most senior share class of the Company or common shares at the issue price of such shares at that date. Further, upon maturity of the 2022 Notes, at the option of a noteholder majority, the principal amount and accrued and unpaid interest shall be repaid in full or converted into the number of the then most senior share class of the Company or common shares at the issue price of such shares at that date. Upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 common shares of the Company.

Upon issuance of the 2022 Notes, the Company identified embedded derivatives related to the equity conversion features which required bifurcation as a single compound derivative instrument. The Company estimated the fair value of the embedded derivative liabilities upon issuance at $3.5 million. Given the close proximity between the issuance date of the notes and the Company's year ended October 31, 2022, no change in fair value was recorded related to the embedded derivative liabilities identified as part of the issuance of the 2022 Notes. During the year ended October 31, 2023, the Company recorded a change in fair value associated with the 2022 Notes embedded derivative liability of $21.2 million in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2023. As of October 31, 2023 no embedded derivative liability is recorded for the 2022 Notes as they converted to shares of the Company upon the consummation of the Reverse Recapitalization. Total interest expense, including the amortization of debt discounts, was $2.8 million for the year ended October 31, 2023, respectively. As part of the issuance of the 2022 Notes, the Company incurred an aggregate of $44 of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the 2022 Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred.

On May 16, 2023, the Company agreed to certain modifications of the 2022 Notes having an aggregate principal amount of $18.4 million (the "Amended 2022 Notes"), which included a change in the definition of the maturity date by allowing an extension of the maturity date upon election of a noteholder majority, increasing the percentage required for a noteholder majority, and modifying terms of certain conversion options. The amendments to the 2022 Notes did not result in the addition or termination of any substantive conversion terms, and the amendment to the 2022 Notes was determined to be non-substantial and was accounted for as a modification. In addition, as part of the May 2023 Financing, the holders of the 2022 Notes which participated in the 2023 Financing received warrants to purchase common shares of the Company. The fair value of the warrants at the time of issuance to the holders of the 2022 Notes was determined to be $0.5 million and was recorded as reduction of the carrying value of the 2022 Notes as part of the modification, which is being amortized to interest expense through the maturity date of the 2022 Notes.

On October 31, 2023 upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 common shares of the Company. The Company accounted for the conversion as an extinguishment and recorded a loss on extinguishment of $3.1 million, relating to the difference between the fair value of the common shares issued and the carrying value of the 2022 Notes and fair value of the embedded derivative liability at the time of conversion.

May 2023 Notes

On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, the Company entered into agreements pursuant to which it issued new convertible notes and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in repayment of the April 2023 Notes in an aggregate amount of $8.0 million (collectively, the "May 2023 Notes" and, together with the warrants purchased concurrently, the "2023 Financing"; the 2023 Financing together with the Amended 2022 Financing, the "Convertible Bridge Financing").

The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash, of which Forbion Growth Sponsor FEAC I B.V. funded an aggregate amount of $20.0 million of the total $38.0 million. The May 2023 Notes issued as part of the 2023 Financing, if not converted, have an initial maturity date of three years from the issuance date and are to accrue interest at 10% per annum, which is payable upon maturity. The May 2023 Notes have the same conversion terms as the Amended 2022 Notes (as described above).

The warrants issued as part of the 2023 Financing were for the purchase of common shares of Old enGene. The number of 2023 Warrants issued to each participating investor in the 2023 Financing was equal to the number of warrants the investor would receive had they invested the same amount in the PIPE Financing, divided by the Company Exchange Ratio. The 2023 Warrants were only to become exercisable upon the completion of the merger. Upon the close of the Reverse Recapitalization, the 2023 Warrants were exchanged for 2,679,432 warrants of the Company and have the same terms as the public warrants issued upon the FEAC initial public offering, with an exercise price of $11.50, and which will expire five years after the completion of the merger. The warrants issued as part of the 2023 Financing were concluded to be liability classified upon issuance, as they failed the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815. The terms of the warrants initially required the Company to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants will become fixed. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities. Refer to Note 3. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815.

