

**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 March 31, 2025

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-35776

**Grace Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

State of Delaware

98-1359336

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

103 Carnegie Center Suite 300

Princeton, New Jersey 08540

(Address of principal executive offices, including zip code)

609-322-1602

Registrant's telephone number, including area code:

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 Stock, par value \$0.0001 per share	GRCE	Nasdaq Stock Market

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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. Yes  No

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 Securities Exchange Act of 1934). Yes  No

The aggregate market value of the voting and non-voting shares of common stock held by non-affiliates of the registrant, based on the closing sale price of the registrant's common stock on September 30, 2024, the last business day of its most recently completed second fiscal quarter, as reported on the Nasdaq Stock Market, was \$24,040,390.

The number of outstanding shares of common stock of the registrant, par value \$0.0001 per share, as of June 19, 2025, was 13,828,562.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain portions of the registrant's definitive proxy statement for its 2025 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year to which this Annual Report on Form 10-K relates, are incorporated by reference into Part III of this Annual Report on Form 10-K.



**GRACE THERAPEUTICS, INC.**  
**(Formerly ACASTI PHARMA INC.)**

**FORM 10-K**

**For the Fiscal Year Ended March 31, 2025**  
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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains information that may be forward-looking statements within the meaning of U.S. federal securities laws and forward-looking information within the meaning of Canadian securities laws, both of which we refer to in this Annual Report on Form 10-K as forward-looking statements. Forward-looking statements can be identified by the use of terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “intend,” “estimate,” “predict,” “potential,” “continue,” or other similar expressions concerning matters that are not statements about the present or historical facts. Forward-looking statements in this Annual Report on Form 10-K include, among other things, information or statements about:

- our ability to build a late-stage pharmaceutical company focused in rare and orphan diseases and, on developing and commercializing products that improve clinical outcomes using our novel drug delivery technologies;
- our ability to apply new proprietary formulations to existing pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, and more convenient drug delivery that can result in increased patient compliance;
- the potential for our drug candidates to receive orphan drug designation and exclusivity from the U.S. Food and Drug Administration (“FDA”) or regulatory approval under the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act (“FDCA”);
- the future prospects of our GTx-104 drug candidate, including but not limited to GTx-104’s potential to be administered to improve the management of hypotension in patients with aneurysmal subarachnoid hemorrhage (“aSAH”); the ability of GTx-104 to achieve a pharmacokinetic (“PK”) and safety profile similar to the oral form of nimodipine; GTx-104’s potential to provide improved bioavailability; GTx-104’s potential to achieve pharmacoeconomic benefit over the oral form of nimodipine; our ability to ultimately file a new drug application (“NDA”) for GTx-104 under Section 505(b)(2) of the FDCA; the acceptance of the NDA by the FDA; and the timing and ability to receive FDA approval for marketing GTx-104;
- our plan to prioritize the development of GTx-104;
- our plan to maximize the value of our de-prioritized drug candidates, GTx-102 and GTx-101, including through potential development, licensing, or sale of those drug candidates;
- the future prospects of our GTx-102 drug candidate, including but not limited to GTx-102’s potential to provide clinical benefits to decrease symptoms associated with Ataxia Telangiectasia; GTx-102’s potential ease of drug administration; the timing and outcomes of a Phase 3 efficacy and safety study for GTx-102; the timing of an NDA filing for GTx-102 under Section 505(b)(2) of the FDCA; and the timing and ability to receive FDA approval for marketing GTx-102;
- the future prospects of our GTx-101 drug candidate, including but not limited to GTx-101’s potential to be administered to postherpetic neuralgia (“PHN”) patients to treat the severe nerve pain associated with the disease; assumptions about the biphasic delivery mechanism of GTx-101, including its potential for rapid onset and continuous pain relief for up to eight hours; and the timing and outcomes of single ascending dose/multiple ascending dose and PK bridging studies, and a Phase 2 and Phase 3 efficacy and safety study; the timing of an NDA filing for GTx-101 under Section 505(b)(2) of the FDCA; and the timing and ability to receive FDA approval for marketing GTx-101;
- the quality of our clinical data, the cost and size of our development programs, expectations and forecasts related to our target markets and the size of our target markets; the cost and size of our commercial infrastructure and manufacturing needs in the United States, European Union, and the rest of the world; and our expected use of a range of third-party contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”) at multiple locations;
- expectations and forecasts related to our intellectual property portfolio, including but not limited to the probability of receiving orphan drug exclusivity from the FDA for our leading pipeline drug candidates; our patent portfolio strategy; and outcomes of our patent filings and extent of patent protection;
- our intellectual property position and duration of our patent rights;

- our strategy, future operations, prospects and the plans of our management with a goal to enhance shareholder value;
- our need for additional financing, and our estimates regarding our operating runway and timing for future financing and capital requirements;
- our expectations regarding our financial performance, including our costs and expenses, liquidity, and capital resources;
- our projected capital requirements to fund our anticipated expenses; and
- our ability to commercialize GTx-104 in the United States or establish strategic partnerships or commercial collaborations or obtain non-dilutive funding.

Although the forward-looking statements in this Annual Report on Form 10-K are based upon what we believe are reasonable assumptions, you should not place undue reliance on those forward-looking statements since actual results may vary materially from them.

In addition, the forward-looking statements in this Annual Report on Form 10-K are subject to a number of known and unknown risks, uncertainties and other factors, many of which are beyond our control, that could cause our actual results and developments to differ materially from those that are disclosed in or implied by the forward-looking statements, including, among others:

- we are heavily dependent on the success of our lead drug candidate, GTx-104;
- clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development;
- we are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our drug candidates, could hinder or prevent our drug candidates' commercial success;
- if we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug products, if approved, we may be unable to generate any revenue;
- if we are unable to differentiate our drug products from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve products that compete with any of our drug products, our ability to successfully commercialize our drug products would be adversely affected;
- our success depends in part upon our ability to protect our intellectual property for our drug candidates;
- intellectual property rights do not necessarily address all potential threats to our competitive advantage;
- we do not have internal manufacturing capabilities, and if we fail to develop and maintain supply relationships with various third-party manufacturers, or if such third parties fail to provide us with sufficient quantities of active pharmaceutical ingredients, excipients or drug products, or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance, we may be unable to develop or commercialize our drug candidates;
- our contract manufacturers may encounter difficulties involving, among other things, production yields, regulatory compliance, quality control and quality assurance, as well as shortages of qualified personnel. Approval of our drug candidates could be delayed, limited, or denied if the FDA does not approve and maintain the approval of our contract manufacturers' processes or facilities;
- the design, development, manufacture, supply, and distribution of our drug candidates are highly regulated and technically complex; and
- the other risks and uncertainties identified in Item 1A. Risk Factors and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations included in this Annual Report on Form 10-K.

All of the forward-looking statements in this Annual Report on Form 10-K are qualified by this cautionary statement. There can be no guarantee that the results or developments that we anticipate will be realized or, even if substantially realized, that they will have the consequences or effects on our business, financial condition, or results of operations

that we anticipate. As a result, you should not place undue reliance on forward-looking statements. Except as required by applicable law, we do not undertake to update or amend any forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are made as of the date of this Annual Report on Form 10-K.

We express all amounts in this Annual Report on Form 10-K in U.S. dollars, except where otherwise indicated. References to “\$” and “U.S.\$” are to U.S. dollars and references to “C\$” or “CAD\$” are to Canadian dollars.

Except as otherwise indicated, references in this Annual Report on Form 10-K to “Grace,” “Grace Therapeutics,” “Acasti,” “the Company,” “we,” “us,” and “our” refer to Grace Therapeutics, Inc. (formerly known as Acasti Pharma, Inc.) and its consolidated subsidiary.

## **Risk Factor Summary**

The risk factors summarized below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of shares of our common stock to decline. For more information, see “Item 1A. Risk Factors” in this Form 10-K. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

### ***Risks Related to our Business***

- We may not achieve our publicly announced milestones on time, or at all.
- We are heavily dependent on the success of our lead drug candidate, GTx-104.
- We may not be able to maximize value from our de-prioritized drug candidates, GTx-102 and GTx-101, through either development, out-licensing or sale.
- We may not be able to maintain our operations and advance our research and development and commercialization of our GTx-104 lead drug candidate without additional funding.
- We have no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Disruptions at the FDA, the SEC and other government agencies caused by the U.S. presidential administration, funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent or delay new products and services from being developed, approved, or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

### ***Risks Related to Development, Testing and Commercialization of Our Products***

- If the FDA does not conclude that our drug candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our drug candidates under Section 505(b)(2) are not as we expect, the approval pathway for our drug candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.
- If a product candidate causes undesirable side effects, then we may be unable to receive regulatory approval or market acceptance for such product candidate.
- Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications often result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.
- If the market opportunities for GTx-104 are smaller than we believe they are, our results of operations may be adversely affected, and our business may suffer.
- We are subject to uncertainty relating to healthcare reform measures and reimbursement policies which, if not favorable to our drug candidates, could hinder or prevent our drug candidates’ commercial success.
- Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.
- Our commercial success depends upon attaining significant market acceptance of our drug candidates and drug products, if approved, among physicians, nurses, pharmacists, patients and the medical community.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may be unable to generate any revenue.

- Even if GTx-104 receives regulatory approval, we will still face regulatory difficulties.
- Even if our drug candidates receive regulatory approval in the United States, we may never obtain regulatory approval or successfully commercialize our products outside of the United States.
- If we are unable to differentiate our drug candidates from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our drug candidates, our ability to successfully commercialize our drug candidates would be adversely affected.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We could incur substantial costs and disruption to our business and delays in the launch of our drug candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.
- We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.
- Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

#### ***Risks Related to Our Intellectual Property***

- If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.
- We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed alleged confidential information or trade secrets of their other clients or former employers to us.
- Our success depends in part upon our ability to protect our intellectual property for our branded products and drug candidates.
- If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

#### ***Risks Related to Our Dependence on Third Parties***

- We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.
- We rely on third parties to manufacture commercial and clinical supplies of our drug candidates, and we intend to rely on third parties to manufacture commercial supplies of any approved drug products. The commercialization of any of our drug products could be stopped, delayed, or made less profitable if those third parties fail to provide us with sufficient quantities of active pharmaceutical ingredients, excipients, or drug products, or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.
- We may not be successful in establishing or maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our drug candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our drug candidates and our financial condition and operating results.

### ***Risks Related to Tax***

- There is a significant risk that we may have been classified as a PFIC for U.S. federal income tax purposes and that such PFIC status may taint our common shares owned by U.S. Holders prior to the Domestication (defined below).
- We may not be able to use our net operating loss carry forwards to offset future taxable income for U.S. federal income tax purposes.
- The IRS may not agree that we should have been treated as a foreign corporation for U.S. federal tax purposes prior to the Domestication.

### ***Risks Related to Ownership of Our Common Stock***

- The price of our common stock may be volatile.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

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## PART I

### Item 1. Business

#### *Overview*

We are focused on developing and commercializing products for rare and orphan diseases that have the potential to improve clinical outcomes by using our novel drug delivery technologies. We seek to apply new proprietary formulations to approved and marketed pharmaceutical compounds to achieve enhanced efficacy, faster onset of action, reduced side effects, more convenient drug delivery and increased patient compliance; all of which could result in improved patient outcomes. The active pharmaceutical ingredients used in the drug candidates under development by us may be already approved in a target indication or could be repurposed for use in new indications.

Our therapeutic pipeline consists of three unique clinical-stage drug candidates supported by an intellectual property portfolio of more than 40 granted and pending patents in various jurisdictions worldwide. These drug candidates aim to improve clinical outcomes in the treatment of rare and orphan diseases by applying proprietary formulation and drug delivery technologies to existing pharmaceutical compounds to achieve improvements over the current standard of care, or to provide treatment for diseases with no currently approved therapies.

The existing well understood efficacy and safety profiles of these marketed compounds provide the opportunity for us to utilize the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act (“FDCA”) for the development of our reformulated versions of these drugs, and therefore may provide a potentially shorter path to regulatory approval. Under Section 505(b)(2), if sufficient support of a product’s safety and efficacy either through previous FDA experience or sufficiently within the existing and accepted scientific literature, can be established, it may eliminate the need to conduct some of the pre-clinical studies and clinical trials that new drug candidates might otherwise require.

We believe rare disorders represent an attractive area for drug development, and there remains an opportunity for us to utilize already approved drugs that have established safety profiles and clinical experience to potentially address significant unmet medical needs. A key advantage of pursuing therapies for rare disorders is the potential to receive orphan drug designation (“ODD”) from the FDA. Our three drug candidates have received ODD status and, provided certain conditions are met at new drug application approval, those candidates, if approved, will be entitled to orphan drug exclusivity (“ODE”), which blocks FDA from approving for seven years any other application for a product that is the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with ODE. ODD status can also result in tax credits of up to 25% of clinical development costs conducted in the United States upon marketing approval and a waiver of the NDA fees, which we estimate can translate into savings of approximately \$4.3 million for our lead drug candidate, GTx-104. Developing drugs for rare diseases can often allow for clinical trials that are more manageably scaled and may require a smaller, more targeted commercial infrastructure.

The specific diseases targeted for drug development by us are well understood, although the patient populations suffering from such diseases may remain poorly served by available therapies or, in some cases, approved therapies do not yet exist. We aim to effectively treat debilitating symptoms that result from these underlying diseases.

Our management team possesses significant experience in drug formulation, drug delivery research and development, clinical and pharmaceutical development, manufacturing, regulatory affairs, business development, as well as late-stage drug development and commercialization. Importantly, our team is comprised of industry professionals with deep expertise and knowledge, including a world-renowned practicing neurosurgeon-scientist and respected authority in aneurysmal subarachnoid hemorrhage, as well as product development, chemistry, manufacturing and controls (“CMC”), planning, implementation, management, and execution of global Phase 2 and Phase 3 trials for GTx-104, and drug commercialization.

## Our Pipeline

- GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for IV infusion in aSAH patients to address significant unmet medical needs. The unique nanoparticle technology of GTx-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion. GTx-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit potentially eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTx-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTx-104 has the potential to better manage hypotension in aSAH patients. GTx-104 has been administered in over 200 patients and healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine.
- GTx-102 is targeted as the first potential therapy for the treatment of ataxia-telangiectasia (“A-T”) in a pediatric population. A-T is caused by mutations in the ataxia telangiectasia mutated gene. Children with A-T experience cerebellar ataxia and other motor dysfunctions, oculomotor apraxia, dysarthria, and dysphagia. A Phase-1 pharmacokinetic study was successfully completed and GTx-102 was well tolerated with no serious events reported.
- GTx-101 is a topical bio adhesive film-forming bupivacaine spray for Postherpetic Neuralgia (“PHN”), which can be persistent and often causes debilitating pain following infection by the shingles virus. Four single-dose Phase 1 studies to evaluate the PK, safety, dose proportionality and tolerability of GTx-101 have been performed. No serious adverse events were reported and GTx-101 was well tolerated. We believe that GTx-101 could be administered to patients with PHN to treat pain associated with the disease.

### **GTx-104**

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for IV infusion in aSAH patients to address significant unmet medical needs. The unique nanoparticle technology of GTx-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion.

#### *About aneurysmal Subarachnoid Hemorrhage (aSAH)*

aSAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is the rupture of an aneurysm in the brain. aSAH is characterized by high mortality (up to 25% early mortality) and significant potential of neurological decline (approximately 40%). The result is a relatively uncommon type of stroke that accounts for about 5% of all strokes and an estimated 42,500 U.S. hospital treated patients per year. Patients are typically hospitalized for two to four weeks following aSAH, with the most severe cases extending to a month or more. Due to the length of hospital stay and disproportionately high mortality and morbidity, aSAH has significant cost of care impact.

In contrast to more common types of ischemic stroke in elderly individuals, aSAH often occurs at a relatively young age, with approximately half the affected patients younger than 60 years old. Approximately 10% to 15% of aSAH patients die before reaching the hospital, and those who survive the initial hours post hemorrhage are admitted or transferred to tertiary care centers with high risk of complications, including rebleeding and systemic manifestations affecting cardiovascular, pulmonary, and renal function.

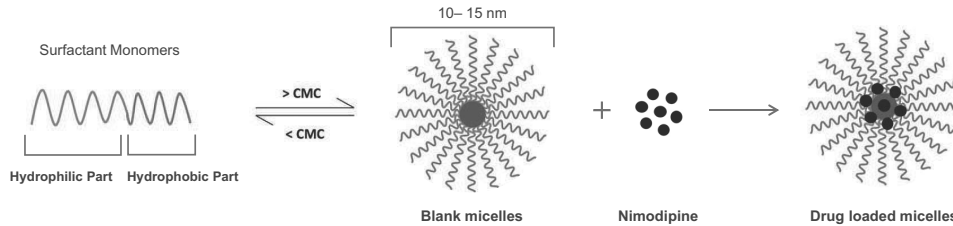
#### *Unmet Needs with Oral Nimodipine*

Nimodipine was granted FDA approval in 1988 and is the only approved drug that has been clinically shown to improve neurological outcomes in aSAH patients. It is only available in the United States as a generic oral capsule and as a branded oral liquid solution called NYMALIZE™, which is manufactured and sold by Arbor Pharmaceuticals (acquired in September 2021 by Azurity Pharmaceuticals). Nimodipine has poor water solubility and high permeability characteristics because of its high lipophilicity. Additionally, orally administered nimodipine has dose-limiting side-effects such as hypotension, poor absorption and low bioavailability resulting from high first-pass metabolism, and a narrow administration window as food effects lower bioavailability significantly. Due to these issues, blood levels of orally administered nimodipine can be highly variable, making it difficult to manage blood pressure in aSAH patients, often leading to frequent dose interruptions. Nimodipine capsules are also difficult to administer, particularly to unconscious patients or those with impaired ability to swallow, while the oral liquid solution has tolerability challenges due to solubility limitations of nimodipine.

## GTx-104 Technology

Our lead drug candidate, GTx-104, is a novel injectable formulation of nimodipine for the treatment of a rare disease, aneurysmal subarachnoid hemorrhage. This formulation offers several potential advantages over oral administration of nimodipine that is the current Standard of Care (SoC) in the United States.

- Novel injectable formulation of nimodipine
- Overcomes solubility limitations of nimodipine
- A patented formulation that uses non-ionic surfactant micelles as the drug carrier to solubilize nimodipine
- Simple to prepare in a pharmacy and stable at room temperature



## Value Proposition

GTx-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit potentially eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTx-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTx-104 has the potential to better manage hypotension in aSAH patients. GTx-104 has been administered in over 200 patients and healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine.

GTx-104 is designed to address significant unmet medical needs for patients with aSAH. We believe that with this novel nimodipine IV formulation may offer a potential value to physicians, hospitals, and their patients.

## GTx-104 Value Proposition

	Risk of Fatal Parenteral Use	Requires Feeding Tube	Excipient Intolerance	Hemodynamic Control	Dose Compliance	Markets
Nimodipine Capsules	Yes	Yes	No	Poor	Poor	U.S. / WW
NYMALIZE (Oral Liquid)	Yes (Reduced)	Yes	Yes	Poor	Poor	U.S. / Select WW
NIMOTOP (Injectable)	No	No	Yes*	Unknown	Rescue Only	EU / China
<b>GTx-104</b>	No	No	No	Optimal	Optimal	Global Rights NDA Submission 1H:25

Sources: Nimodipine capsule packaging insert, Fletcher Spaght market research, Soppi V. (2007).  
 \* High alcohol content (~24% volume/volume) also requires central catheter for administration  
 WW: Worldwide  
 DDI: drug-drug interaction



## GTx-104 Market Opportunity

Approximately 42,500 patients in the United States are affected by aSAH per year. Company sponsored third party market research including claims analysis suggests that incidence may be as high as approximately 70,000. Outside of the United States, annual cases of aSAH are estimated at approximately 60,000 in the European Union, and approximately 150,000 in China.

The unmet needs in the treatment of aSAH and the potential of GTx-104 to address the limitations of the current standard of care were the subject of a Key Opinion Leader event we hosted in November 2024. In an independent market research survey we conducted of hospital administrators and critical and neuro intensive care physicians at institutions with Comprehensive or Advanced Stroke Center certification who are involved in purchasing decisions for their institutions/units, respondents reported 80% likelihood of adopting an IV formulation of nimodipine, assuming 100% bioavailability, better safety, no food effects, effective hypotension management, potential hospital value and patient value.