The Company elected the fair value option of accounting for the May 2023 Notes. The Company recorded May 2023 Notes at fair value upon the date of issuance. At inception the fair value of the May 2023 Notes was determined to be $37.0 million and the fair value of the related warrants was determined to be $1.4 million, of which $0.5 million related to the fair value of the warrants issued to the holders of the 2022 Notes, as described above. During the year ended October 31, 2023, the Company recorded a change in fair value of the May 2023 Notes of $56.2 million. The Company incurred $0.8 million of debt issuance costs associated with the May 2023 Notes which have been expensed and are included within general and administrative expenses. Refer to Note 3.

On October 31, 2023 upon the close of the Reverse Recapitalization, the 2023 Notes were converted into 4,298,463 common shares of the Company. The Company accounted for the conversion as an extinguishment, with no gain or loss recorded on extinguishment as the fair value of the common shares issued was determined to equal the fair value of the 2023 Notes at the time of conversion.

10. Redeemable Convertible Preferred Shares

As of October 31, 2022, Old enGene's Articles of Amendment had an unlimited number of authorized shares of each class of redeemable convertible preferred shares.

Class A Redeemable Convertible Preferred Shares

On July 26, 2013, the Company entered into a subscription agreement (the "Class A Agreement") with multiple investors, whereby the Company agreed to sell to the investors an initial aggregate amount of 610,333 Class A redeemable convertible preferred shares at a price of $1.5929 ($1.63845 CAD) per share for total aggregate proceeds of $1.0 million (the "Class A Initial Closing"). Included within the Class A Agreement were three additional future tranche obligations (the "Class A Second Tranche," "Class A Third Tranche" and "Class A Fourth Tranche") for the Company to issue and sell shares of Class A redeemable convertible preferred shares upon the achievement of certain milestone events. Only the Class A Second Tranche closed under the Class A Agreement. The Class A Second Tranche obligated the Company to sell and the Class A Investors to purchase 1,830,999 shares of Class A redeemable convertible preferred shares at a price of $1.56967 ($1.63845 CAD) per share for total proceeds of $2.9 million, upon the establishment of the

Company's headquarters in Montreal Quebec and completion of experiments required to bolster a patent application for dually-derivatized chitosan (the "Second Closing Milestone Event"), which occurred in 2013. Additionally, upon completing the Class A redeemable convertible preferred share financing, convertible notes of the Company held by multiple investors converted into Class A redeemable convertible preferred shares.

Class B Redeemable Convertible Preferred Shares

On January 6, 2015, the Company entered into a subscription agreement (the "Class B Agreement") with multiple investors, where the Company agreed to sell to the investors an initial aggregate amount of 2,758,221 Class B redeemable convertible preferred shares at a price of $1.85032 ($2.17532 CAD) per share for total proceeds of $5.1 million (the "Class B Initial Closing"). Included within the Class B Agreement were two additional closings (the "Class B Second Tranche," and the "Class B Third Tranche," respectively) which obligated the Company to sell and Class B investors to purchase additional Class B redeemable convertible preferred shares upon certain events. The Class B Second Tranche obligated the Company to sell and the Class B Investors to purchase 1,838,815 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $3.0 million and the Class B Third Tranche obligated the Company the sell and the Class B Investors to purchase 1,608,963 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $2.6 million. The Class B Second Tranche and Class B Third Tranche closed on March 1, 2017.

Class B-1 Redeemable Convertible Preferred Shares

On September 10, 2015, the Company entered into a Subscription Agreement (the Class "B-1 Agreement"), in which the Company was to issue 1,523,809 Class B-1 redeemable convertible preferred shares for a purchase price of $1.64367 ($2.17532 CAD) per share, resulting in aggregate proceeds of $2.5 million. During the year ended October 31, 2020, the Class B-1 redeemable convertible preferred shares converted to common shares on a 1:1 basis. Therefore, as of each of the years ended October 31, 2023, October 31, 2022, and October 31, 2021, no shares of the Class B-1 redeemable convertible preferred shares remained outstanding. The Company presented these shares within temporary equity, as they contained the same redemption features as the Class B redeemable convertible preferred shares (further described above). Upon conversion to common shares, the carrying value of the Class B-1 redeemable convertible preferred shares was reclassified to additional paid in capital within shareholders' deficit.