### Clinical Data

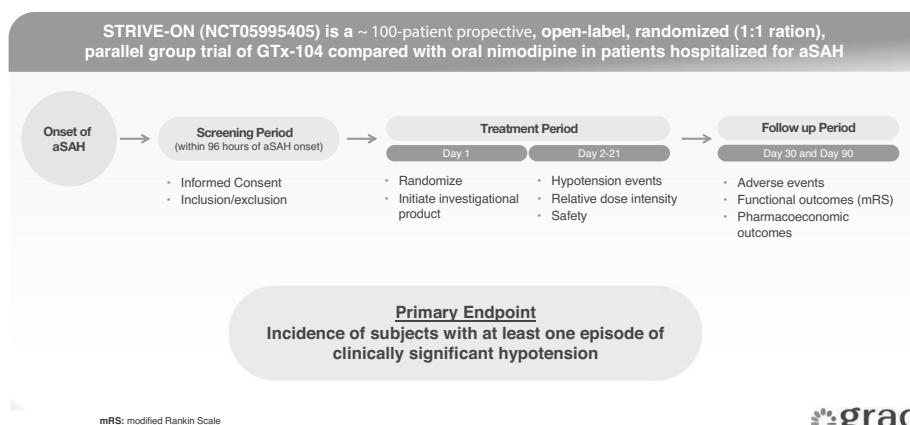
#### Pivotal Phase 3 STRIVE-ON Randomized Safety Trial

The STRIVE-ON trial was a prospective, randomized open-label trial of GTx-104 compared with oral nimodipine in patients hospitalized with aSAH. 50 patients were administered GTx-104 and 52 patients received oral nimodipine. The primary endpoint was the number of patients with at least one episode of clinically significant hypotension reasonably considered to be caused by the drug, and additional endpoints included safety, clinical, and pharmaco-economic outcomes. Each patient was evaluated for up to 90 days inclusive of the 21-day treatment period. There was a higher proportion of the most severe cases of aSAH (Hunt & Hess Grade V) with the worst prognosis in the GTx-104 arm (8%) compared to the oral nimodipine arm (2%).

## GTx-104 STRIVE-ON Phase 3 Pivotal Safety Trial Design



Trial complete and reported topline data in January 2025



On September 25, 2024, we announced the completion of enrollment in our Phase 3 STRIVE-ON trial for GTx-104. On February 10, 2025, we announced the trial met its primary endpoint and provided evidence of clinical benefit for GTx-104 compared to orally administered nimodipine. Patients receiving GTx-104 were observed to have a 19% reduction in at least one incidence of clinically significant hypotension compared to oral nimodipine (28% versus 35%). Other measures also favored or were comparable to GTx-104, including:

- 54% of patients who received GTx-104 had a relative dose intensity of 95% or higher of the prescribed dose compared to only 8% on oral nimodipine.
- 29% relative increase in the number of patients receiving GTx-104 compared to oral nimodipine with favorable outcomes at 90 days follow up on the modified Rankin scale. Quality of life as measured by EQ-5D-3L also favored patients receiving GTx-104 versus oral nimodipine.
- Fewer intensive care unit (ICU) readmissions, ICU days, and ventilator days for patients receiving GTx-104 versus oral nimodipine.
- Adverse events were comparable between the two arms and no new safety issues were identified with patients receiving GTx-104. All deaths in both arms of the trial were due to severity of the patient's underlying disease. There were eight deaths on the GTx-104 arm compared to four deaths on the oral nimodipine arm. The survival status of one patient on the oral nimodipine arm was unknown. No deaths were determined to be related to GTx-104 or oral nimodipine.

Furthermore, pharmacoeconomic measures favored the use of GTx-104 for patients with aSAH.

Pharmacoeconomics



Major patient resource utilization drivers in aSAH favor GTx-104

	GTx-104 (N = 50) n*			Oral Nimodipine (N = 52) n*		
	Day 1	Day 14	% change	Day 1	Day 14	% change
Mechanical Ventilation	14	1	-93%	12	7	-42%
External Ventricular Drain	32	10	-69%	35	17	-51%
Deep Sedation	5	1	-80%	8	5	-38%
Comatose	4	0	-100%	5	2	-60%

\* Excludes patients that died before Day 14 for this analysis.



We believe these data validate the GTx-104 value proposition and we plan to submit an NDA to the FDA in the first half of calendar year 2025. If approved, GTx-104 has the potential to address significant challenges with oral nimodipine administration and may transform the standard of care for patients with aSAH.

GTx-104 Phase 1 PK Trial

In September 2021, we initiated our pivotal pharmacokinetic (“PK”) bridging trial to evaluate the relative bioavailability of GTx-104 compared to currently marketed oral nimodipine capsules in approximately 50 healthy subjects. This PK trial established the 505(b)(2) regulatory pathway for GTx-104.


Final results from this pivotal PK trial were reported in May 2022, and showed that the bioavailability of GTx-104 compared favorably with the oral formulation of nimodipine in all subjects, and no serious adverse events were observed for GTx-104.

All endpoints indicated that statistically there was no difference in exposures between GTx-104 and oral nimodipine over the defined time periods for both maximum exposure and total exposure. Plasma concentrations obtained following IV administration showed significantly less variability between subjects as compared to oral administration of capsules because IV administration is not as sensitive to some of the physiological processes that affect oral administration, such as taking the drug with and without meals, variable gastrointestinal transit time, variable drug uptake from the gastrointestinal tract into the systemic circulation, and variable hepatic blood flow and hepatic first pass metabolism. Previous studies have shown these processes significantly affect the oral bioavailability of nimodipine, and therefore cause oral administration to be prone to larger inter- and intra-subject variability.

The bioavailability of oral nimodipine capsules observed was only approximately 7% compared to 100% for GTx-104. Consequently, about one-twelfth the amount of nimodipine is delivered with GTx-104 to achieve comparable PKs as with the oral capsules. This data is presented in the chart below.

GTx-104-002 Phase 1: Results

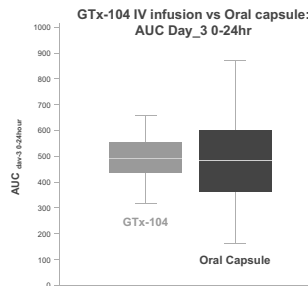
Consistent, predictable plasma concentrations allow for tighter control of hypotension



**GTx-104**

*Consistent and predictable*  
plasma concentrations

Significantly *lower dose*  
variability relative to oral capsule



## GTx-104-002 Phase 1: Results

Established pharmacokinetic bridge with oral nimodipine

PK Parameters	Mean Plasma Nimodipine Concentration			
	GTx-104 (IV)	Nimodipine Capsules	90% Confidence Limits (%)	
	Geometric Mean	Geometric Mean	Lower	Upper
C <sub>max</sub> Day <sub>1</sub> 0-4 hr (ng/mL)	63.1	68.6	81.7	103.6
AUC <sub>Day_3</sub> 0-24hr (ng.h/mL)	491.6	462.6	99.3	114.0
F (%) fraction of drug	100%	7.2%	-	-

### Regulatory

In April 2025, we announced details of a Type C written meeting response with the FDA. The purpose of this meeting was to obtain feedback on the completed Phase 3 STRIVE-ON safety trial of GTx-104 and our planned NDA submission, including clinical, non-clinical, and CMC requirements.

Based on feedback from the FDA, we believe that the data and regulatory packages as currently structured will be sufficient for submission of an NDA. We anticipate filing the NDA for GTx-104 in the second quarter of 2025. Acceptance of the NDA will be subject to the FDA's review of the complete filing.

### GTx-102

GTx-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of A-T for which there are currently no FDA-approved therapies. GTx-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients, can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed.

We have licensed the data from the multicenter, double-blinded, randomized, placebo-controlled crossover trial from Azienda Ospedaliera Universitaria Senese, Siena, Italy, where Dr. Zannolli et. al. studied the effect of oral liquid solution of betamethasone to reduce ataxia symptoms in patients with A-T. This oral liquid solution is not marketed in the United States, and therefore is not available for clinical use. Currently, betamethasone is only available in the United States as an injectable or as a topical cream. This license gives us the right to reference the trial's data in our NDA filing. On November 12, 2015, we submitted the data from the Zannolli trial to the FDA's Division of Neurology at a pre-Investigational New Drug ("IND") meeting and received guidance from the agency on the regulatory requirements to seek approval.

### About Ataxia Telangiectasia

A-T is a rare genetic progressive autosomal recessive neurodegenerative disorder that affects children, with the hallmark symptoms of cerebellar ataxia and other motor dysfunction, and dilated blood vessels (telangiectasia) that occur in the sclera of the eyes. A-T is caused by mutations in the ataxia telangiectasia gene, which is responsible for modulating cellular response to stress, including breaks in the double strands of DNA.

Children with A-T begin to experience balance and coordination problems when they begin to walk (toddler age), and ultimately become wheelchair-bound in their second decade of life. In pre-adolescence (between ages 5 and 8), patients experience oculomotor apraxia, dysarthria, and dysphagia. They also often develop compromised immune systems and are at increased risk of developing respiratory tract infections and cancer (typically lymphomas and leukemia).

### Unmet Needs

There is no known treatment to slow disease progression, and treatments that are used are strictly aimed at controlling the symptoms (or conditions secondary to the disease). There are no FDA-approved therapeutic options currently available. Patients typically die by age 25 from complications of lung disease or cancer.

### Market Opportunity

According to a third-party report we commissioned, A-T affects approximately 4,300 patients per year in the United States and has a potential total addressable market of \$150 million, based on the number of treatable patients in the United States.

## Clinical Data

In a multicenter, double-blind, randomized, placebo-controlled crossover trial conducted in Italy, Dr. Zannolli et al. studied the effect of an oral liquid solution of betamethasone on the reduction of ataxia symptoms in 13 children (between ages 2 to 8 years) with A-T. The primary outcome measure was the reduction in ataxia symptoms as assessed by the International Cooperative Ataxia Rating Scale (“ICARS”).

In the trial, oral liquid betamethasone reduced the ICARS total score by a median of 13 points in the intent-to-treat population and 16 points in the per-protocol population (the median percent decreases of ataxia symptoms of 28% and 31%, respectively). Adverse events in the trial were minimal, with no compulsory withdrawals and only minor side effects that did not require medical intervention. Clinical trial results in A-T patients administered oral betamethasone indicated that betamethasone significantly reduced ICARS total score relative to placebo ( $P = 0.01$ ). The median ICARS change score (change in score with betamethasone minus change in score with placebo) was -13 points (95% confidence interval for the difference in medians was -19 to -5.5 points).

Based on the Zannolli data, we believe that our GTx-102 concentrated oral spray has the potential to provide clinical benefits in decreasing A-T symptoms, including assessments of posture and gait disturbance and kinetic, speech and oculomotor functions. In addition, GTx-102 may ease drug administration for patients experiencing A-T given its application of 1-3x/day of 140 $\mu$ L of concentrated betamethasone liquid sprayed onto the tongue using a more convenient metered dose delivery system, as these A-T patients typically have difficulty swallowing.

## Pharmacokinetic Data

GTx-102 administered as a concentrated oral spray achieves similar blood levels at only 1/70th the volume of an oral solution of betamethasone. This more convenient mode of administration will be important for A-T patients who have difficulties swallowing large volumes of liquids.

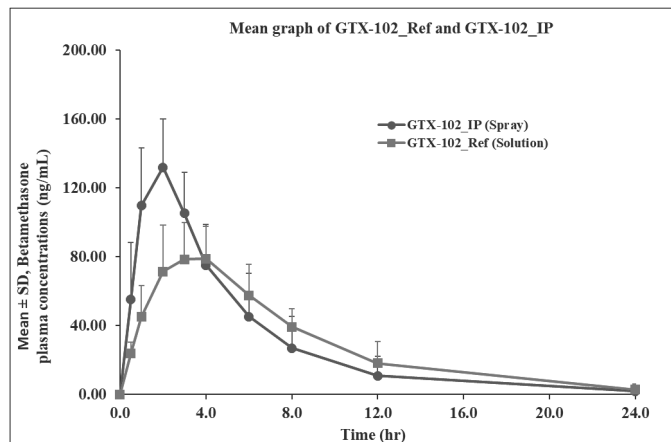
## Nonclinical PK Comparison of GTX-102 Betamethasone Oral Spray vs. Oral Solution Marketed in Europe

Group/Formulation	Group 1, GTX-102_IP	Group 2, GTX-102_Ref
Lot Number	GTX-102-008	GTX-102-009
Pk	0.292 mg/rabbit, Oral	0.25 mg/rabbit, Oral
Parameters/Dose/ROA	Spray	solution
$C_{max}$ (ng/mL)	158.17 $\pm$ 31.30 (20)	82.63 $\pm$ 23.06 (28)
$T_{max}$ (hr) [a]	2.0 (1.0 - 3.0)	3.0 (2.0 - 4.0)
$AUC_{last}$ (ng $\cdot$ hr/mL)	851.16 $\pm$ 314.19 (37)	709.29 $\pm$ 193.51 (27)
$AUC_{inf}$ (ng $\cdot$ hr/mL)	866.02 $\pm$ 336.77 (39)	729.40 $\pm$ 217.86 (30)
Kel (1/hr)	0.19 $\pm$ 0.04 (23)	0.19 $\pm$ 0.06 (29)
$t_{1/2}$ (hr)	3.91 $\pm$ 0.92 (23)	3.93 $\pm$ 1.21 (31)
CL/F (mL/min)	6.19 $\pm$ 1.85 (30)	6.11 $\pm$ 1.67 (27)
$V_d/F$ (L)	2.06 $\pm$ 0.75 (37)	2.00 $\pm$ 0.52 (26)
Relative Bioavailability (% F)	103.70 $\pm$ 23.73 (23)	-

Note: Values are mean  $\pm$  SD (% CV); [a] represents Median (minimum-maximum); ROA=Route of administration; CV=Coefficient of variation

Mean plasma pharmacokinetic parameters of Betamethasone following reference (oral solution) and GTX-102 (oral mucosal spray) administered orally in rabbits show similar characteristics.

Source: GTX-102 nonclinical study report



We initiated a PK bridging trial of GTx-102 as compared to the oral liquid solution of betamethasone used in the Zannolli trial and against the injectable form of betamethasone that is approved in the U.S. in the third calendar quarter of 2022. The primary objectives of the PK bridging trial were to evaluate the bioavailability, pharmacokinetics, and safety of GTx-102. In December 2022, we reported that the topline results of this trial met all primary outcome measures.

## Next Steps

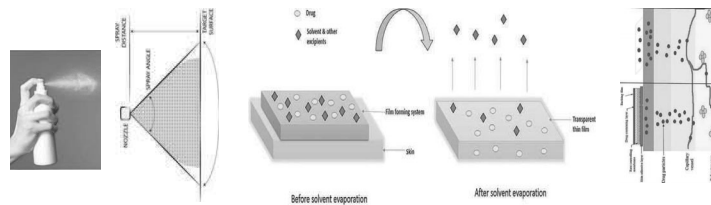
On February 13, 2025, we announced FDA’s written responses to our GTx-102 End of Phase 1 meeting request where FDA made recommendations on the path toward an NDA. They provided guidance on the design of a single pivotal efficacy and safety trial, including the neurological assessment scale for the primary endpoint, that could, with appropriate confirmatory evidence, support an NDA. We plan to collaborate with our scientific advisory board and FDA (via Type C meeting) on the design of a potential pivotal efficacy and safety trial and will determine the next

steps after that time. Further clinical development work will be contingent on additional funding for GTx-102 or the signing of a strategic partnership. It is also possible that we may license or sell our GTx-102 drug candidate.

### **GTx-101**

GTx-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with PHN. GTx-101 is administered via a metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient’s skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches which are used for the treatment of PHN, we believe that the biphasic delivery mechanism of GTx-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial.

### **Mechanism of GTX-101 Bioadhesive Film Formation**



- Metered-dose of bupivacaine spray forms a thin bio-adhesive topical film:
  - **Touch-free, non-greasy** application
  - **Convenient, portable** 30mL plastic bottles
  - **No skin sensitivity** reported in Phase 1 study
- **Non-narcotic**, non-addictive pain management
  - Potentially reduces the need for opioids

### *About Postherpetic Neuralgia (PHN)*

PHN is neuropathic pain due to damage caused by the varicella zoster virus (“VZV”). Infection with VZV causes two distinct clinical conditions. Primary VZV infection causes varicella (i.e., chickenpox), a contagious rash illness that typically occurs among young children. Secondary VZV can reactivate clinically, decades after initial infection, to cause herpes zoster (“HZ”), otherwise known as shingles. Acute HZ arises when dormant virus particles, persisting within an affected sensory ganglion from the earlier, primary infection with VZV become reactivated when cellular immunity to varicella decreases. Viral particles replicate and may spread to the dorsal root, into the dorsal horn of the spinal cord, and through peripheral sensory nerve fibers down to the level of the skin. Viral particles also may circulate in the blood. This reactivation is accompanied by inflammation of the skin, immune response, hemorrhage, and destruction of peripheral and central neurons and their fibers. Following such neural degeneration, distinct types of pathophysiological mechanisms involving both the central and peripheral nervous systems may give rise to the severe nerve pain associated with PHN. While the rash associated with HZ typically heals within two to four weeks, the pain may persist for months or even years, and this PHN manifestation is the most common and debilitating complication of HZ. There is currently no consensus definition for PHN, but it has been suggested by the Centers for Disease Control and Prevention that PHN is best defined as pain lasting at least three months after resolution of the rash.

### *Unmet Need*

PHN is associated with significant loss of function and reduced quality of life, particularly in the elderly. It has a detrimental effect on all aspects of a patient’s quality of life. The nature of PHN pain varies from mild to severe, constant, intermittent, or triggered by trivial stimuli. Approximately half of patients with PHN describe their pain as

“horrible” or “excruciating,” ranging in duration from a few minutes to constant on a daily or almost daily basis. The pain can disrupt sleep, mood, work, and activities of daily living, adversely impacting the quality of life and leading to social withdrawal and depression. PHN is the foremost cause of intractable, debilitating pain in the elderly, and has been cited as the leading cause of suicide in chronic pain patients over the age of 70.

Current treatment of PHN most often consists of oral gabapentin (first line) and prescription lidocaine patches or antidepressants (second line), and refractory cases may be prescribed opioids to address persistent pain. Gabapentin and opioid abuse have continued to proliferate, and lidocaine patches are suboptimal for many reasons. An independent third-party market research firm we commissioned interviewed more than 250 physicians who regularly treat PHN patients and found that approximately 40% of patients using lidocaine patches experience insufficient pain relief. Lidocaine patches are difficult to use, fall off, and look unsightly with possible skin sensitivity and irritation. Additionally, lidocaine patches can only be used for 12 hours and then need to be removed for 12 hours before being reapplied. Prescription lidocaine patches are only approved for PHN, and the market is currently made up of both branded and generic offerings.

### *Market Potential*

It is estimated that PHN affects approximately 120,000 patients per year in the United States. According to a third-party report, the total addressable market for GTx-101 could be as large as \$2.5 billion, consisting of approximately \$200 million for PHN pain and \$2.3 billion for non-PHN pain indications.

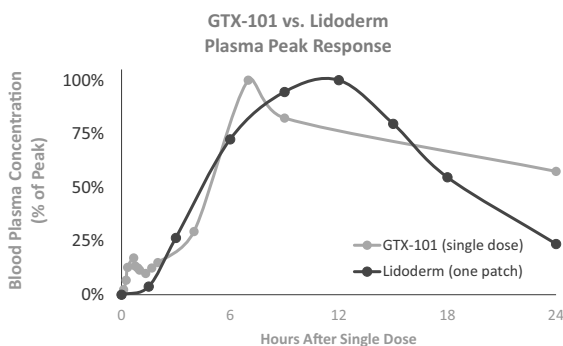
### *Clinical Data*

To date, we have conducted four Phase I trials in healthy volunteers to assess the PK, safety, and tolerability of GTx-101 and to determine the plasma levels of bupivacaine hydrogen chloride administered as a single dose in various concentrations between 30 mg (three sprays) and 2100 mg (twenty sprays).

These trials confirmed that GTx-101 is well absorbed through the skin, as demonstrated in the graph below, while very little is absorbed systemically.

In all four trials, the administration of GTx-101 to healthy volunteers was safe and well tolerated. In addition, no evidence of skin irritation was observed at the application site following the spray administrations. The data below is from two separate trials superimposed on each other – one trial of GTx-101 and one trial of the Lidoderm patch.

#### **Phase 1 Single Dose PK Data in Humans**



**Biphasic drug release profile is expected to provide patients with immediate relief upon first application and continuous relief with consistent use**

### *Regulatory*

The data from the single dose Phase 1 clinical trial for GTx-101 was submitted to the FDA’s Division of Anesthesiology and feedback was received at a pre-IND meeting that informed the design of pre-clinical toxicology studies and a clinical and regulatory pathway to approval under section 505(b)(2). We completed a minipig skin sensitivity study in the second calendar quarter of 2022, and we initiated a single dose PK trial in healthy human volunteers in July 2022. Topline results from this single dose PK trial were reported in December 2022, and the results met all primary outcome measures.

### *Next Steps*

The further development of GTx-101 has been deprioritized in favor of our focus on development of GTx-104. Pending additional funding for GTx-101 or the signing of a strategic partnership, we plan to follow this successful PK trial with the next step of the clinical development plan including a multiple ascending dose trial. Results from these non-clinical studies and clinical trials are required before the initiation of our Phase 2 program in PHN patients. It is also possible that we may license or sell our GTx-101 drug candidate.

### **Commercialization Strategy**

We have worldwide commercialization rights for all our pipeline drug candidates and plan to maximize the value of each of our drug candidates over time. Currently, we have prioritized the development of GTx-104 over that of GTx-102 and GTx-101. If we receive regulatory approval for GTx-104 in the U.S., we plan to commercialize GTx-104 with a highly experienced and targeted hospital-based sales force. We may further seek commercial partnerships to fully exploit the market potential of GTx-104 in territories outside the U.S. It is possible that we out-license or sell GTx-102 and/or GTx-101 for the U.S. and/or global markets.

### ***Manufacturing and Supply***

We currently do not own any manufacturing facilities. The manufacture of our pipeline of drug candidates is highly reliant on complex techniques and personnel aseptic techniques, which present significant challenges and require specialized expertise. Further, these processes undergo a high level of scrutiny by regulatory agencies. Consequently, we utilize a network of third-party CMOs for manufacturing our drug candidates. All CMOs are monitored and evaluated by us to assess compliance with regulatory requirements.

We work with independent consultants to perform periodic quality audits of our manufacturers to review the manufacturing process for our drug candidates and to provide input on quality issues. All lots of the drug substance and drug product used in clinical supply are manufactured under current good manufacturing practices. We plan to continue to rely upon CMOs to manufacture clinical and commercial quantities if a product is approved. We have development agreements in place with these CMOs and we have personnel with pharmaceutical development and manufacturing experience who are responsible for the relationships with our CMOs.

### ***Intellectual Property Portfolio***

We have a multi-layered intellectual property protection strategy, which we believe will create barriers to entry and solidify our position in the market. All of our clinical pipeline drug candidates have received orphan status designation from the FDA, which could result in 7 years of marketing exclusivity in the United States. Orphan status in Europe could result in 10 years of final marketing exclusivity. Such marketing exclusivity is dependent on the candidates receiving final marketing authorizations from the applicable government agencies, and the conditions for receiving such marketing exclusivity. In addition, we protect our drug candidates through a well-defined patent filing strategy. Our patent estate includes more than 40 granted and pending patents in various global jurisdictions, including 8 U.S. issued patents and 4 filed U.S. patent applications. We believe that our intellectual property portfolio, consisting primarily of composition and method-of-use patents, will protect the market value of our products by extending exclusivity beyond what is granted through the orphan designation. We intend to continue to build our patent portfolio by filing for patent protection on new developments with respect to our product candidates. We expect that these patents will, if and when issued, allow us to list our own patents in the Orange Book: Approved Drug Products with Therapeutic Equivalence issued by the FDA, to which potential competitors will be required to certify upon submission of their applications referencing our drug products, if approved.

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets relating to manufacturing know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position. We may also rely on regulatory protections afforded through orphan drug status, data exclusivity, market exclusivity, and patent term extensions, where available.

We are actively seeking U.S. and international patent protection for a variety of technologies and intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel pharmaceutical products. We seek these protections, in part, through confidentiality and proprietary information agreements.

Individual patents extend for varying periods depending on the date of filing or the date of issuance, and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than 5 years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. The actual protection afforded by a patent may vary on a product-by-product basis from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We have several issued U.S. patents and patent applications as well as patents and patent applications in other jurisdictions. Five patents for GTx-104 have been granted in the United States, one patent for GTx-101 has been granted in each of Japan, Europe, Australia, Canada and India. One patent for GTx-101 has been granted in Europe, China, Mexico, Japan and South Africa. One patent for GTx-102 has been granted in each of the United States, Japan, Australia and Canada. One patent for GTx-201 has been granted in each of the United States and Japan.

### ***Government Regulation***

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The FDCA and the FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, sale, advertising and promotion of our product candidates. Although we focus on regulation in the U.S., because that is currently our primary focus, we may seek approval for, and market, our products candidates in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences.

### ***Development and Approval***

Under the FDCA, FDA approval of an NDA is required before any new drug can be marketed in the U.S. NDAs require extensive studies and submission of a large amount of data by the applicant.

*Preclinical Testing.* Before testing any compound in human patients in the U.S., a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice ("GLP") regulations and the U.S. Department of Agriculture's Animal Welfare Act.

*IND Application.* Human clinical trials in the U.S. cannot commence until an IND application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Once human clinical trials have commenced, the FDA may temporarily or permanently stop a clinical trial by placing it on "clinical hold" at any time because of concerns about the safety of the product being tested, or for other reasons.

*Clinical Trials.* Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and current Good Clinical Practice ("cGCP") requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board ("IRB") for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately

monitoring the clinical trial, and timely reporting of adverse events. The FDA enforces good clinical practices through periodic inspections of trial sponsors, clinical investigators, and trial sites. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with cGCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., <https://clinicaltrials.gov>). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap, be combined, or be subdivided in some cases:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse events.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, multi-site, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen. Phase 3 data often form the core basis on which the FDA evaluates a drug's safety and effectiveness when considering the product application.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

*NDA Submission and Review.* The FDCA provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FDCA is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that manufacturing methods and controls are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate including negative or ambiguous results as well as positive findings.

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to obtain FDA approval that permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference drug and submit its own product-specific data — which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the reference drug. We are pursuing the Section 505(b)(2) regulatory approval pathway for GTx-104, with NIMOTOP oral capsules as the reference drug.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. However, such fees can be waived by the FDA for orphan drugs such as GTx-104.

When an NDA is submitted, the FDA makes an initial determination as to whether the application is sufficiently complete to be accepted for review. The FDA may refuse to file an application and/or request additional information before acceptance. A refusal to file, which requires resubmission of the NDA with the requested additional information, delays review of the application. Once accepted for filing, FDA begins an in-depth review of the

application. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency considers such recommendations carefully when making decisions.

The FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are compliant with current Good Manufacturing Practice ("cGMP") requirements and adequate to assure consistent production of the product within required specifications.

Once the FDA accepts an NDA submission which occurs, if at all, within 60 days after submission of the NDA — under the current goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA's standard goal for a review of an NDA is ten months from the filing decision, or six months from the filing decision for a priority application. The FDA does not always meet its PDUFA goal dates, and in certain circumstances, the PDUFA goal date may be extended, by FDA requests for additional information, studies, or clarification. After reviewing an NDA and the facilities where the product is manufactured, the FDA either issues an approval letter or a complete response letter ("CRL") outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor.

Obtaining regulatory approval may take several years, involves the expenditure of substantial resources, and depends on several factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or impose post-approval commitments and requirements, including the completion within a specified time of additional clinical studies or trials, which often are referred to as "Phase 4" or "post-marketing" studies.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

### ***Post-Approval Regulation***

Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution-related restrictions, if there are new safety information developments.

*Good Manufacturing Practices.* Companies engaged in manufacturing drug products, or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product.

Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement action or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

*Advertising and Promotion.* The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for “off-label” uses – that is, uses not approved by the FDA and not described in the product’s labeling – because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers’ communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. In addition to FDA restrictions on the marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the way a company promotes or distributes a drug.

*Other Requirements.* NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

Additionally, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94), which includes bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the “CREATES Act.” The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on “commercially reasonable, market-based terms.”

### ***Hatch-Waxman Act***

The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

*Generic Drugs.* A generic version of an approved drug is approved by means of abbreviated NDA (“ANDA”), by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the reference listed drug (“RLD”). Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product’s safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

*505(b)(2) NDAs.* As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505(b)(2) of the FDCA. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product’s safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which

the applicant has not obtained a right of reference and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

*RLD Patents.* In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” which is referred to as the Orange Book. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A “Paragraph I” certification is the sponsor’s statement that patent information has not been filed for the RLD. A “Paragraph II” certification is the sponsor’s statement that the RLD’s patents have expired. A “Paragraph III” certification is the sponsor’s statement that it will wait for the patent to expire before obtaining approval for its product. A “Paragraph IV” certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

*Regulatory Exclusivities.* The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a “new chemical entity,” or “NCE” — generally meaning that the active moiety has never before been approved in any drug — there is a period of five years from the product’s approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE (i.e., the active moiety has been previously approved) may qualify for a three-year period of exclusivity if the NDA, including a 505(b)(2) application contains new clinical data, (other than bioavailability studies) derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that require submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD or listed drug NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant’s assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

*Patent Term Restoration.* A portion of the patent term lost during product development and FDA review of an NDA, including a 505(b)(2) application, may be restored if approval of the application is the first permitted commercial marketing of a drug product containing an active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office in consultation with the FDA, reviews and approves the application for patent term restoration.

#### ***Other Exclusivities***

*Pediatric Exclusivity.* Section 505A of the FDCA provides for a six-month extension of exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly responds to a written request from the FDA for such

data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's written request, additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever existing statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

*Orphan Drug Exclusivity.* The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which is one that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals, but for which there is no reasonable expectation that the cost of developing the product and making it available in the U.S. for the disease or condition will be recovered from U.S. sales of the product. If a sponsor demonstrates that a drug product qualifies for ODD, the FDA grants ODD to the product for that use. The benefits of ODD include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same drug for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. Clinical superiority can be established by way of greater efficacy, greater safety, or making a major contribution to patient care. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

All our clinical-stage product candidates – GTx-104, GTx-102, and GTx-101 – have an ODD.

### ***U.S. Healthcare Reform***

The Patient Protection and Affordable Care Act, as amended (the "Affordable Care Act"), is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), which was sunset by the Inflation Reduction Act ("IRA") effective January 1, 2025 and replaced with a new manufacturer discount program), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service Act's 340B drug pricing program (340B Program), fraud and abuse, and enforcement. These changes impact existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives.

Certain provisions of the Affordable Care Act have been subject to judicial challenges, as well as efforts to modify them or to alter their interpretation and implementation. For example, in 2017, the U.S. government signed into the Tax Cuts and Jobs Act, which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate."

It is unclear how efforts to modify or invalidate the Affordable Care Act or its implementing regulations, or portions thereof, will affect the Affordable Care Act or our business.

Other legislative changes relating to reimbursement have been adopted in the U.S. since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers. Under current legislation, after a brief pause and reduction to 1% due to COVID-19, sequestration is currently set at 2% through the first 7 months of 2032. As long as these cuts remain in effect, they could adversely impact payment for any products we may commercialize in the future.

Further, the IRA, among other things, established a Medicare Part B and Part D inflation rebate scheme, under which, generally, manufacturers will owe rebates if the average sales price of certain Part B drugs or annual average

manufacturer price of certain covered Part D drugs increases faster than the pace of inflation. The IRA also creates a drug price negotiation program under which the prices for certain Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price, starting in 2026. The IRA further makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and replacement of the coverage gap discount program with a new manufacturer discount program beginning in 2025.

Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the United States with respect to drug pricing practices, and there has been recent interest in incorporating so-called Most Favored Nation pricing into the U.S. healthcare system, under which prices for drugs in the United States could be tied to foreign reference prices through a mechanism that is not yet defined. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products, if approved, or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

### ***Healthcare Privacy Laws***

We may be subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information and/or privacy laws and federal and state consumer protection laws and consumer privacy laws, govern the collection, use, disclosure, and protection of personal information. Such laws and regulations include the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations (collectively, “HIPAA”), Section 5 of the Federal Trade Commission Act (the “FTC Act”), and the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the “CCPA”). Other jurisdictions have enacted or proposed legislation and/or regulations similar to the CCPA, such as consumer privacy laws that went into effect in 2023 in Virginia, Colorado, Utah, and Connecticut. Health-specific consumer privacy laws were also passed in multiple states, including Washington and Nevada. Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general or other regulator to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health data, which may be subject to additional protection.

Outside the United States, our clinical trial programs and other processing activities implicate international data protection laws, including the EU General Data Protection Regulation 2016/679 (the “GDPR”). The GDPR has increased our responsibility and liability in relation to the processing of personal data of individuals located in the EU. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data and samples from clinical trials and adverse event reporting. For example, these obligations and restrictions may require obtaining explicit consent of the individuals to whom the personal data relate, providing transparency notices to individuals, sharing personal data with third parties, transferring personal data out of the EU, reporting personal data breaches with data protection authorities and affected individuals, and ensuring the security and confidentiality of personal data. Violations of EU data protection laws may result in significant financial penalties (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher)). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. EU data protection laws also require us to implement appropriate transfer mechanisms in order to lawfully transfer personal from the EU to countries or organizations outside the EU.

Moreover, as a result of the broad scale release and availability of Artificial Intelligence (“AI”) technologies such as generative AI, there is a global trend towards more regulation (e.g., the EU AI Act and AI laws passed in U.S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.

Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business.

### ***Coverage and Reimbursement***

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One third-party payor’s decision to cover a product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In order to secure coverage and reimbursement for any products, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our products, if approved, may not be considered medically necessary or cost-effective by payors. Further, a payor’s decision to provide coverage for a product does not guarantee that an adequate reimbursement rate will be set, including as commercial payors may establish different rates for different health care providers.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical drug candidates. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit or delay sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

### ***Government Price Reporting***

A manufacturer that participates in the Medicaid Drug Rebate Program is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program, as a condition of having federal funds available for that manufacturer’s drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data the manufacturer reports on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services (“CMS”), the federal agency that administers the Medicare and Medicaid programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug, which best price, in general, represents the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. Where the average manufacturer price of a drug increases faster than the pace of inflation, the drug may be subject to an additional rebate paid by its manufacturer in the amount that the average manufacturer price has exceeded the pace of inflation. In September 2024, CMS further modified the regulations governing the Medicaid Drug Rebate Program, which could increase manufacturer costs and the complexity of compliance, impact rebate liabilities, and be time-consuming to implement.

Federal law requires that each manufacturer that participates in the Medicaid Drug Rebate Program also participate in the 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients, certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and, in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Changes to the Medicaid Drug Rebate amount also could affect a manufacturer's 340B ceiling price calculations and negatively impact results of operations.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that are found to have knowingly and intentionally overcharged covered entities, which became effective on January 1, 2019. It is unclear how the government will apply its enforcement authority under the regulation. Manufacturers also are required to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes them to covered entities. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution ("ADR"), process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed in federal court. HRSA issued a final rule, effective June 2024, that modified aspects of the ADR process, which could impact the procedures that are used to determine whether a manufacturer owes additional 340B discounts. An ADR proceeding could subject a manufacturer to onerous procedural requirements and result in additional liability.

Manufacturers are required to report the average sales price for certain Medicare Part B-covered products under the Medicare program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS may use these submissions to determine payment rates for drugs under Medicare Part B. Since 2023, manufacturers must pay refunds to Medicare for single source drugs or biologics, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of ten percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount. In addition, as noted previously, a manufacturer may be liable for Part B inflation rebates for utilization in quarters starting with the first quarter of 2023. Manufacturers may be liable for civil monetary penalties for violations of this program.

Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for approved products and the resulting Medicare payment rate, and could negatively impact results of operations. For example, the IRA, among other things, requires the Secretary of Health and Human Services to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologics per year with the first negotiated prices taking effect starting in 2026. The IRA established a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty.

These or any other public policy changes could impact the market conditions for our product candidates. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies, and are seeing an increase in state interest in price reporting, transparency, and other policies to address drug pricing concerns.

In order to be eligible to have products paid for with federal funds under the Medicaid and Medicare Part B programs, as applicable, and purchased by certain federal agencies and grantees, a manufacturer is required to participate in the U.S. Department of Veterans Affairs (the "VA") Federal Supply Schedule ("FSS") pricing program. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U.S. Department of Defense (DoD) Public Health Service and U.S. Coast Guard — that is no higher than the statutory Federal Ceiling Price (the "FCP"). The FCP is based on the

non-federal average manufacturer price (“Non-FAMP”), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. A manufacturer would also need to participate in the Tricare Retail Pharmacy program, under which it will pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by the manufacturer, governmental or regulatory agencies, and the courts. Significant civil monetary penalties can be applied a manufacturer is found to have knowingly submitted any false average manufacturer price, best price, or Non-FAMP information to the government or fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for covered outpatient drugs. Civil monetary penalties could also be applied if a manufacturer is found to have charged 340B covered entities more than the statutorily mandated ceiling price. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the False Claims Act.

### ***Healthcare Fraud and Abuse Laws***

In addition to FDA restrictions on marketing of pharmaceutical products, our business is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These laws include, but are not limited to, the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, damages, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing, or recommending pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor. Federal enforcement agencies also have shown increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Arrangements that implicate the Anti-Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case-by-case basis to determine whether, based on the facts and circumstances, they violate the statute.
- The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the U.S. federal government. Actions under the False Claims Act may be brought by private individuals known as qui tam relators in the name of the government, and who may share in any monetary recovery. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the

product and distributing guidance to prescribers and other customers that affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing of the product for unapproved uses.

- HIPAA prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. HIPAA also imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. HIPAA has four tiers of civil monetary penalties and grants state attorneys enforcement authority. The Department of Justice also may impose criminal penalties. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA, and numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including, for example, Section 5 of the Federal Trade Commission Act, as amended, and the California Consumer Privacy Act, govern the collection, use, and disclosure and protection of certain health-related and other personal information.
- Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA, and other privacy and data security and consumer protection laws, and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA, and could also potentially be subject to other civil and/or criminal penalties if we obtain, use or disclose information in a manner not permitted by other privacy and data security and consumer protection laws.
- The majority of states, as well as many of the non-US jurisdiction where we may operate, also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.
- The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics 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 CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members.

Compliance with such laws and regulations requires substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose

sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. 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.

### ***Foreign Corrupt Practices Act***

In addition, the U.S. Foreign Corrupt Practices Act of 1997 prohibits corporations and their intermediaries from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate to obtain or retain business or to otherwise influence a person working in that capacity.

### ***Human Capital Resources***

As of March 31, 2025, we had a total of six full-time employees, all of whom are located in the United States. Our employees have significant prior experience within the pharmaceutical, and biotech industries. We continue to focus on building a high performing organization through our emphasis on accountability for results as measured by our performance development process. To help ensure that employees fully understand the Company's long-term strategy, and how their work contributes to the Company's success, we utilize a variety of channels to facilitate open and direct communication, including: regular calls with all employees, and ongoing update communications as needed.

### ***Corporate Structure***

We were incorporated on February 1, 2002 under Part 1A of the *Companies Act* (Québec) under the name "9113-0310 Québec Inc." On February 14, 2011, the *Business Corporations Act* (Québec) came into effect and replaced the *Companies Act* (Québec). On August 7, 2008, pursuant to a Certificate of Amendment, we changed our name to "Acasti Pharma, Inc." We became a reporting issuer in the Province of Québec on November 17, 2008. On August 27, 2021, Acasti Pharma, Inc. completed its acquisition of Grace Therapeutics Inc., a privately held emerging biopharmaceutical company focused on developing innovative drug delivery technologies for the treatment of rare and orphan diseases via a merger. Following completion of the merger, Grace Therapeutics Inc. became our wholly owned subsidiary and was renamed Acasti Pharma U.S. Inc.

On October 1, 2024, we changed our jurisdiction of incorporation from the Province of Québec in Canada to the Province of British Columbia in Canada ("Acasti British Columbia") pursuant to a "continuance" effected in accordance with Chapter XII of the Business Corporations Act (Québec) (the "Continuance"). On October 7, 2024, we changed our jurisdiction of incorporation from the Province of British Columbia in Canada to the State of Delaware ("Acasti Delaware") in the United States pursuant to a "continuance" effected in accordance with Section 308 of the Business Corporations Act (British Columbia) and a "domestication" (the "Domestication") under Section 388 of the General Corporation Law of the State of Delaware (the "DGCL"). Both the Continuance and the Domestication were approved by our shareholders at our Annual and Special Meeting of Shareholders held on September 30, 2024. Effective on October 28, 2024, we changed our corporate name to "Grace Therapeutics, Inc.". Effective on October 28, 2024, we changed the corporate name of our subsidiary to "Grace Therapeutics U.S., Inc." ("Grace U.S.").

Prior to the Continuance and Domestication, our Class A common shares, without par value per share ("common shares"), were listed on The Nasdaq Stock Market LLC ("Nasdaq") under the symbol "ACST." Upon the effectiveness of the Continuance, each of our outstanding common shares at the time of the Continuance remained issued and outstanding as a common share, without par value per share, of Acasti British Columbia. Upon effectiveness of the Domestication, each outstanding common share of Acasti British Columbia at the time of the Domestication automatically became one outstanding share of common stock, par value \$0.0001 per share, of Acasti Delaware ("common stock").