Class C Redeemable Convertible Preferred Shares

The Class C redeemable convertible preferred shares are issuable in series, of which an unlimited number are designated as Series 1 Class C redeemable convertible preferred shares with an issue price per share of $1.5929 ($1.63845 CAD); an unlimited number are designated as Series 2 Class C redeemable convertible preferred shares with an issue price per share of $1.85032 ($2.175315 CAD); an unlimited number are designated as Series 3 Class C redeemable convertible preferred shares with an issue price per share of $2.12376 ($2.6320 CAD); and an unlimited number are designated as Series 4 Class C redeemable convertible preferred shares that is reserved for the potential conversion of the BDC Notes, and will each have an issue price per share of $1.69901 ($2.10559 CAD).

On June 30, 2021, the Company entered into a subscription agreement (the "Class C Agreement") with multiple investors, where the Company agreed to sell to the Investors an initial aggregate amount of 3,662,813 Series 3 Class C redeemable convertible preferred shares (the "Series 3 Class C Shares") at a price of $2.12376 ($2.6320 CAD) per share for total proceeds of $7.8 million (the "Class C Initial Closing"). Included within the Class C Agreement was one additional closing (the "Class C Second Tranche") which obligated the Company to sell and Class C investors to purchase additional Class C redeemable convertible preferred shares upon the achievement of certain milestone events. The Class C Second Tranche obligated the Company to sell and the Class C investors to purchase 3,662,810 Series 3 Class C Shares at a price of $2.13192 ($2.6320 CAD) per share for total proceeds of $7.8 million. The Class C Second Tranche closed on October 29, 2021.

As part of each of the Class C Initial Closing and Class C Second Tranche, each Class C investor received 3,662,813 and 3,662,810 warrants, respectively, to purchase Class C redeemable convertible preferred shares (the "Class C Warrants"), resulting in an aggregate issued amount of 7,325,623 Class C Warrants. The Class C Warrants have an exercise price of $2.12376 ($2.6320 CAD) per share and a term of 10 years. The Class C Warrants were determined to be liabilities. The Company estimated the fair value of the warrant liabilities upon issuance and remeasured the fair value of the warrant liabilities at each reporting period, with the subsequent changes in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Company's consolidated statements of operations and comprehensive loss. Upon the completion of the merger with FEAC, all existing Class C Warrants of the Company will be extinguished.

Under the terms of the Class C Agreement, certain convertible notes held by various Class C investors and other investors were exchanged for an aggregate amount of 16,464,646 Class B redeemable convertible preferred shares. Additionally, upon entering into the Class C Agreement, the Company also entered into a share exchange agreement (the "Share Exchange Agreement") with the Class A investors and the Class B investors. As part of the Share Exchange Agreement, certain of the Class A redeemable convertible preferred shares issued to Class A investors were exchanged for Series 1 Class C redeemable convertible preferred shares and certain of the Class B redeemable convertible preferred shares issued to the Class B investors were exchanged for Series 2 Class C redeemable convertible preferred shares. This exchange resulted in the derecognition of Class A and B redeemable convertible preferred shares and the recognition of Class C redeemable convertible preferred shares at the fair value of the Class C redeemable convertible preferred shares. The difference between the carrying value of the Class A and Class B redeemable convertible preferred shares and the fair value of the Class C redeemable convertible preferred shares for which they converted into was recorded within additional paid in capital and no gain or loss on extinguishment was recorded within the consolidated statements of operations and comprehensive loss. Further, the February 2020 Warrants, June 2020 Warrants, and 2021 Warrants, which consisted of warrants to purchase the Company's Class B redeemable convertible preferred shares and were issued as part of the convertible debentures were cancelled and replaced by the terms of the Class C Warrants. The aggregate amount of outstanding warrants of 10,242,130 from the February 2020 Warrants, the June 2020 Warrants, and the 2021 Warrants converted into 10,242,130 Class C Warrants, which have an exercise price of $2.12376 ($2.6320 CAD) per share and a term expiring on February 14, 2030. Immediately prior to conversion, the warrants were marked to fair value, with the change in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Company's consolidated statements of operations and comprehensive loss.

Upon issuance of each series of Class A, Class B, and Class C Preferred Shares, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

Conversion of Redeemable Convertible Preferred Stock

Pursuant to the terms of the Merger Agreement, upon the consummation of the Reverse Recapitalization, each share of Old enGene's redeemable convertible preferred stock issued and outstanding immediately prior to the close was exchanged for common shares of the Company using the Company Exchange Ratio of approximately 0.18048. A retrospective adjustment has been applied to all periods presented to reflect the Reverse Recapitalization. Refer to Note 3 for additional discussion.