Information regarding stockholder tax consequences of the Domestication and potential tax elections is available in our Registration Statement on Form S-4 originally filed with the SEC on June 27, 2024, as amended on July 31, 2024.

YOU SHOULD CONSULT YOUR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF U.S. FEDERAL TAX LAWS TO YOUR PARTICULAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. JURISDICTION.

### ***Available Information***

This Annual Report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and any amendments to these reports are filed, or will be filed, as applicable, with the SEC, and the Canadian Securities Administrators (“CSA”). These reports are available free of charge on our website, <https://www.gracetx.com/>, as soon as reasonably practicable after we electronically file such reports with or furnish such reports to the SEC and the CSA. Information contained on, or accessible through, our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this document is an inactive textual reference.

Additionally, our filings with the SEC may be accessed through the SEC’s website at <https://www.sec.gov> and our filings with the CSA may be accessed through the CSA’s System for Electronic Document Analysis and Retrieval at <https://www.sedarplus.ca/>.

## **Item 1A. Risk Factors**

### **Risks Factors Relating to our Business**

#### ***We may not achieve our publicly announced milestones on time, or at all.***

From time to time, we may publicly announce the timing of certain events that we expect to occur, such as the anticipated timing of upcoming new drug application filing. These statements are forward-looking and are based on the best estimate of management at the time relating to the occurrence of the events. However, the actual timing of these events may differ from what has been publicly disclosed. The timing of events such as completion of a clinical trial, discovery of a new product candidate, filing of an application to obtain regulatory approval, beginning of commercialization of products, completion of a strategic partnership, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, problems with a supplier or a distribution partner or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business, financial condition, operating results or the trading price of our common stock.

#### ***We are heavily dependent on the success of our lead drug candidate, GTx-104***

Our business and future success are substantially dependent on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize our lead product candidate, GTx-104. Any delay or setback in the development of GTx-104 could adversely affect our business. Our planned development, approval and commercialization of GTx-104 may fail to be completed in a timely manner or at all. As part of our strategic realignment plan, we determined to focus primarily on the development of GTx-104, which concentrates the level of our drug development risk on one drug candidate. We cannot provide assurance that we will be able to obtain approval for GTx-104 or any other of our drug candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner.

#### ***We may not be able to maximize value from our de-prioritized drug candidates, GTx-102 and GTx-101, through either development, out-licensing or sale.***

Our GTx-102 and GTx-101 drug candidates are at an earlier development stage than GTx-104 and will require additional time and resources to develop. As part of our strategic realignment plan, we determined to focus primarily on the development of GTx-104 and to de-prioritize the development of GTx-102 and GTx-101. While we will continue to seek ways to maximize the value of GTx-102 and GTx-101, including through subsequent development, out-licensing or sale, we may not be successful in doing so.

#### ***We may not be able to maintain our operations and advance our research and development and commercialization of our GTx-104 lead drug candidate without additional funding.***

We have incurred operating losses and negative cash flows from operations since our inception. To date, we have financed our operations through public offerings and private placements of securities, proceeds from exercises of warrants, rights and options, and receipt of research tax credits and research grant programs. Our cash and cash equivalents were \$22.0 million as of March 31, 2025 and \$23.0 million as of March 31, 2024.

Our current assets, as of March 31, 2025, are projected to support our current liabilities as at that date when combined with the projected level of our expenses through at least twelve months from the issuance date of the audited consolidated financial statements included with this Annual Report on Form 10-K, including expenses in connection with the NDA for GTx-104, pre-commercial planning, commercial team buildout, and product launch if GTx-104 is approved. We expect that additional capital will be required by us to support the commercial launch of GTx-104, if approved. To fully execute our business plan, we plan to raise the necessary capital primarily through additional securities offerings and multiple sources of non-dilutive capital, such as grants or loans and strategic alliances. Therefore, if we determine to continue development of GTx-102 and GTx-101, significant additional funding will be needed.

***We have no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Our operations to date have been largely focused on raising capital and developing products for rare and orphan diseases, including undertaking preclinical studies and conducting clinical trials. We have not yet received FDA approval of GTx-104, and as such we have not yet demonstrated our ability to successfully supply GTx-104 for commercial sale or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the principal members of our executive team. While members of our executive team have significant industry experience, they have not been with the Company for long. Any of our executive officers could leave our employment at any time, as all of our employees are “at will” employees. Recruiting and retaining qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and other personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. As we build our organization in accordance with our strategic realignment, we may not be able to attract and retain personnel on terms that are favorable to us given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

***We may need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations and our ability to compete.***

If our drug development efforts are successful, we expect to expand our employee base to increase our managerial, scientific, engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, or give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Our future financial performance and our ability to sell and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

***We face potential product liability, and if claims are brought against us, we may incur substantial liability.***

The use of our product candidates in clinical trials, and the sale of any drug candidates for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants
- costs due to related litigation
- distraction of management’s attention from our primary business
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our product candidates.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able

to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claims or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

***We rely on information technology and any failure, inadequacy, interruption, or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.***

Despite the implementation of security measures, our internal computer systems, and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security incidents could cause interruptions in our operations and could result in a material disruption of our drug product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs, and the development of our product candidates could be delayed, which could adversely affect our financial position, results of operations and business.

***Disruptions at the FDA, the SEC and other government agencies caused by the U.S. presidential administration, funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent or delay new products and services from being developed, approved, or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including government budget and funding levels, a reduction in the FDA's workforce and its ability to hire and retain key personnel and accept the payment of user fees, shifting policy priorities as a result of changes in the U.S. presidential administration and political appointees tasked to oversee the agency, and statutory, regulatory and policy changes. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also increase the time to meet with and receive agency feedback, accept, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Further, the current U.S. presidential administration recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the current U.S. presidential administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. These budgetary pressures may reduce the FDA's ability to perform its responsibilities. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or marketing of our product candidates, which could have a material adverse effect on our business.

***Unfavorable global economic conditions and geopolitical events, including as a result of trade tensions between the U.S. and China, could adversely affect our business, financial condition or results of operations, including conduct of our clinical trials and our manufacturing activities.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other

political events, including as a result of trade tensions between the U.S. and China. Sanctions imposed by the U.S. and other countries in response to conflicts, including in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. We have conducted business outside of the U.S. in the past and may do so in the future. Clinical trials for our product candidates outside of the U.S. and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, higher inflation and interest rates, political disruption or other geopolitical events, including an expansion of the conflict between Russia and Ukraine or instigation of other military conflicts, could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if authorized or approved, and our ability to raise additional capital when needed on acceptable terms, if at all.

A weak or declining economy or political disruption, including any international trade disputes, or changes in laws or policies governing the terms of international trade, and in particular increased trade restrictions, tariffs or taxes on imports from countries where we manufacture products could strain our manufacturers or suppliers, possibly resulting in supply disruption or increased manufacturing and distribution costs. For example, in 2025, the U.S. imposed tariffs on certain imports from Canada, Mexico and China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets.

***We face risks related to the personal data we collect, process, and share.***

Our ability to conduct our business is dependent on the data that we collect, process, and share in discovering, developing, and commercializing drug products. These data are often considered personal data and are therefore regulated by data privacy laws in the United States and abroad.

We have conducted business outside the U.S. in the past and may do so in the future. These activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws, including the EU’s General Data Protection Regulations (the “GDPR”). The GDPR has a wide range of compliance obligations relating to the processing and protection of personal data, including obligations to having a lawful basis for processing personal data (which may in certain situations require explicit consent of data subjects), providing detailed information about the processing activities, dealing with restrictions on sharing of personal data with third parties and the transferring of personal data out of the EU, having contractual arrangements in place where required (such as with clinical trial sites and vendors), reporting in certain instances personal data breaches to data protection authorities and/or affected individuals, appointing data protection officers, conducting data protection impact assessments, responding to privacy rights requests and keeping records of processing activities. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million, whichever is higher). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

In addition to the GDPR, EU Member States have issued their own implementation legislation and other privacy, data protection and ePrivacy legislation. Moreover, other countries are issuing privacy and data protection legislation, generally modeled after the GDPR. These privacy and data protection laws and regulations increase our responsibility and liability in relation to personal data that we process, and compliance has been and is expected to continue to be difficult, constantly evolving, costly and time consuming. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data protection laws, to protect against security incidents, or to alleviate issues caused by such incidents. In addition, if our efforts to comply with applicable privacy and data protection laws and regulations are not successful, it could adversely affect our business. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us, including but not limited to imposition of significant penalties, private litigation (including class actions) and/or adverse publicity that could negatively affect our business.

Several U.S. states have proposed and passed consumer privacy laws. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act, includes certain transparency and other requirements to protect personal data and grants California consumers with certain rights regarding their personal data. In addition,

California consumers have the right to bring a private right of action in connection with data security incidents involving certain elements of personal data. Additionally, other jurisdictions, such as Virginia, Colorado, Utah, and Connecticut, have enacted similar legislation and/or regulations. Health-specific consumer privacy laws were also passed in multiple states, including Washington and Nevada. These laws and regulations are constantly evolving and may impose limitations on our business activities.

At the federal level, the Federal Trade Commission (the “FTC”) sets expectations for taking appropriate steps to safeguard consumers’ personal information and providing a level of privacy or security commensurate to promises made to individuals. The FTC expects a company’s data privacy and security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to help manage risks. Failure to meet these standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. The FTC has brought enforcement actions under both Section 5 of the FTC Act and the Health Breach Notification Rule.

If we fail to comply with applicable federal, state, local, or foreign regulatory requirements, we could be subject to a range of regulatory actions that could affect our ability to commercialize our products. Any threatened or actual government enforcement action could also generate adverse publicity and could result in additional regulatory oversight.

### **Risks Related to Development, Testing and Commercialization of Our Products**

***If the FDA does not conclude that our drug candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our drug candidates under Section 505(b)(2) are not as we expect, the approval pathway for our drug candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.***

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our lead drug candidate GTx-104. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for GTx-104, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our drug candidates would likely substantially increase. Moreover, an inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our drug candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a drug candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such drug candidate.

In addition, it is possible that our competitors may file citizens’ petitions with the FDA in an attempt to persuade the FDA that our drug candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

***Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.***

Clinical testing, even when utilizing the 505(b)(2) pathway, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our drug candidates are in various stages of development. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or

efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of our drug candidates or conduct additional clinical trials or pre-clinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

***Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence drug product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our drug candidates.***

We may experience delays in clinical trials of our drug candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract manufacturing organizations (“CMOs”), or contract research organizations (“CROs”), and clinical trial sites, or failure by such CMOs to complete the manufacturing of clinical trial materials or CROs to follow and carry out the clinical study protocol at each site in accordance with the terms of our agreements with them;
- delays in obtaining required institutional review board (“IRB”), approval at each site;
- difficulties or delays in having patients’ complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- time required to add new clinical sites; or
- delays by our CMOs to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our drug candidates could be materially harmed, which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our drug candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our drug candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment is and completion of the trials are affected by a variety of factors, including:

- severity and prevalence of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the drug candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;

- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing drug candidates or any drug candidates we may seek to develop will ever obtain regulatory approval in the United States or other jurisdictions.

Our drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory 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 comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market our drug candidates, which would harm our business, results of operations and prospects significantly. The development of our product candidates also may be delayed by other events beyond our control. For example, actions to limit federal agency budgets or personnel, may result in reductions to the FDA's budget, employees, and operations, as well as changes to FDA regulatory programs, all of which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates, undergo regulatory inspections or obtain regulatory approval for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our drug candidates will receive regulatory approval. If we do not receive regulatory approvals for our drug candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our drug candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such drug products, if approved.

***If a product candidate causes undesirable side effects, then we may be unable to receive regulatory approval or market acceptance for such product candidate.***

We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent the commercialization of any of our product candidates, including the occurrence of significant adverse events in clinical trials. Such significant adverse events could lead to clinical trial challenges, such as difficulties in patient recruitment, retention, and adherence, potential product liability claims, and possible trial termination by us, regulatory authorities, and/or an IRB or ethics committees. These types of adverse events and clinical trial challenges could delay or prevent regulatory approval of our product candidates. Significant adverse events may also lead regulatory authorities to require additional warnings on the label for such product, require us to conduct additional

costly post-marketing studies or trials, require us to develop a REMS, among other possible requirements. If the product candidate has already been approved, such approval may be withdrawn. Any delay in, denial, or withdrawal of marketing approval for one of our product candidates will adversely affect our financial position. Even if our product candidates receive marketing approval, undesirable side effects may limit the product's commercial viability. Patients may not wish to use our product, physicians may not prescribe our product, and our reputation may suffer. Any of these events may significantly harm our business and financial prospects.

***Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications often result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.***

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our drug candidates, or to prevent third parties from competing with our drug products and drug candidates.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we intend to utilize the 505(b)(2) regulatory pathway for the approval of our drug products and drug candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products.

Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our drug products or drug candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our drug candidates, including the formulation, method of use, any method or process involved in the manufacture of any of our drug candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our drug candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our drug candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, 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 or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our drug candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

***If the market opportunities for GTx-104 are smaller than we believe they are, our results of operations may be adversely affected, and our business may suffer.***

We are focused on developing and commercializing products for rare and orphan diseases that have the potential to improve clinical outcomes by using our novel drug delivery technologies. Our projections of both the number of people who have these conditions, as well as the subset of people with these conditions who have the potential to benefit from treatment with GTx-104, are based on estimates. These estimates may prove to be incorrect and new studies or clinical trials may change the estimated incidence or prevalence of these conditions. The number of patients in the United States and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with GTx-104, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

***We are subject to uncertainty relating to healthcare reform measures and reimbursement policies which, if not favorable to our drug candidates, could hinder or prevent our drug candidates' commercial success.***

Our ability to commercialize our drug candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish appropriate coverage and reimbursement levels for our drug candidates and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. These restrictions and limitations influence the purchase of healthcare services and products. The cost containment measures that healthcare payors and providers are instituting, and the effect of any healthcare reform could significantly reduce our revenues from the sale of any approved drug. We cannot provide any assurances that we will be able to obtain third-party coverage or reimbursement for our drug candidates in whole or in part.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some payors may require pre-approval of coverage for new or innovative devices or drug therapies before they reimburse healthcare providers who use such therapies. Coverage and reimbursement for products can differ significantly from payor to payor, and one payor's decision to cover a product does not ensure that other payors will also provide similar coverage. It is difficult to predict at this time what payors will decide with respect to the coverage and reimbursement for our commercialized products.

Additionally, the process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the price of such product or establishing the reimbursement rate that the payor will pay for the product once coverage is approved. As a result, the determination of coverage and reimbursement is often a time-consuming and costly process that will require the seller to provide scientific and clinical support for the use of the drug candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenues and profitability and the future revenues and profitability of our potential customers. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If our products are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could be harmed.

There also have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare costs to contain or reduce costs of healthcare may adversely affect one or more of the following:

- our ability to set a price that we desire for our drug products, if any are approved
- our ability to generate revenues and achieve profitability;
- the future revenues of our potential customers, suppliers and collaborators; and
- the availability of capital to us.

Any of these scenarios could harm our ability to market our products and generate revenues. It is also possible that other proposals having a similar effect will be adopted.

***Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.***

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact the future results of our operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels with the stated objective to reduce healthcare costs and improve the quality of healthcare. For example, the Patient Protection and

Affordable Care Act (the “ACA”) substantially changed the way healthcare is financed by both governmental and private insurers. The ACA and its implementation continue to evolve as a result of legislative, administrative, and judicial developments. Further changes remain possible, which may potentially negatively affect pricing, coverage, or reimbursement for any products, if approved.

In addition to the ACA, U.S. governments continue to seek to adopt healthcare policies and reforms intended to curb healthcare costs, such as federal or state controls on payment for drugs (including under Medicare, Medicaid, and commercial health plans). For example, the Budget Control Act of 2011 resulted in aggregate reductions, or sequestration, of Medicare payments to providers. Under current legislation, after a brief pause and reduction to 1% due to COVID-19, sequestration is currently set at 2% through the first 7 months of 2032. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, adjusted Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

More recently, the Inflation Reduction Act of 2022 (the “IRA”) requires, among other things, the U.S. Secretary of the Department of Health and Human Services (the “HHS”) to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high spend Medicare Part B and D drugs and biologicals per year, with prices taking effect starting in 2026. Failures to comply with requirements under the drug price negotiation program could subject us to an excise tax and/or a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme, under which manufacturers will owe rebates to Medicare if, generally speaking, the average sales price of a Part B drug increases faster than the pace of inflation. The failure to timely pay an inflation rebate may result in a civil monetary penalty. The IRA and any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our future revenues and results of operations.

Individual states in the United States have also become increasingly aggressive in seeking to pass legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Such measures could harm our business, results of operations, financial condition, and prospects. For example, an emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be “high-cost”. We expect that additional state reform measures will be adopted in the future, any of which could limit the amounts that state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for any approved product, or additional pricing pressures.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. For example, there has been recent interest in incorporating so-called Most Favored Nation pricing into the U.S. healthcare system, under which prices for drugs in the United States could be tied to foreign reference prices through a mechanism that is not yet defined. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

***If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, if we participate in these programs, we could be subject to additional rebate requirements, penalties, or other sanctions, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.***

Under the Medicaid Drug Rebate program, a participating manufacturer is required to pay a rebate to each state Medicaid program for its covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by the state Medicaid program as a condition of having federal funds being made available for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by the manufacturer on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. If we fail to pay the required rebate amount or report pricing data on a timely basis, if we are found to have knowingly submitted any false pricing or product information to the government, if we fail to submit the required pricing data on a timely basis, or if we misclassify or misreport product information, we may be subject to civil monetary penalties. CMS could also

decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Federal law requires that a manufacturer also participate in the 340B Drug Pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to specified "covered entities," including community health centers and other entities that receive certain federal grants, as well as certain hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated based on the information reported under the Medicaid Drug Rebate program. If we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and/or such failure also could be grounds for HRSA to terminate our agreement to participate in the 340B program, in which case our covered outpatient drugs would no longer be eligible for federal payment under the Medicaid or Medicare Part B program.

Federal law also requires that manufacturers report to CMS, on a quarterly basis, average sales price information for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate average sales price based on a statutorily defined formula as well as regulations and guidance. CMS may use the reported information to determine payment rates for drugs under Medicare Part B. If we are found to have made a misrepresentation in the reporting of our average sales price, we may be subject to civil monetary penalties. In addition, if we fail to provide timely information or knowingly provide false information, then we may also be subject to significant civil monetary penalties.

In addition, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. A failure to pay refunds for discarded drugs under the discarded drug refund program could subject us to civil monetary penalties of 125 percent of the refund amount.

Pricing and rebate calculations are complex, vary across products and programs, and are often subject to interpretation by the manufacturer, governmental agencies, and courts. A manufacturer that becomes aware that its Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, is obligated to resubmit corrected data up to three years after those data originally were due. Restatements and recalculations increase the costs for complying with the laws and policies governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. They also may affect the 340B ceiling price and therefore liability under the 340B program.

In order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the Department of Veterans Affairs (the "VA"), Department of Defense ("DoD"), Public Health Service, and Coast Guard (the Big Four agencies), and certain federal grantees, a manufacturer is required to participate in the VA Federal Supply Schedule pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, the manufacturer is obligated to make its covered drugs available for procurement on an FSS contract and charge a price to the Big Four agencies that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FCP is derived from a calculated price point called the "non-federal average manufacturer price" (the "Non FAMP"), which the manufacturer calculates and reports to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non FAMP filing can subject a manufacturer to significant penalties for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, the manufacturer is required to pay quarterly rebates to DoD on utilization of its innovator products that are dispensed through DoD's Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non FAMP and FCP for the calendar year that the product was dispensed.

A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations.

***Our commercial success depends upon attaining significant market acceptance of our drug candidates and drug products, if approved, among physicians, nurses, pharmacists, patients and the medical community.***

Even if we obtain regulatory approval for our drug product candidates, our drug product candidates may not gain market acceptance among physicians, nurses, pharmacists, patients, the medical community or third-party payors, which is critical to commercial success. Market acceptance of our drug candidates and any drug product for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the drug candidate or drug product as well as competitive products;
- the clinical indications for which the drug product is approved;
- the convenience and ease of administration to patients of the drug candidate or drug product;
- the potential and perceived advantages of such drug candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' drug products that include the same active ingredient;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a drug product's FDA-approved labeling; and
- the effectiveness of our sales and marketing efforts.

If our drug candidates or drug products, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients, and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may be unable to generate any revenue.***

Although we intend to establish a small, focused, specialty sales and marketing organization to promote GTx-104, if approved for marketing in the United States, we currently have no such organization and the cost of establishing and maintaining such an organization may exceed the benefit of doing so. We believe that GTx-102 could also be marketed by a small, focused, specialty sales and marketing organization if and when we decide to resume development of GTx-102. Given the size of its potential market, we anticipate that commercializing GTx-101 would require entering into a strategic partnership with a larger marketing partner, if GTx-101 is approved by the FDA for marketing, and the ability to find any such strategic partnership would be uncertain. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

***Even if GTx-104 receives regulatory approval, we will still face regulatory difficulties.***

Even if we obtain regulatory approval for GTx-104, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, patient registry, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of GTx-104 will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If new safety information becomes available after approval of GTx-104, the FDA or comparable foreign regulatory authorities may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on GTx-104's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval trials or post-market surveillance. We will also be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and other regulations. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, GTx-104 or the manufacturing facilities for GTx-104 fail to comply with applicable regulatory requirements, a regulatory authority may, among other things:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit or preclude our ability to commercialize GTx-104 and generate revenue.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted. 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 for GTx-104 that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Advertising and promotion of GTx-104, if approved by the FDA, will be heavily scrutinized by, among others, the FDA, the DOJ, the HHS OIG, state attorneys general, members of Congress and the public. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action, including enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies. In addition, advertising and promotion of GTx-104, if approved outside of the United States, will be heavily scrutinized by comparable foreign regulatory authorities.

In the United States, promoting GTx-104 for unapproved indications can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present

such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. If we do not lawfully promote our approved products, we may become subject to such litigation and/or investigation and, if we are not successful in defending against such actions, those actions could adversely affect our business prospects, financial condition and results of operations.

In the European Union, strict requirements and restrictions regarding advertising and promotion apply, the details of which may vary per European Union Member States. Violation of those rules could subject us to litigation, investigations and/or civil and criminal penalties, which could adversely affect our business, prospects, financial condition and results of operations.

***Even if our drug candidates receive regulatory approval in the United States, we may never obtain regulatory approval or successfully commercialize our products outside of the United States.***

Our business plan is highly dependent upon our ability to obtain regulatory approval to market and commercialize our lead drug candidate, GTx-104 in the United States. As GTx-104 is currently the focus of our drug development program, the failure to commercialize it would have a material adverse effect on our ability to execute on our business plan and generate revenue. In addition, even if we obtain U.S. regulatory approvals to commercialize GTx-104, we may not be able to do so in other international jurisdictions.

***If we obtain approval to commercialize any approved drug products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.***

If any of our drug candidates are approved for commercialization, we may enter into agreements with third parties to market these drug products outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- ability to secure third-party marketing and selling agreements outside of the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

***We are required to obtain regulatory approval for each of our drug candidates in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.***

In order to market drug products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory

requirements can vary widely from country to country and could delay or prevent the introduction of our drug products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our drug products will be harmed.

***If we are unable to differentiate our drug candidates from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our drug candidates, our ability to successfully commercialize our drug candidates would be adversely affected.***

Although we believe that our drug candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our product candidates against other drugs, the opportunity for our product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

In addition to existing branded reference drugs and the related generic products, the FDA or other applicable regulatory authorities may approve generic products that compete directly with our drug candidates, if approved. Once an NDA, including a 505(b)(2) application, is approved, the product covered thereby becomes a “listed drug” which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application (“ANDA”). The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our drug product. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their drug products at lower prices. After the introduction of a generic competitor, a significant percentage of the sales of any branded drug product is typically lost to the generic drug product. Accordingly, competition from generic equivalents of our drug candidates would materially adversely impact our ability to successfully commercialize our drug candidates.

***We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.***

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. If our competitors market products that are more effective, safer or less expensive than our drug products, if any, or that reach the market sooner than our drug products, if any, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or drug products developed by our competitors may render our drug products, if any, or drug candidates obsolete, less competitive or not economical.

***We could incur substantial costs and disruption to our business and delays in the launch of our drug candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.***

We cannot predict whether our competitors or potential competitors, may bring legal actions against us based on our research, development, and commercialization activities, as well as any drug candidates or drug products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our drug candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such drug candidates. Some of our competitors

have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

***We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.***

The research, testing, development, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, marketing, distribution, possession and use of our drug candidates, among other things, are subject to regulation by numerous governmental authorities in the United States and elsewhere. The FDA regulates drugs under the FDCA, and implementing regulations. Non-compliance with any applicable regulatory requirements can result in refusal of the governmental authority to approve products for marketing, criminal prosecution and fines, warning letters, product recalls or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. In addition, the regulatory requirements relating to our drug candidates and drug products, if any, may change from time to time and it is impossible to predict what the impact of any such changes may be.

***Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) the laws of the FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete, and accurate information to such regulatory bodies; (2) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### **Risks Relating to Our Intellectual Property**

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success also depends upon our ability and the ability of our future collaborators to develop, manufacture, market and sell our drug candidates and to use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. Because patent applications

can take many years to issue, there may be currently pending applications, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our drug candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. In particular, the generic drug industry is characterized by frequent litigation between generic drug companies and branded drug companies. If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, including, but not limited to, treble damages, punitive damages, loss of profits and attorneys' fees, which we may have to pay if a court decides that the drug product or proprietary technology at issue infringes on or violates the third-party's rights;
- if a license is available from the third-party, we may have to pay substantial royalties, fees and/or grant cross licenses to our technology; and
- redesigning our drug candidates or processes so they do not infringe, which may not be possible or may require substantial funds and time.

We have not conducted an extensive search of patents issued to third parties, and no assurance can be given that third-party patents containing claims covering our drug candidates, technology or methods do not exist, have not been filed, or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a significant risk that third parties may allege they have patent rights encompassing our products, technology, or methods. Other drug candidates that we may in-license or acquire could be subject to similar risks and uncertainties.

***We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed alleged confidential information or trade secrets of their other clients or former employers to us.***

As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our drug candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Any such litigation would be protracted, expensive, and potentially subject to an unfavorable outcome.

***Our success depends in part upon our ability to protect our intellectual property for our branded products and drug candidates.***

Our commercial success with respect to our drug products and drug candidates, depends on obtaining and maintaining patent protection in the United States and in other countries and trade secret protection for our drug candidates, proprietary technologies and their uses. Our ability to protect our drug products from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

Due to evolving legal standards relating to patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value and the scope of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to file patent applications for these or similar inventions;
- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our or our licensors' pending patent applications will result in issued patents;
- any patents we obtain, or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties for lack of novelty, obviousness, lack of demonstrated or predicted utility, or other technical reasons related to the drafting of the patent itself;
- any patents we obtain, or our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with certain of our employees, consultants, and advisors, third parties may still obtain this information, or we may be unable to protect our rights. Enforcing a claim that a third-party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how, and we would not be able to prevent their use.

***If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.***

We may be a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. Under these agreements, we must rely on our licensor to comply with their obligations under the primary license agreements under which such third-party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, which may impact our ability to continue to develop and commercialize our drug candidates and companion diagnostic incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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. 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.

***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. The following examples are illustrative:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively 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 will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- 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, results of operations and prospects.

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

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

***If our estimates or judgments relating to our critical accounting policies for intangible assets prove to be incorrect, further impairment charges could result.***

We carry a significant amount of intangible assets on our consolidated balance sheet, associated with acquired in process research and development. In the ordinary course of business, circumstances may arise, including manifestation of any of the risks identified in this section, that could result in further recognition that the carrying values of our assets may not be recovered from future operations. Under such circumstances, it is possible we may be required to further impair our asset values to the extent that their remaining value after any such impairment can be recovered by our business going forward. Intangible assets with an indefinite useful life are subject to an impairment review at least annually.

## Risks Related to Our Dependence on Third Parties

***We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates, and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice (“GCP”), which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, guidelines for all of our drug candidates in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current Good Manufacturing Practice (“cGMP”) regulations. While we have agreements governing the activities of our CROs and CMOs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our drug candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our drug candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

***We rely on third parties to manufacture commercial and clinical supplies of our drug candidates, and we intend to rely on third parties to manufacture commercial supplies of any approved drug products. The commercialization of any of our drug products could be stopped, delayed, or made less profitable if those third parties fail to provide us with sufficient quantities of active pharmaceutical ingredients, excipients, or drug products, or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.***

We do not own any manufacturing facilities, and we do not currently, and do not expect in the future, to independently conduct any aspects of our product manufacturing and testing, or other activities related to the clinical development and commercialization of our drug candidates. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our drug candidate development and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and scientific standards such as the requirement for our product candidates and any future commercialized products to be manufactured according to cGMP and any applicable product specifications. Additionally, the facilities used by any contract manufacturer to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our manufacturing in accordance with regulatory requirements or contractual requirements, we may not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval, or may have a material effect on our ability to commercialize our drug candidates, if approved.

Certain changes in the manufacturing process or procedure, including a change in the location where the drug candidate is manufactured or a change of a third-party manufacturer, generally require prior FDA, or foreign regulatory authority, review and/or approval of the manufacturing process and procedures in accordance with current cGMP. We may need to conduct additional pre-clinical studies and clinical trials to support approval of such changes. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate.

More generally, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial commercial production. These problems include difficulties with production costs

and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to commercialize any of our product candidates in the United States would be jeopardized. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's cGMP requirements, and other requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls or other negative actions. Additionally, any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Accordingly, switching manufacturers or adding a new manufacturing site/manufacturer may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

***We may not be successful in establishing or maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our drug candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our drug candidates and our financial condition and operating results.***

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. In situations where we enter into a development and commercial collaboration arrangement for a drug candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such drug candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our drug candidates and/or effectively market and sell future approved drug products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

Even if we are able to establish collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third-party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third-party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our drug candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such drug candidate could be delayed or terminated, and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing the development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex, and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our drug candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

### **Risks Related to Tax**

*There is a significant risk that we may have been classified as a PFIC for U.S. federal income tax purposes and that such PFIC status may taint our common shares owned by U.S. Holders prior to the Domestication.*

Following the Domestication, we are now a U.S. corporation for U.S. federal income tax purposes and thus, we generally cannot be treated as PFIC in future taxable years. However, investors who owned our common shares prior to the Domestication and who are U.S. Holders (as defined below) should be aware that, based on our most recent financial statements and projections and given uncertainty regarding the composition of our income and assets, there is a significant risk that we may have been classified as a “passive foreign investment company” or “PFIC” for the 2024 taxable year and may be classified as a PFIC for our current taxable year during which the Domestication occurred. Any U.S. Holder who held our common shares prior to the Domestication may continue to be treated as holding common stock in a PFIC even subsequent to the Domestication if such U.S. Holder has not made certain elections to mitigate the adverse U.S. federal income tax consequences of holding shares of a PFIC.

The rules governing PFICs can have adverse tax effects on U.S. Holders, which effects may be mitigated by making certain elections for U.S. federal income tax purposes, which elections may or may not be available. If we were a PFIC in any year, a U.S. Holder in such year would be required to file an annual information return with the IRS on IRS Form 8621 to report distributions received on their common shares, any gain realized on disposition of such common shares and any other information required by such form. Additionally, if we were classified as a PFIC in any taxable year with respect to which a U.S. Holder owned common shares, we generally would continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, unless the U.S. Holder makes a “deemed sale election.”

Each investor who owned our common shares prior to the Domestication and who is a U.S. Holder should consult his, her or its own tax advisor regarding the U.S. federal, state and local, and non-U.S. tax consequences of the acquisition, ownership, and disposition of our common stock, the U.S. federal tax consequences of the PFIC rules, and the availability of any election that may be available to the holder to mitigate adverse U.S. federal income tax consequences of holding shares of a PFIC, including on a go-forward basis.

For purposes of this disclosure, a “U.S. Holder” is a beneficial owner of shares of our Common Stock that, for U.S. federal income tax purposes, is (a) an individual who is a citizen or resident of the United States, (b) a company, or other entity classified as a company for U.S. federal income tax purposes, that is created or organized in or under the laws of the United States, any state in the United States or the District of Columbia, (c) an estate if the income of such estate is subject to U.S. federal income tax regardless of the source of such income, or (d) a trust if (i) such trust has validly elected to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust.

***We may not be able to use our net operating loss carry forwards to offset future taxable income for U.S. and Canadian federal income tax purposes.***

At March 31, 2025, Grace Therapeutics U.S., Inc. (“Grace U.S.”) (formerly Acasti Pharma U.S.) and Grace Therapeutics, Inc. had net operating loss carry forwards (“NOLs”) for U.S. federal income tax purposes of approximately \$16.4 million and \$2.2 million, respectively, which have no expiry.

Grace U.S. underwent an “ownership change” within the meaning of Section 382 of the Code as a result of the 2021 merger with Grace Therapeutics, the privately held company, and therefore Grace U.S. and/or the Company may be subject to an annual limit on the amount of NOLs that may be used to offset future taxable income of Grace U.S. and/or the Company for U.S. federal income tax purposes. Such annual limit is generally equal to the product of (i) the total value of the loss company’s (in this case, Grace U.S.) outstanding equity immediately prior to an “ownership change” (subject to certain adjustments); and (ii) the applicable federal long-term tax-exempt interest rate for the month that includes the “ownership change.”

At March 31, 2025, we had NOLs for Canadian federal income tax purposes of approximately \$143 million, which expire at various dates through 2043. The extent to which we can utilize any or all of our NOLs will depend on many factors, including the jurisdiction applicable to any of our future taxable revenue. In connection with our shift of our operations to the United States, we may not be able to justify the allocation of revenue to Canada sufficient to recover the tax benefits arising from NOLs and other tax credits.

Our ability to use NOLs will also depend on the amount of taxable income generated in future periods. The NOLs may expire before we can generate sufficient taxable income to use the NOLs.

***The IRS may not agree that we should be treated as a foreign corporation for U.S. federal tax purposes prior to the Domestication.***

Although prior to the Domestication, we were incorporated in Quebec, Canada, the IRS may assert that since August 27, 2021, we should have been treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the U.S. Internal Revenue Code of 1986, as amended (the “Code”). For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because prior to the Domestication we were an entity incorporated in Canada, we generally have been classified as a foreign corporation (and, therefore, not a U.S. tax resident) for U.S. federal tax purposes at all times prior to the Domestication). However, Section 7874 of the Code provides an exception under which a foreign corporation may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes.

Under Section 7874, if (1) in the 2021 merger with Grace Therapeutics, former Grace Therapeutics stockholders owned (within the meaning of Section 7874) 80% or more (by vote or value) of our ordinary shares after the merger by reason of holding Grace Therapeutics common stock (such ownership percentage, the “Section 7874 ownership percentage”), and (2) our “expanded affiliated group” did not have “substantial business activities” in Canada (“the substantial business activities test”), we would have been treated as a U.S. corporation for U.S. federal tax purposes following the 2021 merger with Grace Therapeutics. If the Section 7874 ownership percentage of the former Grace Therapeutics stockholders after the merger was less than 80% but greater than or equal to 60%, and the substantial business activities test was not met, we and our U.S. affiliates may have been in some circumstances, subject to certain adverse U.S. federal income tax provisions (which, among other things, could have limited their ability to utilize certain U.S. tax attributes such as NOLs to offset U.S. taxable income or gain resulting from certain transactions). Following the 2021 merger and prior to the Domestication, the application of these rules could have resulted in significant additional U.S. tax liability and limited our ability to restructure or access cash earned by certain of our non-U.S. subsidiaries, in each case, without incurring substantial U.S. tax liabilities.

Based on the terms of the merger, the rules for determining share ownership under Section 7874 and certain factual assumptions, we believe that former Grace Therapeutics stockholders owned (within the meaning of Section 7874) less than 60% (by both vote and value) of our ordinary shares after the merger by reason of holding shares of Grace Therapeutics common stock. Therefore, we believe that we should not have been treated as a U.S. corporation for U.S. federal tax purposes prior to the Domestication and that Section 7874 should otherwise not have applied to us or our affiliates as a result of the 2021 merger with Grace Therapeutics.

## **Risks Relating to Our Common Stock**

### ***We do not expect to pay any cash dividends for the foreseeable future.***

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

### ***The price of our common stock may be volatile.***

Market prices for securities of pharmaceutical companies can fluctuate significantly. Factors such as the announcement to the public or in various scientific or industry forums of technological innovations; new commercial products; patents or exclusive rights obtained by us or others; disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; the commencement, enrollment or announcement of results of clinical trials we conduct, or changes in the development status of our drug candidates; results or delays of pre-clinical and clinical studies by us or others; any delay in our regulatory filings for our drug candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings; a change of regulations; additions or departures of key scientific or management personnel; overall performance of the equity markets; general political and economic conditions; publications; failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; research reports or positive or negative recommendations or withdrawal of research coverage by securities analysts; actual or anticipated variations in quarterly operating results; announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; public concerns over the risks of pharmaceutical products; unanticipated serious safety concerns related to the use of our drug candidates or drug products; our access to financial resources, future sales of securities by us or our stockholders; and many other factors, many of which are beyond our control, could have considerable effects on the price of our common stock. The price of our common stock has fluctuated significantly in the past and there can be no assurance that the market price of our common stock will not experience significant fluctuations in the future.

In addition, securities of pharmaceutical companies often experience extreme price and volume fluctuations that are unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against pharmaceutical companies following periods of volatility in the market price of their securities. This type of litigation, if instituted against us, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

### ***Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or drug candidates.***

We will need to raise additional capital in the future in order to fully execute on our business plan. We may seek additional capital through a combination of public and private equity offerings, debt financing, and non-dilutive strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness by us would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms unfavorable to us.

### ***We may pursue opportunities or transactions that adversely affect our business and financial condition and the public announcement of any of these or similar strategic opportunities or transactions might have a significant effect on the price of our common stock***

Our management, in the ordinary course of our business, regularly explores potential strategic opportunities and transactions. These opportunities and transactions may include strategic joint venture relationships, significant debt or equity investments in us by third parties, the acquisition or disposition of material assets, the licensing, acquisition

or disposition of material intellectual property, the development of new drug candidates, the sale of our common stock and other similar opportunities and transactions. The public announcement of any of these or similar strategic opportunities or transactions might have a significant effect on the price of our common stock. Our policy is to not publicly disclose the pursuit of a potential strategic opportunity or transaction unless we are required to do so by applicable law, including applicable securities laws relating to periodic disclosure obligations. There can be no assurance that investors who buy or sell common stock are doing so at a time when we are not pursuing a particular strategic opportunity or transaction that, when announced, would have a significant effect on the price of our common stock.

In addition, any such future corporate development may be accompanied by certain risks, including exposure to unknown liabilities of the strategic opportunities and transactions, higher than anticipated transaction costs and expenses, the difficulty and expense of integrating operations and personnel of any acquired companies, disruption of our ongoing business, diversion of management's time and attention, and possible dilution to stockholders. We may not be able to successfully overcome these risks and other problems associated with any future acquisitions and this may adversely affect our business and financial condition.

#### **Item 1B. Unresolved Staff Comments**

Not applicable.

#### **Item 1C. Cybersecurity**

We are increasingly dependent on third-party provided software applications and computing infrastructure to conduct key operations. We depend on both our own procured systems, networks, and technology as well as the systems, networks and technology of our contractors, consultants, vendors and other business partners.

Given the importance of cybersecurity to our business, we maintain a cybersecurity program that is based on a set of cybersecurity policies and processes to support our controls and our preparedness for treatment of identified information security risks. We also undergo periodic evaluations of our cybersecurity program through cybersecurity assessment and cybersecurity incident response tabletop exercises, conducted by our cybersecurity advisors. As a result of such assessments and exercises, a number of processes have been established or are being improved upon to support the protection of our data and systems.

#### **Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats**

In the event of a cybersecurity incident, we maintain a Cybersecurity Incident Response Plan. Pursuant to the plan and its escalation protocols, designated personnel are responsible for assessing the severity of an incident and associated threat, containing the threat, remediating the threat, including recovery of data and access to systems, analyzing any reporting obligations associated with the incident, and performing post-incident analysis and program enhancements. We have a relationship with various law firms to assist with advisory on legal aspects of containing incidents and communicating accordingly.

#### **Governance**

##### *Management Oversight*

The existing controls and processes employed to assess, identify and manage material risks from cybersecurity threats are implemented and overseen by our information technology ("IT") consultant. Our IT consultant leverages its over 35 years of experience. Our IT consultant is responsible for the day-to-day management of the cybersecurity program, including the prevention, detection, investigation, response to, and recovery from cybersecurity incidents. Our IT consultant reports on its activities to senior management who then assess and manage risks of cybersecurity threats.

##### *Board Oversight*

While our Board of Directors (the "Board") has overall responsibility for risk oversight, the Audit Committee of the Board (the "Audit Committee") oversees cybersecurity risk matters. The Audit Committee is responsible for reviewing, monitoring, reporting and, where appropriate, providing recommendations to the Board regarding compliance with our internal policies and its progress in remedying any material deficiencies, including those related

to our security policies, including the physical safeguarding of corporate assets and security of our networks and information systems. The Audit Committee receives periodic updates regarding the cybersecurity program, including top threats and risks, and updates on the cybersecurity roadmap.