Undesignated Preferred Stock

The Company's Certificate of Incorporation, as amended and restated, authorizes the Company to issue an unlimited number of preferred shares with no par value. The shares of preferred stock are currently undesignated.

11. Common Shares

The Company has an unlimited number of authorized shares of common shares, with no par value. As of October 31, 2023 and 2022 there were 23,197,976 and 665,767 common shares outstanding, respectively, as adjusted to reflect the Reverse Recapitalization through the application of a retrospective adjustment.

The holders of the common stock are entitled to one vote for each share of common stock 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, or the Board, if any, subject to the preferential dividend rights of preferred stock. Through October 31, 2023, no cash dividends had been declared or paid.

Common share warrants

As of October 31, 2023, the Company had 10,411,641 warrants to purchase common shares of the Company outstanding. As of October 31, 2022 the Company did not have any warrants to purchase common shares outstanding.

The warrants to purchase common shares as of October 31, 2023 have the same terms as the FEAC public warrants issued in connection with FEAC's IPO, have an exercise price of $11.50, are exercisable beginning 30 days after the completion of the Reverse Recapitalization and expire on October 31, 2028, or five years after the completion of the Reverse Recapitalization. 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 own stock as prescribed by ASC 815.

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As of October 31, 2023, and 2022, the Company has reserved the following shares of common shares for the exercise of common share warrants, share options, and remaining shares reserved for future issuance under the Plan:

	October 31, 2023	October 31, 2022
Preferred Stock, as converted	—	5,983,339
Warrants to purchase redeemable convertible preferred shares	—	3,194,756
Warrants to purchase common shares	10,411,641	—
Options to purchase common shares*	2,706,941	1,575,785
Remaining shares reserved for future issuance under the equity plans	2,607,943	170,158
Total	15,726,525	10,924,038

*As of October 31, 2023, amount includes the 1,046,764 shares with exercisability conditions of (i) the completion of the Reverse Recapitalization, and (ii) the filing an effective registration statement to register the shares underlying the option award, which is deemed probable as of October 31, 2023.

12. Share-Based Compensation

Pursuant to the terms of the Reverse Recapitalization, upon the Closing Date, each outstanding option to purchase Old enGene's common stock issued under the Old Plan's was exchanged for an option to purchase common shares of the Company, and the number of shares and exercise price of each granted option was adjusted using the exchange ratio of approximately 0.18048. Further, the currency of all exercise prices of the options issued under the Old Plans were converted from CAD to USD using the exchange rate in effect on the day immediately prior to the Closing Date. A retrospective adjustment has been applied to the number of options and exercise price of stock options for all periods presented to reflect the Reverse Recapitalization as discussed further in Note 3.

The Old Plans

Old enGene had an employee share option plan (the "ESOP") and an equity incentive plan (the "EIP") (collectively, the " Old Plans") which was adopted by the Board of Directors, and approved by the shareholders, effective July 5, 2018.

Under the Old Plans, options to purchase non-voting common shares of Old enGene's shares may be granted to directors, officers, employees, consultants and members of the scientific advisory board. The Old Plans provide for the issuance of common stock options up to a maximum of 15% of the aggregate issued and outstanding common shares and non-voting common shares of Old enGene calculated on an as converted and fully diluted basis. The Old Plans were administered by Old enGene's Board of Directors. Old enGene's Board of Directors determined the number of options to be granted, the vesting period and the exercise price of new options. It was Old enGene's policy to establish the exercise price at an amount that approximates the fair value of the underlying shares on the date of grant as determined by Old enGene's Board of Directors. The options vest in accordance with the vesting terms determined for each grant by Old enGene's Board of Directors. The vesting terms of Old enGene's granted stock options with service only conditions are typically 100% vesting immediately upon grant date, or over a three- or four-year service period. Upon the consummation of the Reverse Recapitalization, the Company recognized share-based compensation expense of $0.4 million associated with the acceleration of the vesting for the outstanding awards with service only vesting conditions under the Old Plan. As of October 31, 2023, no unrecognized compensation cost remains for the outstanding awards granted under the Old Plan with service only vesting conditions.

On July 7, 2023, the Board of Directors approved the reservation of an additional 1,046,764 non-voting common shares for issuance under the Company's employee equity incentive plan, revising the number of shares reserved from 1,775,729 to 2,822,493. Also on July 7, 2023, the Company granted 1,046,764 options to employees at an exercise price of $5.87 CAD ($4.24 USD). These options are not exercisable unless and until the completion of the Reverse Recapitalization and there is an effective registration statement for the shares underlying such granted options and will terminate automatically in the event of the termination of the Merger Agreement. The Company has valued these awards at the grant date using Black-Scholes pricing model in which the fair value of the stock on the grant date was equal to the exercise price of the award. 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. Upon the grant date, 794,643 of the issued options were fully vested, and the remaining 252,121 options will vest over varying terms up to four years on a pro rata basis. The Company recognizes compensation 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. During the year ended October 31, 2023, $2.6 million

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of stock based compensation expense was recorded associated with the 1,046,764 stock options granted in July 2023 because the Reverse Recapitalization was completed and the Company determined that the filing of the registration statement was probable to occur. As of October 31, 2023, there was $0.6 million of unrecognized compensation expense related to outstanding stock options associated with the 1,046,764 stock options granted in July 2023, which is expected to be recognized over a weighted-average period of 3.68 years.

Upon the consummation of the Reverse Recapitalization on October 31, 2023, all options outstanding under the Old Plans were exchanged for 2,706,941 shares options to purchase common shares of the Company based on the Exchange Ratio determined in accordance with the terms of the Merger Agreement. Further, all exercise prices were adjusted by the Exchange Ratio and the currency of the exercise prices was changed from CAD to USD based on the exchange rate in effect on October 30, 2023, the day immediately before the consummation of the Reverse Recapitalization. No incremental compensation cost was recorded as a result of the change in underlying common shares from Old enGene to the Company, or as a result of the change of the exercise prices to reflect the adjustment for the Exchange Ratio and the change in currency from CAD to USD, as it was concluded that the fair value of the awards immediately before and immediately after the modifications did not change. No options remain available for grant under the Old Plans as of October 31, 2023.

The 2023 Plan

On October 31, 2023, upon the completion of the Reverse Recapitalization, the shareholders approved and the Company adopted the 2023 Plan, which superseded the Old Plans. The 2023 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 stock bonus awards.

The number of shares initially reserved for issuance under the 2023 Plan is 2,607,943 shares of common stock, plus 2,706,941 shares of common stock subject to the outstanding grants under the Old Plans, and shall automatically increase on January 1 of each calendar year beginning in 2024 by a number of shares equal to the lesser of 1,946,226 million common shares and such lesser number as may be determined by the Board.

The 2023 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. 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 share of common stock on the date of grant and the term of stock option may not be greater than ten years. Shares that are expired terminated, surrendered or cancelled under the 2023 Plan without having been fully exercised will be available for future awards.

Stock Options

The assumptions that the Company used to determine the grant-date fair value of stock options, were as follows:

	Year ended October 31,	
	2023	2022
Expected term (in years)	5.2 – 6.08	6.08
Expected volatility	79.92 – 81.48%	75.3%
Risk-free interest rate	3.56 – 4.35%	2.16%
Expected dividend yield	—	—
Fair value of common shares and exercise price of options (CAD)	$ 2.11 – 12.36	$ 1.22
Fair value of common shares and exercise price of options (USD)	$ 1.52 – 8.93	$ 0.88

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

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, 2022	1,575,785	$ 0.88	7.7	$ 1,026
Granted	1,308,081	4.05		
Exercised	(84,072)	0.88		
Forfeited or expired	(92,853)	0.88		
Outstanding as of October 31, 2023	2,706,941	$ 2.40	8.1	$ 52,192
Options vested and exercisable as of October 31, 2023	1,660,177	$ 1.26	7.1	$ 33,921
Options vested and not exercisable as of October 31, 2023	807,025	$ 4.24	9.7	$ 14,087
Options unvested as of October 31, 2023	239,739	$ 4.24	9.7	$ 4,185

* - All options outstanding at October 31, 2022 were issued in Canadian dollars with an exercise price of $1.22. All options granted during the year ended October 31, 2023 were issued in Canadian dollars at exercise prices of $2.11, $5.87, and $12.36. Upon the close of the Reverse Recapitalization, all exercise prices were converted to United States dollars at the exchange rate in effect on the day immediately before the close of the Reverse Recapitalization. The Weighted Average Exercise Price above was adjusted to reflect such change.