#### *Cybersecurity Risks*

We maintain a Risk Management Policy that governs the process in which we identify cybersecurity risks, evaluate their associated impacts and risk levels, and document them accordingly in the Cybersecurity Risk Register.

For additional information, see “Item 1A — Risk Factors.” In the last reporting year, we did not experience any material cybersecurity incidents or threats.

#### **Item 2. Properties**

Our head office and operations are located at 103 Carnegie Center Suite 300 Princeton, New Jersey, 08540.

#### **Item 3. Legal Proceedings**

In the ordinary course of business, we are at times subject to various legal proceedings and disputes. We assess our liabilities and contingencies in connection with outstanding legal proceedings utilizing the latest information available. Where it is probable that we will incur a loss and the amount of the loss can be reasonably estimated, we record a liability in our consolidated financial statements. These legal contingencies may be adjusted to reflect any relevant developments on a quarterly basis. Where a loss is not probable or the amount of loss is not estimable, we do not accrue legal contingencies. While the outcome of legal proceedings is inherently uncertain, based on information currently available and available insurance coverage, our management believes that it has established appropriate legal reserves. However, it is possible that the ultimate resolution of these matters, if unfavorable, may be material to our financial position, results of operations, or cash flows. We are not currently a party to any legal proceedings that, in the opinion of management, are likely to have a material adverse effect on our business.

#### **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 Market Information**

Shares of our common stock are traded on the Nasdaq Capital Market under the symbol “GRCE.”

#### ***Holder***

As of June 18, 2025, there were 32 holders of record of our common stock. The actual number of our stockholders is greater than this number of record holders because most of our stockholders are beneficial owners whose shares are held in street name by brokers and other nominees.

#### ***Dividends***

We do not anticipate paying any cash dividend on our common stock in the foreseeable future. We presently intend to retain any future earnings to finance the expansion and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors the board of directors deems relevant. In addition, the terms of any future debt or credit facility may preclude us from paying dividends.

#### ***Recent Sales of Unregistered Securities***

None.

#### ***Issuer Repurchases of Equity Securities***

None.

### **Item 6. Reserved**

## **Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operation**

The following discussion should be read in conjunction with our consolidated financial statements and notes thereto found elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. You should review our Special Note Regarding Forward-Looking Statements presented at the beginning of this Annual Report on Form 10-K. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Item 1A, “Risk Factors” of this Annual Report on Form 10-K. We caution readers not to place undue reliance on these forward-looking statements, which reflect management’s analysis only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update forward-looking statements which reflect events or circumstances occurring after the date of this Annual Report on Form 10-K, unless required by applicable securities laws.

### ***Overview***

This management’s discussion and analysis (“MD&A”) is presented in order to provide the reader with an overview of the financial results and changes to our financial position as at March 31, 2025 and for the year then ended. This MD&A explains the material variations in our operations, financial position and cash flows for the years ended March 31, 2025 and 2024.

Market data, and certain industry data and forecasts included in this MD&A were obtained from internal surveys and market research conducted by third parties hired by us, publicly available information, reports of governmental agencies and industry publications, and independent third-party surveys. We have relied upon industry publications as our primary sources for third-party industry data and forecasts. Industry surveys, publications and forecasts generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of that information are not guaranteed. We have not independently verified any of the data from third-party sources or the underlying economic assumptions they have made. Similarly, internal surveys, industry forecasts and market research, which we believe to be reliable based upon management or contracted third parties’ knowledge of our industry, have not been independently verified. Our estimates involve risks and uncertainties, including assumptions that may prove not to be accurate, and these estimates and certain industry data are subject to change based on various factors, including those discussed in this Annual Report on Form 10-K.

This MD&A should be read in conjunction with our consolidated financial statements for the years ended March 31, 2025 and 2024 included elsewhere in this Annual Report on Form 10-K.

Our annual financial statements, which include the accounts of our wholly owned subsidiary, have been prepared in accordance with U.S. GAAP and the rules and regulations of the SEC related to reports filed in Form 10-K. All intercompany transactions and balances are eliminated on consolidation.

All amounts appearing in the MD&A for the period-by-period discussions are in thousands of U.S. dollars, except share and per share amounts or unless otherwise indicated.

Our assets as of March 31, 2025 include cash and cash equivalents of \$22,133 and intangible assets and goodwill of \$49,266. Our current liabilities were \$1,930 as of March 31, 2025 and were comprised primarily of amounts due to or accrued for creditors.

In February 2025, we completed a private placement of Company securities with certain institutional and accredited investors. Net proceeds to the Company were \$13,705. Refer to Note 8, 2025 Private Placement, in the accompanying consolidated financial statements elsewhere in this document for additional information. We believe our existing cash and cash equivalents will be sufficient to sustain planned operations through at least 12 months from the issuance date of these consolidated financial statements included with this Annual Report on Form 10-K.

## Results of Operations

### Comparison of the years ended March 31, 2025, and 2024

The following table summarizes our results of operations for the years ended March 31, 2025 and 2024:

	Year ended		
	March 31, 2025	March 31, 2024	Increase (Decrease)
	\$	\$	\$
	(in thousands)		
<b>Operating expenses</b>			
Research and development expenses, net of government assistance . . . . .	9,511	4,683	4,828
General and administrative expenses . . . . .	7,168	6,684	484
Restructuring costs . . . . .	—	1,485	(1,485)
<b>Loss from operating activities . . . . .</b>	<b>(16,679)</b>	<b>(12,852)</b>	<b>3,827</b>
Change in fair value of derivative warrant liabilities . . . . .	3,218	(2,728)	5,946
Interest and other income, net . . . . .	711	911	(200)
Foreign exchange loss . . . . .	(17)	(16)	(1)
Income tax benefit . . . . .	3,199	1,832	1,367
<b>Net loss . . . . .</b>	<b>(9,568)</b>	<b>(12,853)</b>	<b>(3,285)</b>

### *Net Loss*

The net loss of \$9,568 or \$0.79 loss per share for the year ended March 31, 2025, decreased by \$3,285 from the net loss of \$12,853 or \$1.35 loss per share for the year ended March 31, 2024. The decrease in net loss was primarily due to a \$5,946 difference in change in fair value of derivative warrant liabilities, a \$1,485 decrease in restructuring costs, and a \$1,367 increase in income tax benefits, partially offset by a \$4,828 increase in research and development expenses, net of government assistance, a \$484 increase in general and administrative expenses and a \$200 decrease in interest and other income, net.

### *Research and development expenses*

Research and development expenses consist primarily of:

- fees paid to external service providers such as contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”) related to clinical trials, including contractual obligations for clinical development, clinical sites, manufacturing and scale-up, and formulation of clinical drug supplies;
- fees paid to contract service providers related to drug discovery efforts including chemistry and biology services; and
- salaries and related expenses for research and development personnel, including expenses related to stock options.

We record research and development expenses as incurred.

Our research and development during the year ended March 31, 2025 was focused primarily on our clinical development program for our GTx-104 drug candidate. Research and development expenses during the year ended March 31, 2024, were focused primarily on our clinical development programs GTx-104, GTx-102, and GTx-101 drug candidates.

The following table summarizes our research and development expenses:

### Research and development expenses

	Year ended		
	March 31, 2025	March 31, 2024	Increase (Decrease)
	\$	\$	\$
	(in thousands)		
Total third-party research and development expenses <sup>1</sup> . . . . .	8,486	3,576	4,910
Government grants & tax credits . . . . .	—	55	(55)
Salaries and benefits . . . . .	<u>809</u>	<u>844</u>	<u>(35)</u>
Research and development expense before stock-based compensation and depreciation . . . . .	9,295	4,475	4,820
Stock-based compensation . . . . .	216	198	18
Depreciation and loss on disposal of equipment . . . . .	<u>—</u>	<u>10</u>	<u>(10)</u>
<b>Total</b> . . . . .	<u><u>9,511</u></u>	<u><u>4,683</u></u>	<u><u>4,828</u></u>

<sup>1</sup> Total third-party research and development expenses are calculated before salaries and benefits, depreciation, write-off of equipment and stock-based compensation.

Total research and development expenses for the year ended March 31, 2025 were \$9,511, compared to \$4,683 for the year ended March 31, 2024. This increase of \$4,828 was primarily due to the increase in research activities for the GTx-104 pivotal Phase 3 safety clinical trial.

There were no government grants and tax credits for the year ended March 31, 2025, compared to \$55 for the year ended March 31, 2024. The changes within government grants and tax credits in the prior year were due to adjustments of provisions regarding realizability of credit receivables after assessments and correspondences from tax authorities.

Stock-based compensation of \$216 for the year ended March 31, 2025, increased by \$18 compared to \$198 for the year ended March 31, 2024. The increase was primarily due to the issuance of new stock option awards during the year ended March 31, 2025.

### General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, and support functions, including professional fees for auditing, tax, legal, consulting, rent and utilities and insurance.

### General and administrative expenses

	Year ended		
	March 31, 2025	March 31, 2024	Increase (Decrease)
	\$	\$	\$
	(in thousands)		
Professional fees . . . . .	3,455	3,208	247
Salaries and benefits . . . . .	2,031	1,184	847
Other . . . . .	<u>1,161</u>	<u>1,537</u>	<u>(376)</u>
General and administrative expense before stock-based compensation and depreciation <sup>1</sup> . . . . .	6,647	5,929	718
Stock-based compensation . . . . .	514	715	(201)
Depreciation and loss on disposal . . . . .	<u>7</u>	<u>40</u>	<u>(33)</u>
<b>Total</b> . . . . .	<u><u>7,168</u></u>	<u><u>6,684</u></u>	<u><u>484</u></u>

<sup>1</sup> General and administrative sub-total expenses are calculated before stock-based compensation and depreciation.

General and administrative expenses were \$7,168 for the year ended March 31, 2025, an increase of \$484 from \$6,684 for the year ended March 31, 2024. The increase was primarily a result of increased legal, tax, accounting and

other professional fees primarily related to the Continuance and Domestication, increased salaries and benefits due to merit increases and hiring of a new employee, offset in part by a decrease in other expenses due primarily to adjustments for Canadian goods and services tax and a decrease in miscellaneous expenses as a result of restructuring in the prior year period. Stock-based compensation of \$514 for the year ended March 31, 2025, decreased by \$201 compared to \$715 for the year ended March 31, 2024. The decrease was primarily due to fewer stock option awards granted during the year ended March 31, 2025.

### ***Restructuring Costs***

On May 8, 2023, we announced our decision to terminate a substantial amount of our workforce as part of a plan intended to align our organizational and management cost structure to prioritize resources to GTx-104, thereby reducing losses to improve cash flow and extend available cash resources. We incurred \$1,485 of related costs primarily consisting of employee severance costs. There were no restructuring costs for the year ended March 31, 2025.

### ***Change in fair value of derivative warrant liabilities***

The decrease in the fair value of derivative warrant liabilities for the year ended March 31, 2025 of \$5,946 was mainly attributable to the decrease in our stock price.

### ***Interest income***

Interest and other income, net was \$711 for the year ended March 31, 2025, compared to \$911 for the year ended March 31, 2024. The \$200 decrease in our interest and other income was due to withdrawals of short-term investments upon their maturity used to fund operations, and a decrease in interest rates.

### ***Income tax benefit***

Income tax benefit was \$3,199 for the year ended March 31, 2025, an increase of \$1,367 compared to \$1,832 for the year ended March 31, 2024, due to net losses recognized by our subsidiary, Grace Therapeutics U.S., Inc., which are deemed to be recoverable to us and can be taken as a benefit over time.

### ***Liquidity and Capital Resources***

#### ***Cash flows and financial condition for the years ended March 31, 2025 and March 31, 2024***

##### ***Summary***

As of March 31, 2025, cash and cash equivalents were \$22,133, a net decrease of \$872 compared to cash and cash equivalents of \$23,005 at March 31, 2024.

In February 2025, we completed a private placement of our securities with certain institutional and accredited investors. Net proceeds to us were \$13,705. Refer to Note 8, 2025 Private Placement in the accompanying consolidated financial statements elsewhere in this document for additional information. We believe our existing cash and cash equivalents will be sufficient to sustain planned operations through at least 12 months from the issuance date of the consolidated financial statements included with this Annual Report on Form 10-K.

We will require additional capital to fund our daily operating needs beyond that time. We do not expect to generate revenue from product sales unless and until we successfully complete drug development and obtain regulatory approval, which is subject to significant uncertainty. To date, we have financed our operations primarily through public offerings and private placements of our common equity, warrants and convertible debt and the proceeds from research tax credits. Until such time that we can generate significant revenue from drug product sales, if ever, we will require additional financing, which is expected to be sourced from a combination of public or private equity or debt financing or other non-dilutive sources, including fees, milestone payments and royalties from collaborations with third parties. Arrangements with collaborators or others may require us to relinquish certain rights related to our technologies or drug product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategy. We plan to raise additional capital in order to maintain adequate liquidity. Negative results from studies or trials, if any, or depressed prices of our Common Stock could impact our ability to raise additional financing. Raising additional equity capital is subject to market conditions that are not within our control.

### *Net cash used in operating activities*

Net cash used in operating activities for the year ended March 31, 2025 was \$14,904, compared to \$12,333 for the year ended March 31, 2024, an increase of \$2,571. The increase in net cash used in operating activities was primarily due to a \$4,828 increase in research and development activities for our GTx-104 pivotal Phase 3 STRIVE-ON trial, a \$484 increase in general and administrative expenses for legal, tax, accounting and other professional fees primarily related to the Continuance and Domestication, changes in prepaid expenses of \$485, offset in part by a \$1,485 decrease in restructuring costs, change in receivables of \$516 and change in trade and other payables of \$1,568.

### *Net cash provided by investing activities*

Net cash used in investing activities for the year ended March 31, 2025, was from our purchase of short-term investments of \$15 and maturity of short-term investments of \$15. Net cash used in investing activities for the year ended March 31, 2024, was from the purchase of short-term investments of \$6,554, proceeds from the sale of equipment of \$111, offset by proceeds from short-term investments of \$6,569 and proceeds from the sale of equipment of \$22.

### *Net cash provided by financing activities*

Net cash provided by financing activities for the year ended March 31, 2025, was attributable to the \$13,705 net proceeds received from the 2025 private placement. Net cash provided by financing activities of \$7,359 for the year ended March 31, 2024, was primarily attributable to the \$7,338 net proceeds received from the 2023 private placement.

### **2025 Private Placement**

In February 2025, we agreed to offer and sell in a private placement (the “2025 Private Placement”) an aggregate of 3,252,132 shares of Common Stock, at a purchase price of \$3.395 per share of Common Stock (the “Shares”), and pre-funded warrants to purchase up to 1,166,160 shares of Common Stock, at a purchase price equal to the purchase price per Share less \$0.0001 (the “2025 Pre-Funded Warrants”). Each 2025 Pre-Funded Warrant is exercisable for one share of Common Stock at an exercise price of \$0.0001 per share, is exercisable immediately and will expire once exercised in full. For each Share and 2025 Pre-Funded Warrant issued, we agreed to issue to each purchaser an accompanying common warrant to purchase shares of Common Stock (or 2025 Pre-Funded Warrants in lieu thereof), exercisable for an aggregate of 4,418,292 shares of Common Stock (or 2025 Pre-Funded Warrants in lieu thereof) (the “2025 Common Warrants”). Each 2025 Common Warrant is exercisable for one share of Common Stock at an exercise price of \$3.395 per share, is immediately exercisable and will expire on the earlier of (i) the 60th day after the date the FDA approves the NDA for GTx-104 and (ii) September 25, 2028. The 2025 Private Placement closed on February 11, 2025. The net proceeds to us from the 2025 Private Placement were \$13,705, after deducting fees and expenses.

### **2023 Private Placement**

In September 2023, we entered into a securities purchase agreement (the “Purchase Agreement”) with certain institutional and accredited investors in connection with a private placement offering of our securities (the “2023 Private Placement”). Pursuant to the Purchase Agreement, we sold 1,951,371 Common Shares, at a purchase price of \$1.848 per Common Share and pre-funded warrants (the “2023 Pre-Funded Warrants”) to purchase up to 2,106,853 Common Shares at a purchase price equal to the purchase price per Common Share less \$0.0001. Each 2023 Pre-Funded Warrant is exercisable for one Common Share at an exercise price of \$0.0001 per Common Share, is immediately exercisable, and will expire once exercised in full. Pursuant to the Purchase Agreement, we also issued to such institutional and accredited investors common warrants (the “Common Warrants”, and together with the 2023 Pre-Funded Warrants, the “Warrants”) to purchase Common Shares, exercisable for an aggregate of 2,536,391 Common Shares. Under the terms of the Purchase Agreement, for each Common Share and each 2023 Pre-Funded Warrant issued in the 2023 Private Placement, an accompanying five-eighths (0.625) of a Common Warrant was issued to the purchaser thereof. Each whole Common Warrant is exercisable for one Common Share at an exercise price of \$3.003 per Common Share, is immediately exercisable, and will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of an NDA for our product candidate GTx-104 and (ii) five years from the date of issuance. The 2023 Private Placement closed on September 25, 2023. The net proceeds to us from the 2023 Private Placement were \$7,338, after deducting fees and expenses.

### ***Contractual Obligations and Commitments***

Our contractual obligations and commitments primarily include trade payables, CMO and CRO agreements.

#### ***Research and development contracts and contract research organizations agreements***

We utilize CMOs, for the development and production of clinical materials and CROs to perform services related to our clinical trials. Pursuant to the agreements with CMOs and CROs, we have either the right to terminate the agreements without penalties or under certain penalty conditions. As of March 31, 2025, we had \$300 of commitments to CMOs and \$100 of commitments to CROs for the next twelve months.

### ***Contingencies***

We evaluate contingencies on an ongoing basis and establish loss provisions for matters in which losses are probable, and the amount of the loss can be reasonably estimated.

### ***Use of Estimates and Measurement of Uncertainty***

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, income, and expenses. Actual results may differ from these estimates.

Estimates are based on management's best knowledge of current events and actions that management may undertake in the future. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Estimates and assumptions include the measurement of stock-based compensation, derivative warrant liabilities, accruals for research and development contracts and contract organization agreements, and valuation of intangibles and goodwill. Estimates and assumptions are also involved in determining which research and development expenses qualify for research and development tax credits and in what amounts. We recognize the tax credits once we have reasonable assurance that they will be realized.

While our significant accounting policies are described in the notes to our financial statements, we believe that the following critical accounting policies are most important for understanding and evaluating our reported financial results, as these policies relate to the more significant areas involving management's judgments and estimates.

### ***Critical Accounting Policies***

#### ***Research and development costs***

Research and developments expenditures are expensed as incurred. These costs consist of employees' salaries and benefits related to research and development activities, contractors and consultants that conduct the Company's clinical trials, laboratory material and small equipment, clinical trial materials, stock-based compensation expense, and other non-clinical costs and regulatory fees. The Company accrues research and development expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment and completion of patient studies, invoices received and contracted costs. Advance payments for goods and services that will be used in future research and development are recognized in prepaids or other assets and are expensed when the services are performed, or the goods are used.

#### ***Valuation of Intangible Assets and Goodwill***

In a business combination, the fair value of in-process research and development ("IPR&D") assets acquired is capitalized and accounted for as indefinite-lived intangible assets, and not amortized until the underlying project receives regulatory approval, at which point the intangible assets will be accounted for as definite-lived intangible assets or discontinued. If discontinued, the intangible assets will be written off. R&D costs incurred after the acquisition are expensed as incurred.

Our IPR&D and goodwill was \$49,300 as of March 31, 2025, which represents 68% of total assets. Goodwill and indefinite lived assets are not amortized but are subject to an impairment review annually and more frequently when indicators of impairment exist. An impairment of goodwill could occur if the carrying amount of a reporting unit exceeds the fair value of that reporting unit. An impairment of indefinite-lived intangible assets would occur if the fair value of the intangible asset is less than the carrying value.

The nature of the assumptions in the intangible assets' impairment tests are considered critical due to a high level of subjectivity and judgment necessary to account for highly uncertain matters, and the impact of the assumptions on our financial condition and our operating performance could be material.

We test goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that fair value of the reporting unit is less than its carrying amount, a quantitative impairment test is performed. We test indefinite lived intangible assets for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. Events that could result in an impairment, or trigger an interim impairment assessment, include the decision to discontinue the development of a drug, the receipt of additional clinical or nonclinical data regarding our drug candidates or a potentially competitive drug candidates, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug candidates and increases in our weighted average cost of capital.

Individual IPR&D projects and goodwill are tested for impairment on an annual basis in the fourth quarter, and in between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of each technology or our reporting unit below its carrying value. No impairment of the identified intangible assets was recognized for the years ended March 31, 2025 and 2024.

## ***Financial Instruments***

### *Credit Risk*

Financial instruments that potentially subject us to a concentration of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are all invested in accordance with our investment policy with the primary objective being the preservation of capital and the maintenance of liquidity, which risk is managed by dealing only with highly rated U.S. and Canadian institutions. We maintain our cash and cash equivalents at accredited financial institutions in amounts that exceed federally insured limits. We do not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

### *Interest Rate Risk*

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market rates. Our exposure to interest rate risk as of March 31, 2025 was as follows:

Cash and cash equivalents

Short-term fixed interest rate

Our capacity to reinvest the short-term amounts with equivalent return will be impacted by variations in short-term fixed interest rates available on the market. Management believes the risk we will realize a loss as a result of the decline in the fair value of our short-term investments is limited because these investments have short-term maturities and are held to maturity.

Our contractual obligations related to financial instruments and other obligations and liquidity resources are presented in the liquidity and capital resources of this MD&A.

We expect to incur significant expenses and continued operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, particularly as we advance clinical development for our drug candidates in our pipeline; continue to engage contract manufacturing organizations to manufacture our clinical study materials and to ultimately develop large-scale manufacturing capabilities in preparation for commercial launch; seek regulatory approval for our drug candidates; and add personnel to support our drug product development and future drug product launch and commercialization.

We expect to have sufficient cash resources to satisfy our objectives into the third calendar quarter of 2026, which is 13 months from the issuance date of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We require additional capital to fund our daily operating needs beyond that time. We plan to raise additional capital prior to that time in order to maintain adequate liquidity. Negative results from studies, if any, and depressed prices of our common stock could impact our ability to raise additional financing. Raising additional equity capital is subject to market conditions not within our control. If we do not raise additional funds in this time period, we may not be able to realize our assets and discharge our liabilities in the normal course of business.

### ***Recent Accounting Pronouncements***

In November 2023, the FASB issued ASU 2023-07, “Improvements to Reportable Segment Disclosures” (“ASU 2023-07”). The ASU includes enhanced disclosure requirements, primarily related to significant segment expenses that are regularly provided to and used by the chief operating decision maker (“CODM”). The amendments are to be applied retrospectively to all prior periods presented in the financial statements. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Our adoption of the requirements of ASU 2023-07 at March 31, 2025 did not result in a material impact on our consolidated financial statements and disclosures.

We have considered recent accounting pronouncements and concluded that they are either not applicable to our business or that the effect is not expected to be material to our consolidated financial statements as a result of future adoption.

### **Item 7A. Quantitative and Qualitative Disclosure About Market Risk**

As a smaller reporting company, we are not required to provide this information.

### **Item 8. Financial Statements and Supplementary Data**

See our consolidated financial statements 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. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

As of the end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our chief executive officer (“CEO”) and principal financial officer (“PFO”), has performed an evaluation of the effectiveness of our disclosure controls and procedures within the meaning of Rules 13a-15 (e) and 15d-15(e) of the Exchange Act. Based upon this evaluation, our management has concluded that, as of March 31, 2025, our existing disclosure controls and procedures were effective. It should be noted that while the CEO and PFO believe that our disclosure controls and procedures provide a reasonable level of assurance that they are effective, they do not expect the disclosure controls and procedures to be capable of preventing all errors and fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

***Management’s Report on Internal Controls over Financial Reporting***

Our management, with the participation of our CEO and PFO, is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation and fair presentation of our consolidated financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management conducted an assessment of the design and operation effectiveness of our internal control over financial reporting as of March 31, 2025. In making this assessment, we used the criteria established within the Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based on this assessment, our management has concluded that, as of March 31, 2025, our internal control over financial reporting was effective.

***Changes in Internal Control over Financial Reporting***

No changes were made to our internal controls over financial reporting that occurred during the fiscal quarter ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

We are a non-accelerated filer under the Exchange Act and not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, this Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding our management’s assessment of internal control over financial reporting.

**Item 9B. Other Information**

(b) During the fiscal quarter ended March 31, 2025, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

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

None.

## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance**

#### ***Code of Conduct and Ethics***

The Board has adopted a written Code of Business Conduct and Ethics for Directors, Officers and Employees (the “Code of Conduct”) within the meaning of Item 406(b) of Regulation S-K. This Code of Conduct applies to our directors, officers and employees. A current copy of the Code of Conduct is posted on the Governance Documents section of the Investors page of our website, which is located at [www.gracctx.com](http://www.gracctx.com). We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any substantive amendment to, or waiver from, a provision of the Code of Conduct by posting such information on the website address and location specified above.

The additional information required by this Item will be set forth under the sections entitled “Information Regarding the Board of Directors and Corporate Governance” and “Executive Officers” in our 2025 Proxy Statement to be filed with the SEC within 120 days of March 31, 2025 and is incorporated by reference into this Annual Report on Form 10-K.

### **Item 11. Executive Compensation.**

The information required by this Item will be set forth under the sections entitled “Executive Compensation” and “Director Compensation” in our 2025 Proxy Statement to be filed with the SEC within 120 days of March 31, 2025 and is incorporated by reference into this Annual Report on Form 10-K.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters Equity Compensation Plan Information**

The information required by this Item will be set forth under the sections entitled “Securities Authorized for Issuance under Equity Compensation Plans” and “Security Ownership of Certain Beneficial Owners and Management” in our 2025 Proxy Statement to be filed with the SEC within 120 days of March 31, 2025 and is incorporated by reference into this Annual Report on Form 10-K.

### **Item 13. Certain Relationships and Related Transactions and Director Independence.**

The information required by this Item will be set forth under the sections entitled “Transactions with Related Persons and Indemnification” and “Information Regarding the Board of Directors and Corporate Governance” in our 2025 Proxy Statement to be filed with the SEC within 120 days of March 31, 2025 and is incorporated by reference into this Annual Report on Form 10-K.

### **Item 14. Principal Accountant Fees and Services.**

The information required by this Item will be set forth under the section entitled “Proposal No. 3 - Ratification of Appointment of Independent Registered Public Accounting Firm” in our 2025 Proxy Statement to be filed with the SEC within 120 days of March 31, 2025 and is incorporated by reference into this Annual Report on Form 10-K.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements — The consolidated financial statements included in Item 8 are filed as part of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules — All schedules have been omitted because they are not applicable or required, or the information required to be set forth therein is included in the consolidated financial statements or notes thereto included in Item 8 of this Annual Report on Form 10-K.

(a)(3) Exhibits — The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits — The exhibits listed on the Exhibit Index below are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

### EXHIBITS INDEX

<u>Exhibit No.</u>	<u>Description</u>
2.1	Agreement and Plan of Merger dated as of May 7, 2021 among Acasti Pharma Inc., Acasti Pharma U.S., Inc. and Grace Therapeutics Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on May 7, 2021)
3.1	Certificate of Incorporation of Grace Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the SEC on October 7, 2024)
3.2	Certificate of Amendment to the Certificate of Incorporation of Grace Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on October 28, 2024)
3.3	Bylaws of Grace Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on October 28, 2024)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 7, 2024)
4.2*	Description of Securities
4.3	Form of Common Warrant, dated September 25, 2023 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 26, 2023)
4.4	Form of Pre-Funded Warrant, dated September 25, 2023 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on September 26, 2023)
4.5	Form of Pre-Funded Warrant, dated February 11, 2025 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on February 10, 2025)
4.6	Form of Warrant to Purchase Common Warrants or Pre-Funded Warrants (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on February 10, 2025)
10.1+	Acasti Pharma Inc. Stock Option Plan, as amended August 4, 2022 (incorporated by reference to Schedule A to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on August 31, 2022)
10.2+	Form of Stock Option Agreement for Employees under the Acasti Pharma Inc. Stock Option Plan (incorporated by reference to Exhibit 10.1 to the Company Quarterly Report on Form 10-Q filed with the SEC on August 11, 2023)
10.3+	Form of Stock Option Agreement for Non-Employee Directors under the Acasti Pharma Inc. Stock Option Plan (incorporated by reference to Exhibit 10.2 to the Company Quarterly Report on Form 10-Q filed with the SEC on August 11, 2023)
10.4+	Acasti Pharma Inc. Equity Incentive Plan, as amended August 4, 2022 (incorporated by reference from Schedule B to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on August 31, 2022)
10.5+	Grace Therapeutics, Inc. 2024 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's the Quarterly Report on Form 10-Q filed with the SEC on February 13, 2025)
10.6+	Form of 2024 Incentive Stock Option Award Agreement under the Grace Therapeutics, Inc. 2024 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on February 13, 2025)

Exhibit No.	Description
10.7+	Form of 2024 Non-Qualified Stock Option Award Agreement under the Grace Therapeutics, Inc. 2024 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on February 13, 2025)
10.8+	Offer Letter by and between Robert J. DelAversano and the Company, dated November 21, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report Form 8-K filed with the SEC on January 8, 2024)
10.9+	Letter Agreement by and between Prashant Kohli and the Company, dated August 12, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 16, 2024)
10.10*+	Employment Agreement by and between Amresh Kumar and the Company, dated May 8, 2023
10.11*+	Employment Agreement by and between Carrie D'Andrea and the Company, dated July 1, 2023
10.12*+	Form of Indemnification Agreement between Grace Therapeutics, Inc. and its directors and officers
10.13	Settlement Agreement, dated October 18, 2023, by and between the Company and Aker BioMarine Antarctic AS (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 23, 2023)
10.14	Form of Securities Purchase Agreement, dated September 24, 2023, by and between Acasti Pharma Inc. and each of the Purchasers signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 26, 2023)
10.15	Form of Placement Agent Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 10, 2025)
10.16	Form of Non-Placement Agent Securities Purchase Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 10, 2025)
10.17	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on February 10, 2025)
10.18*+	Employment Agreement by and between R. Loch Macdonald and the Company, dated May 7, 2024
16.1	Letter from Ernst & Young LLP (Canada), dated December 15, 2023 (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2023)
19.1*	Grace Therapeutics, Inc. Insider Trading Policy
21.1*	List of Subsidiaries
23.1*	Consent of KPMG LLP, an Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1*	Certification of the Chief 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 the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1*	Grace Therapeutics, Inc. Incentive Compensation Recoupment Policy
101.INS*	Inline XBRL Instance 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 (formatted as Inline XBRL and contained in Exhibit 101)

\* Filed or furnished herewith.

+ Management contract, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: June 23, 2025

### GRACE THERAPEUTICS, INC.

By: /s/ Prashant Kohli  
Name: Prashant Kohli  
Title: Chief Executive Officer and  
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Prashant Kohli</u> Prashant Kohli	Chief Executive Officer (Principal Executive Officer)	June 23, 2025
<u>/s/ Robert DelAversano</u> Robert DelAversano	Principal Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 23, 2025
<u>/s/ Brian Davis</u> Brian Davis	Director	June 23, 2025
<u>/s/ Vimal Kavuru</u> Vimal Kavuru	Director	June 23, 2025
<u>/s/ Edward Neugeboren</u> Edward Neugeboren	Director	June 23, 2025
<u>/s/ George Kottayil</u> George Kottayil	Director	June 23, 2025

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**GRACE THERAPEUTICS, INC.**  
**(Formerly ACASTI PHARMA INC.)**

Consolidated Financial Statements

For the years ended March 31, 2025 and 2024

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors  
Grace Therapeutics, Inc.:

### *Opinion on the Consolidated Financial Statements*

*We have audited the accompanying consolidated balance sheets of Grace Therapeutics, Inc. and subsidiary (the Company) as of March 31, 2025 and 2024, the related consolidated statements of loss and comprehensive loss, stockholders' equity, 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 March 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.*

### *Basis for Opinion*

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

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

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

### *Critical Audit Matter*

*The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.*

### *Going concern analysis*

*As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses and negative cash flows from operations in each period since its inception. As of March 31, 2025, the Company had an accumulated deficit of \$220.7 million. To date, the Company has financed its operations primarily through public offerings and private placements of its common equity, warrants and convertible debt and the proceeds from research tax credits. The Company believes its existing cash and cash equivalents will be sufficient to sustain planned operations through at least one year from the issuance of the consolidated financial statements. Until such time that the Company can generate significant revenue from drug product sales, if ever, it will require additional financing, which is expected to be sourced from a combination of public or private equity or debt financing or other non-dilutive sources, which may include fees, milestone payments and royalties from collaborations with third parties. Arrangements with collaborators or others may require the Company to relinquish certain rights related to its*

*technologies or drug candidates. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategy. The Company plans to raise additional capital in order to maintain adequate liquidity.*

*We identified the assessment of liquidity and the Company's ability to continue as a going concern as a critical audit matter. A high degree of subjective auditor judgment was required to evaluate the Company's forecasted cash flows used in its liquidity analysis due to uncertainty in certain assumptions used to estimate the cash flows. Specifically, auditor judgment was required to evaluate management's estimated expenses associated with its plans to develop, obtain regulatory approval for, and commercialize a certain drug candidate.*

*The following are the primary procedures we performed to address this critical audit matter: We evaluated management's assessment and assessed the reasonableness of certain assumptions underlying management's conclusion. We compared the Company's historical forecasted cash flows to actual results to assess the Company's ability to accurately forecast. We evaluated management's estimated expenses associated with its plans to develop, obtain regulatory approval for, and commercialize a certain drug candidate by (1) conducting interviews with management to gain an understanding of the Company's strategy, research and development, commercialization, and selling and marketing activities required to execute their plan, (2) evaluating the consistency of information used in management's analysis with management's plans for expense and working capital management activities presented to the Board of Directors and other public information disseminated by the Company, and (3) comparing the information used in management's analysis with evidence obtained in other areas of the audit to evaluate whether it supported or contradicted the conclusions reached by management. We performed sensitivity analyses on forecasted expenses by evaluating the impact of changes in forecasted expenses on the Company's going concern assessment.*

/s/ KPMG LLP

We have served as the Company's auditor since 2023.

Philadelphia, Pennsylvania

June 23, 2025

**GRACE THERAPEUTICS, INC.**  
(Formerly ACASTI PHARMA INC.)  
Consolidated Balance Sheets

<i>(Expressed in thousands except share data)</i>	<b>March 31, 2025</b>	<b>March 31, 2024</b>
	<b>\$</b>	<b>\$</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents . . . . .	22,133	23,005
Receivables . . . . .	126	722
Prepaid expenses . . . . .	<u>453</u>	<u>283</u>
Total current assets . . . . .	22,712	24,010
Equipment, net . . . . .	15	24
Intangible assets . . . . .	41,128	41,128
Goodwill . . . . .	<u>8,138</u>	<u>8,138</u>
Total assets . . . . .	<u><u>71,993</u></u>	<u><u>73,300</u></u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Trade and other payables . . . . .	<u>1,930</u>	<u>1,684</u>
Total current liabilities . . . . .	1,930	1,684
Derivative warrant liabilities . . . . .	1,141	4,359
Deferred tax liability . . . . .	<u>2,312</u>	<u>5,514</u>
Total liabilities . . . . .	<u>5,383</u>	<u>11,557</u>
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value per share; 10,000,000 authorized, none issued and outstanding as of March 31, 2025 and 2024 . . . . .	—	—
Common stock, \$0.0001 par value per share; 100,000,000 authorized; 13,718,106 and 9,399,404 shares issued and outstanding as of March 31, 2025 and 2024, respectively . . . . .	1	1
Additional paid-in capital . . . . .	293,334	278,899
Accumulated other comprehensive loss . . . . .	(6,038)	(6,038)
Accumulated deficit . . . . .	<u>(220,687)</u>	<u>(211,119)</u>
Total stockholders' equity . . . . .	<u>66,610</u>	<u>61,743</u>
Total liabilities and stockholders' equity . . . . .	<u><u>71,993</u></u>	<u><u>73,300</u></u>

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

**GRACE THERAPEUTICS, INC.**  
(Formerly ACASTI PHARMA INC.)  
Consolidated Statements of Loss and Comprehensive Loss

	Year Ended March 31, 2025 \$	Year Ended March 31, 2024 \$
<i>(Expressed in thousands, except share and per share data)</i>		
<b>Operating expenses</b>		
Research and development expenses, net of government assistance . . . . .	(9,511)	(4,683)
General and administrative expenses . . . . .	(7,168)	(6,684)
Restructuring cost . . . . .	—	(1,485)
<b>Loss from operating activities</b> . . . . .	(16,679)	(12,852)
Foreign exchange (loss) gain . . . . .	(17)	(16)
Change in fair value of derivative warrant liabilities . . . . .	3,218	(2,728)
Interest and other income, net . . . . .	711	911
Total other income, net . . . . .	3,912	(1,833)
Loss before income tax benefit . . . . .	(12,767)	(14,685)
Income tax benefit . . . . .	3,199	1,832
<b>Net loss and total comprehensive loss</b> . . . . .	(9,568)	(12,853)
Basic and diluted loss per share . . . . .	(0.79)	(1.35)
<b>Weighted-average number of shares outstanding</b> . . . . .	12,087,270	9,529,123

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

**GRACE THERAPEUTICS, INC.**  
(Formerly ACASTI PHARMA INC.)  
Consolidated Statements of Stockholders' Equity

<i>(Expressed in thousands except share data)</i>	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Number	Amount				
		\$	\$	\$	\$	\$
<b>Balance, March 31, 2024</b> .....	9,399,404	1	278,899	(6,038)	(211,119)	61,743
Issuance of common stock upon cashless exercise of pre-funded warrants .....	740,457	—	—	—	—	—
Net loss .....	—	—	—	—	(9,568)	(9,568)
Stock-based compensation .....	—	—	730	—	—	730
Issuance of common stock and warrants through private placement, net of offering costs .....	3,252,132	—	13,705	—	—	13,705
Issuance of common stock in exercise of pre-funded warrants .....	<u>326,113</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
<b>Balance at March 31, 2025</b> .....	<u>13,718,106</u>	<u>1</u>	<u>293,334</u>	<u>(6,038)</u>	<u>(220,687)</u>	<u>66,610</u>

<i>(Expressed in thousands except share data)</i>	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Number	Amount				
		\$	\$	\$	\$	\$
<b>Balance, March 31, 2023</b> .....	7,435,533	1	272,259	(6,038)	(198,266)	67,955
Net loss .....	—	—	—	—	(12,853)	(12,853)
Stock-based compensation .....	—	—	913	—	—	913
Issuance of common stock and pre-funded warrants through private placement, net of offering costs .....	1,951,371	—	5,707	—	—	5,707
Issuance of common stock upon the exercise of stock options .....	<u>12,500</u>	<u>—</u>	<u>21</u>	<u>—</u>	<u>—</u>	<u>21</u>
<b>Balance at March 31, 2024</b> .....	<u>9,399,404</u>	<u>1</u>	<u>278,899</u>	<u>(6,038)</u>	<u>(211,119)</u>	<u>61,743</u>

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

**GRACE THERAPEUTICS, INC.**  
(Formerly ACASTI PHARMA INC.)  
Consolidated Statements of Cash Flows

	<u>Year Ended</u> <u>March 31, 2025</u>	<u>Year Ended</u> <u>March 31, 2024</u>
<i>(Expressed in thousands)</i>	\$	\$
<b>Cash flows from operating activities:</b>		
Net loss .....	(9,568)	(12,853)
Adjustments:		
Depreciation expense .....	7	11
Gain on sale of equipment .....	—	(59)
Loss on disposal .....	2	39
Stock-based compensation .....	730	913
Change in fair value of derivative warrant liabilities .....	(3,218)	2,728
Deferred income tax benefit .....	(3,199)	(1,832)
Changes in operating assets and liabilities:		
Receivables .....	596	80
Prepaid expenses .....	(170)	315
Trade and other payables .....	(84)	(1,652)
Operating lease right of use asset .....	—	(23)
Net cash used in operating activities .....	<u>(14,904)</u>	<u>(12,333)</u>
<b>Cash flows from investing activities:</b>		
Maturity of short-term investments .....	15	6,569
Purchase of short-term investments .....	(15)	(6,554)
Purchase of equipment .....	—	(22)
Sale of equipment .....	—	111
Net cash provided by investing activities .....	<u>—</u>	<u>104</u>
<b>Cash flows from financing activities:</b>		
Gross proceeds from issuance of common stock and warrants from private placement .....	14,999	7,500
Stock issuance costs .....	(967)	(162)
Proceeds from issuance of common stock from exercise of stock options .....	—	21
Net cash provided by financing activities .....	<u>14,032</u>	<u>7,359</u>
Net decrease in cash and cash equivalents .....	(872)	(4,870)
Cash and cash equivalents, beginning of year .....	<u>23,005</u>	<u>27,875</u>
Cash and cash equivalents, end of year .....	<u>22,133</u>	<u>23,005</u>
<b>Cash and cash equivalents are comprised of:</b>		
Cash .....	830	3,280
Cash equivalents .....	<u>21,303</u>	<u>19,725</u>
<b>Supplemental schedule of non-cash financing activities are comprised of:</b>		
Issuance costs in accounts payable .....	<u>327</u>	<u>—</u>

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

## **GRACE THERAPEUTICS, INC.**

(Formerly ACASTI PHARMA, INC.)