** - Retrospectively restated to reflect exchange of shares upon the close of Reverse Recapitalization. See Notes 1 and 3.

During the year ended October 31, 2023, included within the stock options exercised are 15,494 shares of common shares issued upon cashless exercise of the stock options.

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 October 31, 2023, and 2022, respectively.

The weighted-average grant-date fair value per share of share options granted during the year ended October 31, 2023 and 2022 was $3.90 CAD and $0.82 CAD, respectively.

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,	
	2023	2022
Research and development	$ 780	$ 31
General and administrative	2,670	85
Total share-based compensation expense	$ 3,450	$ 116

As of October 31, 2023, there was $0.6 million of unrecognized compensation, which is expected to be recognized over a weighted-average period of 3.68 years.

(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)

13. 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,	
	2023	2022
Numerator:		
Net loss	$ 99,917	$ 24,462
Deemed dividend attributable to redeemable convertible preferred shareholders	4,822	4,562
Net loss attributable to common shareholders, basic and diluted	$ 104,739	$ 29,024
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	692,609	655,153
Net loss per common share, basic and diluted	$ 151.22	$ 44.30

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, 2023, and 2022 because including them would have had an anti-dilutive effect:

	Year Ended October 31,	
	2023	2022
Redeemable convertible preferred shares	—	5,983,339
Warrants to purchase redeemable convertible preferred shares	—	3,194,756
Warrants to purchase common shares	10,411,641	—
Options to purchase common shares	2,706,941	1,575,785
Total	13,118,582	10,753,880

14. Income Taxes

Loss before provision for income taxes consisted of the following:

	Year ended October 31,	
	2023	2022
Domestic (Canada)	$ (99,157)	$ (23,965)
Foreign (US)	(743)	(475)
Loss before provision for income taxes	$ (99,900)	$ (24,440)

The components of the provision for income taxes is as follows:

	Year ended October 31,	
	2023	2022
Current expense (benefit):		
Domestic (Canada)	$ —	$ —
Foreign (US)	17	22
Total current expense (benefit)	17	22
Deferred expense (benefit)		
Domestic (Canada)	—	—
Foreign (US)	—	—
Total deferred tax expense (benefit)	—	—
Total income tax expense (benefit)	$ 17	$ 22

(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,	
	2023	2022
Income at Canada statutory rate	26.50%	26.50%
Conversion of debentures	(21.90)%	—
State taxes, net of federal benefit	0.05%	0.12%
Permanent differences	1.68%	(3.90)%
Tax credits	0.19%	0.29%
Foreign rate differential	(0.04)%	(0.11)%
Valuation allowance	(6.52)%	(22.86)%
Other	0.03%	(0.14)%
	(0.01)%	(0.09)%

The net deferred income tax balances related to the following:

	October 31,	
	2023	2022
Deferred tax assets:		
R&D expenditures	7,012	6,441
Net operating loss (NOL) carryforwards	18,918	13,862
ITC credits	1,210	963
Property and equipment	791	742
Convertible debenture embedded derivative liabilities	—	13
Financing costs	2,440	—
Accruals	149	101
Section 174 capitalized R&D costs	393	—
Other	172	—
Total deferred tax assets	31,085	22,122
Valuation allowance	(31,085)	(22,048)
Net deferred tax assets (liability)	-	74
Deferred tax liabilities:		
Convertible debentures	—	(9)
Other	—	(65)
Total deferred tax liabilities	—	(74)
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 in. 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 the evaluation of 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, 2023 and 2022, 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, 2023 and 2022, 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, 2023, the Company has Canadian Federal NOL carryforwards of $71.9 million, that expire between 2028 and 2043 and Canadian provincial NOL carryforwards of $68.5 million, that expire between 2031 and 2043. As of October 31, 2023, the Company has a U.S. Federal NOL carryforward of $0.9 million, that may be carried forward indefinitely, and a U.S. state NOL carryforward of $0.5 million, that begin to expire in 2039.

As of October 31, 2023, the Company also has Canadian investment tax credits of $1.8 million that expire between 2028 and 2043.

15. Leases

The Company's leases are comprised of all operating leases for office and lab space.

In April 2019, the Company entered into an office space lease approximating 12,271 rentable square feet or a portion of an office building located at 201 Jones Road, Waltham, Massachusetts. The lease commenced in April 2019 and the lease term is to expire on March 30, 2022, with no options to renew. The lease expired on March 30, 2022.

In November 2021, the Company entered into an office and lab space lease approximating 9,360 of rentable square feet for designated office and lab spaces located at 7171 Frederick-Banting, City of Montreal, judicial district of Montreal, Province of Quebec. The lease commenced in November 2021 and had an initial term of 12 months that would have expired on October 31, 2022, and includes options to renew for consecutive twelve-month periods upon landlord consent at new lease rates. As the Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet, this was considered short-term leases, and no operating lease right of use assets and liabilities were recognized. In October 2022, the Company entered into a lease amendment to extend the lease for an additional term of six months through April 2023, with an option to extend the lease through September 2023. In April 2023, the Company extended the lease through September 2023. The lease was further extended through November 5, 2023. The amendment resulted in $0.2 million of additional lease commitments to be paid during the extended term, inclusive of the extension through November 5, 2023.

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 did not commence as of October 31, 2023 as the Company did not have access to the space as of that date. The lease commenced in November 2023.

During the year ended October 31, 2023, and 2022, 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,	
	2023	2022
Lease Cost:		
Operating lease cost	—	62
Variable operating lease cost	62	53
Short-term operating lease cost	411	355
Total operating lease cost	473	470

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, 2023, and 2022:

	Year Ended October 31,	
	2023	2022
Cash paid for amounts included in the measurement of operating lease liabilities	$ —	$ 62

As of October 31, 2023, the Company does not have any operating lease liabilities recorded on the balance sheet.

16. 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, 2023 and 2022, there were no matters which would have a material impact on the Company's financial results.

Purchase and Other Obligations

The Company enters into contracts in the normal course of business with CROs, CDMOs 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.

17. Related Party Transactions

During the year ended October 31, 2023, the Company had the following transactions with shareholders that hold more than 10% of the total outstanding shares of the Company:

On April 4, 2023, the Company entered into the April 2023 Notes for a principal amount of $8.0 million with the April 2023 investors, as described in Note 8. The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, is to accrue interest at a rate of 15% per annum. The April 2023 Notes had a maturity date which was the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing, which met the definition of a qualified financing as defined within the April 2023 Notes, the Company issued and aggregate amount of $8.0 million of convertible debentures and warrants of the Company to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, for the extinguishment and settlement of the April 2023 Notes.

On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, the Company entered into agreements pursuant to which it issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in settlement and extinguishment of the April 2023 Notes for an aggregate amount of $8.0 million, as described in Note 9. The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash. The 2023 Notes issued as part of the 2023 Financing have an initial maturity date of three years from the closing date and are to accrue interest at 10% per annum, which is payable upon maturity. The 2023 Notes have the same conversion terms as the 2022 Notes (as described in Note 9). Of the $38.0 million of convertible debentures and warrants issued, $8.0 million was issued to existing shareholders of the Company, $20.0 million was issued to Forbion Growth Sponsor FEAC I B.V., and $10 million which was issued to Investissement Québec.

On October 31, 2023, upon the consummation of the Reverse Recapitalization, all of the Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close were exchanged for shares of the Company's common shares, with no dividends or distributions being declared or paid on Old enGene's redeemable convertible preferred shares. Further, certain of Old enGene's existing convertible notes were converted into common shares of Old enGene at the conversion ratio in place at the time of conversion, and all of Old enGene's common shares were exchanged for common shares of Company at the Exchange Ratio of approximately 0.18048. A total of 13,091,608 common shares of the Company were issued to the Old enGene's equity and convertible note holders upon the close of the Reverse Recapitalization, of which 2,262,351 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of its' participation in the 2023 Financing. Each of Old enGene's outstanding warrants to purchase common shares were exchanged for 2,679,432 common share warrants upon the close of the Reverse Recapitalization of which 950,153 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of its' participation in the 2023 Financing. All of Old enGene's existing outstanding Class C Warrants outstanding at the time of the Reverse Recapitalization were terminated. Additionally, there were 3,670,927 common shares of the Company issued to FEAC and its shareholders, as part of the Reverse Recapitalization, along with 5,029,444 warrants to purchase common shares.

During the years ended October 31, 2022, the Company had the following transactions with shareholders that hold more than 10% of the total outstanding shares of the Company:

On October 20, 2022, the Company issued an aggregate amount of $18.4 million of convertible debentures to existing shareholders including Forbion Capital Fund III Cooperatief U.A. ("Forbion Capital Fund III"), Fonds de Solidarité des Travailleurs du Québec

(F.T.Q.) (“FSTQ”), Lumira Ventures III, L.P. (“Lumira III”), Lumira Ventures III (International), L.P. (“Lumira International III”), Merck Lumira Biosciences Fund, L.P. (“Merck”), Merck Lumira Biosciences Fund (Québec), L.P. Refer to Note 9.

18. 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 additional subsequent events have occurred that require disclosure.

On November 30, 2023, the Company granted 385,000 options to purchase common shares in connection with the hiring of the Company's Chief Financial Officer and Chief Medical Officer, which vest over a four-year period, and 203,000 options to purchase common shares other various employees, which vest over three- and four-year periods, under the 2023 Plan. All the options granted have an exercise price of $7.66 per share, which is equal to the closing price of the Company’s common stock on the date of the grant.

On December 22, 2023, 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 (with Hercules, the "Lenders”). The Amended Loan Agreement amends and restates in its entirety that certain Loan and Security Agreement with Hercules dated December 30, 2021 (the "Prior Loan Agreement”). See Note 8.

The Amended Loan Agreement provides for a term loan facility of up to $50 million available in multiple tranches (the "Amended Term Loan”), as follows: (i) an initial term loan advance (the "Tranche 1 Advance”) that was made on the Amended Term Loan 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”) and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $7.5 million from the achievement of the Interim Milestone through the earlier of (x) 60 days following 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 (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 are required to pay upon the earlier of January 1, 2028 (the “Amended Term Loan Maturity Date”) or payment in full of the Amended Term Loans, an end of term fee equal to 5.50% of the aggregate principal amount of the Amended Term Loans. The Company is also required to pay on July 1, 2025 or, if earlier, the date the Company prepays the Amended Term Loans, $0.7 million representing the end of term charge under the Prior Loan Agreement.

The Amended Term Loans mature on January 1, 2028, with no option for extension.

The Amended 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 Amended 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 Amended Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement are repayable in monthly interest-only payments through the "Amortization Date”, which is either: (x) July 1, 2025 or (y) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (z) 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 Amended Term Loans and interest shall be repayable in equal monthly payments of principal and accrued interest until the Amended Term Loan Maturity Date.

At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding Amended Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge of 1.0% to 3.0% of the principal amount being repaid, the rate depending upon the date of repayment.

In connection with the Amended Loan Agreement, 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 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 also contains certain events of default and representations, warranties and non-financial covenants of the Company. Beginning from an initial test date of October 1, 2024 (which date can be extended based on certain milestones), the Amended Loan Agreement contains a minimum liquidity covenant requiring the Company to maintain at least 35% of the aggregate outstanding principal as unrestricted cash. This percentage can be lowered based on certain milestones and other events.

In connection with the Amended Loan Agreement, the Company also agreed to issue to the Lenders in connection with each advance of Term Loans warrants ("Lender Warrants") to purchase that number of the Company's common shares as shall equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrant 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 Closing Date and is subject to customary adjustments under the terms of the Warrants). Warrants are exercisable for a period of seven years from issuance.

On the Amended Term Loan Closing Date, the Company issued to the Lenders 62,413 Warrants in connection with the Tranche 1 Advance of the Term Loans. Under the terms of the Amended Loan Agreement, the maximum number of Warrants and resultant underlying common shares of the Company that could be issued is 138,696.

On January 1, 2024, the Company 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.

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Directors and Executive Officers

Jasper Bos, *Director*
Gerry Brunk, *Director*
Dr. Richard Glickman, *Director*
Lota S. Zoth, *Director*
Jason D. Hanson, *Chief Executive Officer and Director*
Ryan Daws, *Chief Financial Officer*
Dr. Alex Nichols, *President and Chief Operating Officer*
Dr. Richard Bryce, *Chief Medical Officer*
Dr. Anthony T. Cheung, *Chief Technology Officer*
Dr. James C. Sullivan, *Chief Scientific Officer*
Lee Giguere, *Chief Legal Officer and Corporate Secretary*

CORPORATE AND SHAREHOLDER INFORMATION

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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, 2023, and other investor information are available free of charge at https://engene.com/sec-filings/

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