Notes to the Consolidated Financial Statements

*(Expressed in thousands except share and per share data)*

### **1. Nature of Operations**

#### *General*

Grace Therapeutics, Inc. (formerly known as Acasti Pharma Inc.) (“Acasti Delaware” or “the Company”), is a Delaware corporation that, as further described below, previously existed under the laws of the Province of Québec, Canada (“Acasti Québec”), before changing its jurisdiction on October 1, 2024 to the Province of British Columbia, Canada (“Acasti British Columbia”). On October 7, 2024, Acasti British Columbia changed its jurisdiction to the State of Delaware. Effective October 28, 2024, the Company changed its corporate name to Grace Therapeutics, Inc.

#### *Continuance and Domestication*

On October 1, 2024, Acasti Québec changed its jurisdiction of incorporation from the Province of Québec in Canada to the Province of British Columbia in Canada pursuant to a “continuance” effected in accordance with Chapter XII of the Business Corporations Act (Québec) (the “Continuance”). Subsequently on October 7, 2024 (the “Effective Date”), Acasti British Columbia changed its jurisdiction of incorporation from the Province of British Columbia in Canada to the State of Delaware in the United States of America pursuant to a “continuance” effected in accordance with Section 308 of the Business Corporations Act (British Columbia) and a “domestication” (the “Domestication”) under Section 388 of the General Corporation Law of the State of Delaware. Both the Continuance and the Domestication were approved by the Company’s shareholders at the Company’s Annual and Special Meeting of Shareholders held on September 30, 2024.

Prior to the Continuance and Domestication, the Company’s Class A common shares, without par value per share (“Common Shares”), were listed on The Nasdaq Stock Market LLC (“Nasdaq”) under the symbol “ACST.” Upon the effectiveness of the Continuance, each outstanding Class A common share of Acasti Québec at the time of the Continuance remained issued and outstanding as a common share, without par value per share, of Acasti British Columbia. Upon effectiveness of the Domestication, each outstanding common share of Acasti British Columbia at the time of the Domestication automatically became one outstanding share of common stock, par value \$0.0001 per share, of Acasti Delaware (“Common Stock”). The Common Stock continues to be listed for trading on Nasdaq and in connection with its corporate name change to Grace Therapeutics, Inc., commenced trading under the symbol “GRCE” on October 28, 2024.

The Continuance and Domestication has been accounted for as an exchange of equity interest among entities under common control resulting in a change in reporting entity, and has been retroactively reflected in the accompanying consolidated financial statements and notes thereto. All assets and liabilities of Acasti British Columbia were deemed assumed by the Company at the Effective Date, resulting in the retention of the historical basis of accounting as if they had always been combined for accounting and financial reporting purposes. Any excess resulting from the automatic conversion of each outstanding Common Share of Acasti British Columbia into one outstanding share of Common Stock of Acasti Delaware, is presented as Additional Paid-in Capital in the equity section of the accompanying consolidated financial statements and notes thereto. All per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the effect of the change in par value.

#### *Liquidity and Financial Condition*

The Company has incurred operating losses and negative cash flows from operations in each period since its inception. The Company expects to incur significant expenses and continued operating losses for the foreseeable future.

In May 2023, the Company implemented a strategic realignment plan to enhance shareholder value that resulted in the Company engaging a new management team, streamlining its research and development activities, and greatly reducing its workforce. Following the realignment, the Company is a smaller, more focused organization, based in the United States, and concentrated on its development of its lead product candidate GTx-104. Further development of GTx-102 and GTx-101 will occur at such a time when the Company is able to secure additional funding or enters into strategic partnerships for license or sale with third parties.

In February 2025, the Company completed a private placement of Company securities with certain institutional and accredited investors. Net proceeds to the Company were \$13,705. Refer to Note 8, *2025 Private Placement*, for additional information.

The Company plans to use its current cash to further the regulatory review process for GTx-104, pre-commercial planning, commercial team buildout, and product launch if GTx-104 is approved, working capital and other general corporate purposes. The Company believes its existing cash and cash equivalents will be sufficient to sustain planned operations through at least 12 months from the issuance date of these consolidated financial statements included in the Company's Annual Report on Form 10-K.

The Company will require additional capital to fund its daily operating needs. The Company does not expect to generate revenue from product sales unless and until it successfully completes drug development and obtains regulatory approval, which is subject to significant uncertainty. To date, the Company has financed its operations primarily through public offerings and private placements of its common equity, warrants and convertible debt and the proceeds from research tax credits. Until such time that the Company can generate significant revenue from drug product sales, if ever, it will require additional financing, which is expected to be sourced from a combination of public or private equity or debt financing or other non-dilutive sources, which may include fees, milestone payments and royalties from collaborations with third parties. Arrangements with collaborators or others may require the Company to relinquish certain rights related to its technologies or drug product candidates. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategy. The Company plans to raise additional capital in order to maintain adequate liquidity. Negative results from studies or trials, if any, the timing and ability to receive U.S. Food and Drug Administration ("FDA") approval for marketing our drug candidates or depressed prices of the Company's stock could impact the Company's ability to raise additional financing. Raising additional equity capital is subject to market conditions that are not within the Company's control. If the Company is unable to raise additional funds, the Company may not be able to realize its assets and discharge its liabilities in the normal course of business.

The Company remains subject to risks similar to other development stage companies in the biopharmaceutical industry, including compliance with government regulations, protection of proprietary technology, dependence on third-party contractors and consultants and potential product liability, among others. Please refer to the risk factors included in Part 1, "Item 1A – Risk Factors" of this Annual Report on Form 10-K.

## **2. Summary of significant accounting policies**

### **Basis of presentation**

These consolidated financial statements of Grace Therapeutics, Inc., which include the accounts of its subsidiary, have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). All intercompany transactions and balances are eliminated on consolidation.

### ***Use of estimates***

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, income, and expenses. Actual results may differ from these estimates.

Estimates are based on management's best knowledge of current events and actions that management may undertake in the future. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Estimates and assumptions include the measurement of stock-based compensation, derivative warrant liabilities, accruals for research and development contracts and contract organization agreements, and valuation of intangibles and goodwill. Estimates and assumptions are also involved in determining the extent to which research and development expenses qualify for research and development tax credits. The Company recognizes tax credits once it has reasonable assurance that they will be realized.

### ***Reclassifications***

The Company reclassified sales and marketing expenses to general and administrative expenses to conform to the current period reporting classifications. This reclassification did not have an impact on previously reported results of operations.

### ***Cash equivalents***

Cash equivalents comprise of highly liquid investments purchased with original maturities of 90 days or less. Cash equivalents consist of United States Treasury bills.

### ***Equipment***

Equipment is measured at cost less accumulated depreciation and accumulated impairment losses, if any. Cost includes expenditures that are directly attributable to the acquisition of the asset, including all costs incurred in bringing the asset to its present location and condition. Gains and losses on disposal of equipment are determined by comparing the proceeds from disposal with the carrying amount of the equipment.

Depreciation is recognized on a declining basis over the estimated useful lives of equipment, since this most closely reflects the expected pattern of consumption of the future economic benefits embodied in the asset. Items of equipment are depreciated from the date that they are available for use or, in respect of assets not yet in service, from the date they are ready for their intended use.

### ***Intangible assets - acquired in-process research and development***

In a business combination, the fair value of in-process research and development (“IPR&D”) acquired is capitalized and accounted for as indefinite-lived intangible assets, and not amortized until the underlying project receives regulatory approval, at which point the intangible assets will be accounted for as definite-lived intangible assets and amortized over the remaining useful life or discontinued. If discontinued, the intangible asset will be written off. Research and development (“R&D”) costs incurred after the acquisition are expensed as incurred.

### ***Impairment of long-lived assets***

The Company reviews the recoverability of its finite long-lived assets whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. The carrying amount is first compared with the undiscounted cash flows. If the carrying amount is higher than the sum of undiscounted cash flows, then the Company determines the fair value of the underlying asset group. Any impairment loss to be recognized is measured as the difference by which the carrying amount of the asset group exceeds the estimated fair value of the asset group.

Goodwill and indefinite-lived assets are not amortized but are subject to an impairment review annually and more frequently when indicators of impairment exist. An impairment of goodwill could occur if the carrying amount of a reporting unit exceeds the fair value of that reporting unit. An impairment of indefinite-lived intangible assets would occur if the fair value of the intangible asset is less than the carrying value.

The Company tests its goodwill for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If the Company concludes it is more likely than not that fair value of the reporting unit is less than its carrying amount, a quantitative impairment test is performed.

The Company tests indefinite-lived intangible assets for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than its carrying amount, a quantitative impairment test is performed. The Company’s annual impairment test is performed in the fourth quarter of the fiscal year.

### ***Research and development costs***

Research and development expenditures are expensed as incurred. These costs consist of employees’ salaries and benefits related to research and development activities, contractors and consultants that conduct the Company’s clinical trials, laboratory material and small equipment, clinical trial materials, stock-based compensation expense, and other non-clinical costs and regulatory fees. Advance payments for goods and services that will be used in future research and development are recognized in prepaids or other assets and are expensed when the services are performed, or the goods are used.

### ***Stock-based compensation***

The Company has in place a stock option plan for directors, officers, employees, and consultants of the Company, with grants under the stock option plan approved by the Company’s Board of Directors. The plan provides for the granting of options to purchase Common Stock and the exercise price of each option equals the closing trading price

of Common Stock on the day prior to the grant. The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Standards Codification (“ASC”) 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company measures the cost of such awards based on the fair value of the award at grant date and recognizes stock-based compensation expense in the consolidated statements of operations and comprehensive loss on a tranche by tranche basis. The fair value of options is estimated for each tranche of an award that vests on a graded basis. The fair value of options is estimated using the Black-Scholes option pricing model, which uses various inputs including fair value of the Common Stock at the grant date, expected term, historical volatility, risk-free interest rate and expected dividend yields of the Common Stock. The Company applies an estimated forfeiture rate derived from historical employee termination behavior in determining compensation expense. If the actual forfeitures differ from those estimated by management, adjustment to compensation expense may be required in future periods.

### ***Government grants***

Government grants are recorded as a reduction of the related expenses or costs of the asset acquired. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the approved grant program and there is reasonable assurance that the grant will be received.

### ***Leases***

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. The Company has elected not to recognize leases with an original term of one year or less on the consolidated balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company’s assessment unless there is reasonable certainty that the Company will renew. The Company’s lease expense is recognized in research and development expenses. The Company does not have financing leases.

In accordance with FASB ASC 842—*Leases* (“Topic 842”), components of a lease should be split into three categories: lease components, non-lease components and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

### ***Income taxes***

Income taxes comprise of current and deferred taxes. The provision for income taxes is computed using the asset and liability method.

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted at the reporting date, and any adjustment to tax payable in respect of previous years.

Deferred tax is recognized in respect of temporary differences between the carrying amounts (tax base) of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax assets and liabilities are measured at the tax rate expected to apply when the underlying asset or liability is realized (settled) based on the rates that are enacted at the reporting date. Deferred tax assets and liabilities are offset if the Company has the right to set off the amount owed by with the amount owed by the other party, the Company intends to set off and the offset right is enforceable at law. A deferred tax asset is recognized for unused tax losses, and tax credits, reduced by a valuation allowance. A valuation allowance is recorded to reduce the carrying amount of deferred income tax assets when it is more likely than not that these assets will not be realized. tax benefits related to tax positions not deemed to meet the “more-likely-than-not” threshold are not permitted to be recognized in the consolidated financial statements.

Additionally, the Company accrues interest and penalties, if any, related to unrecognized tax benefits as a component of income tax expense. The unrecognized tax benefits, including accrued interest and penalties, if any, are included in income taxes payable in the accompanying Consolidated Balance Sheets.

### ***Earnings per share***

The Company presents basic and diluted earnings per share (“EPS”) data for its Common Stock. Basic EPS is calculated by dividing the net income or loss attributable to the holders of Common Stock by the weighted average number of Common Stock outstanding during the year. Diluted EPS is determined by adjusting the net income or loss attributable to the holders of Common Stock and the weighted average number of Common Stock outstanding adjusted for the effects of all dilutive potential Common Stock, which comprise warrants and share options granted to employees. The basic and diluted EPS are the same due to loss position.

### ***Segment reporting***

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures* (“ASU 2023-07”). The ASU includes enhanced disclosure requirements, primarily related to significant segment expenses that are regularly provided to and used by the chief operating decision maker (“CODM”). The amendments are to be applied retrospectively to all prior periods presented in the financial statements. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. As discussed further in Note 12, the Company’s adoption of the requirements of ASU 2023-07 at March 31, 2025 annual financial reporting did not result in material impact on its consolidated financial statements and disclosures. Refer to Note 12 for detailed discussions.

### ***Derivative warrant liabilities***

Derivative warrant liabilities are recognized initially at fair value. Subsequent to initial recognition, derivative warrant liabilities are measured at fair value, with changes in fair value recognized in the consolidated statement of operations and comprehensive loss.

### ***Fair value measurements***

Certain of the Company’s accounting policies and disclosures require the determination of fair value, for both financial assets and liabilities.

In establishing fair value, the Company uses a fair value hierarchy based on levels as defined below:

- Level 1: defined as observable inputs such as quoted prices in active markets.
- Level 2: defined as inputs other than quoted prices in active markets that are either directly or indirectly observable.
- Level 3: defined as inputs that are based on little or no observable market data, therefore requiring entities to develop their own assumptions.

The Company has determined that the carrying values of its short-term financial assets and liabilities (cash and cash equivalents and trade and other payables) approximate their fair value given the short-term nature of these instruments. The Company measured its derivative warrant liabilities at fair value on a recurring basis using level 3 inputs.

### ***Financial Instruments***

#### ***Concentration of credit risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are all invested in accordance with the Company’s Investment Policy with the primary objective being the preservation of capital and the maintenance of liquidity, which risk is managed by dealing only with highly rated U.S. and Canadian institutions. The Company maintains its cash and cash equivalents at accredited financial institutions in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

### Recent accounting pronouncements

On November 4, 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)*, to improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization and depletion) in commonly presented expense captions (such as cost of sales, SG&A and research and development).

ASU 2024-03 applies to all public business entities and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. The Company is currently evaluating the effect of adopting this new guidance on its consolidated financial statements and disclosures. The Company does not expect that the adoption of ASU 2024-03 will have a material impact on its consolidated financial statements and disclosures.

The Company has considered all other recent accounting pronouncements and concluded that they are either not applicable to the Company's business or that the effect is not expected to be material to the consolidated financial statements as a result of future adoption.

### 3. Fair value measurements

Assets and liabilities measured at fair value on a recurring basis as of March 31, 2025 are as follows:

	Total \$	Quoted prices in active markets (Level 1) \$	Significant other observable inputs (Level 2) \$	Significant unobservable inputs (Level 3) \$
Assets				
Treasury bills classified as cash equivalents . . . . .	21,304	21,304	—	—
Total assets . . . . .	21,304	21,304	—	—
Liabilities				
Derivative warrant liabilities . . . . .	1,141	—	—	1,141
Total liabilities. . . . .	1,141	—	—	1,141

Assets and liabilities measured at fair value on a recurring basis as of March 31, 2024 are as follows:

	Total \$	Quoted prices in active markets (Level 1) \$	Significant other observable inputs (Level 2) \$	Significant unobservable inputs (Level 3) \$
Assets				
Guaranteed investment certificates and term deposits classified as cash equivalents . . . . .	19,725	19,725	—	—
Total assets . . . . .	19,725	19,725	—	—
Liabilities				
Derivative warrant liabilities . . . . .	4,359	—	—	4,359
Total liabilities. . . . .	4,359	—	—	4,359

There were no changes in valuation techniques or transfers between Levels 1, 2 or 3 during the years ended March 31, 2025 and 2024. The Company's derivative warrant liabilities are measured at fair value on a recurring basis using unobservable inputs that are classified as Level 3 inputs. Refer to Note 8, *Stockholders' Equity*, for the valuation techniques and assumptions used in estimating the fair value of the derivative warrant liabilities.

#### 4. Receivables

	March 31, 2025	March 31, 2024
	\$	\$
Sales tax receivables . . . . .	106	316
Government assistance . . . . .	—	356
Interest receivable . . . . .	—	15
Other receivables . . . . .	<u>20</u>	<u>35</u>
Total receivables . . . . .	<u>126</u>	<u>722</u>

Government assistance is comprised of research and development investment tax credits from the Québec provincial government, which relate to quantifiable research and development expenditures under the applicable tax laws. The amounts recorded as receivables are subject to a government tax audit and the final amounts received may differ from those recorded.

#### 5. Equipment

The following is a summary of equipment, net:

	Cost	Accumulated depreciation	Write-off	Net book value
	\$	\$	\$	\$
<b>March 31, 2025</b>				
Furniture and office equipment . . . . .	2	(1)	(1)	—
Computer equipment . . . . .	5	(2)	(1)	2
Software . . . . .	<u>19</u>	<u>(6)</u>	<u>—</u>	<u>13</u>
	<u>26</u>	<u>(9)</u>	<u>(2)</u>	<u>15</u>
<b>March 31, 2024</b>				
Furniture and office equipment . . . . .	18	(13)	(4)	1
Computer equipment . . . . .	114	(76)	(34)	4
Laboratory equipment . . . . .	571	(519)	(52)	—
Software . . . . .	<u>19</u>	<u>0</u>	<u>0</u>	<u>19</u>
	<u>722</u>	<u>(608)</u>	<u>(90)</u>	<u>24</u>

Depreciation expense was \$7 and \$11 for the years ended March 31, 2025 and 2024, respectively.

#### 6. Intangible assets and goodwill

Individual IPR&D projects and goodwill are tested for impairment on an annual basis in the fourth quarter, and in between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of each technology or our reporting unit below its carrying value. The impairment assessments resulted in the following activity during the years ended March 31, 2025 and 2024:

	GTx-104	GTx-102	GTx-101	Total
	\$	\$	\$	\$
<b>Intangible assets – in-process research and development</b>				
Balance, March 31, 2023 . . . . .	27,595	9,196	4,337	41,128
Impairment . . . . .	—	—	—	—
<b>Balance, March 31, 2024 . . . . .</b>	<b>27,595</b>	<b>9,196</b>	<b>4,337</b>	<b>41,128</b>
Impairment . . . . .	—	—	—	—
<b>Balance, March 31, 2025 . . . . .</b>	<b><u>27,595</u></b>	<b><u>9,196</u></b>	<b><u>4,337</u></b>	<b><u>41,128</u></b>

	\$
<b>Goodwill</b>	
Balance, March 31, 2023 . . . . .	8,138
Impairment . . . . .	—
<b>Balance, March 31, 2024</b> . . . . .	<b><u>8,138</u></b>
Impairment . . . . .	—
<b>Balance, March 31, 2025</b> . . . . .	<b><u>8,138</u></b>

The Company’s IPR&D projects, consistent with others in our industry, have risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. It is not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized values, if any, of acquired IPR&D projects may vary from their estimated fair values.

## 7. Trade and other payables

	March 31, 2025	March 31, 2024
	\$	\$
Trade payables . . . . .	601	1,007
Accrued research and development expenses . . . . .	565	133
Accrued liabilities and other payables . . . . .	103	43
Employee salaries and benefits payable . . . . .	<u>661</u>	<u>501</u>
Total trade and other payables . . . . .	<u>1,930</u>	<u>1,684</u>

## 8. Stockholders’ equity

### *Preferred Stock*

The Company is authorized to issue up to 10,000,000 shares of preferred stock, par value \$0.0001 per share. No shares of the Company’s preferred stock are issued or outstanding.

### *Common Stock*

In connection with the consummation of the Domestication, on October 7, 2024, the Company adopted a Certificate of Incorporation (as amended, the “Charter”) and Bylaws (as amended, the “Bylaws”). The rights of holders of the Company’s Common Stock are now governed by the Charter, the Bylaws, and the General Corporation Law of the State of Delaware. The Company is authorized to issue up to 100,000,000 shares of Common Stock, par value \$0.0001 per share.

### *2025 Private Placement*

In February 2025, the Company agreed to offer and sell in a private placement (the “2025 Private Placement”) an aggregate of 3,252,132 shares of the Company Common Stock at a purchase price of \$3.395 per share of Common Stock (the “Shares”) and pre-funded warrants (the “2025 Pre-Funded Warrants”) to purchase up to 1,166,160 shares of Common Stock at a purchase price equal to the purchase price per Share less \$0.0001 (the “2025 Pre-Funded Warrant Shares”). Each 2025 Pre-Funded Warrant is exercisable for one share of Common Stock at an exercise price of \$0.0001 per share, exercisable immediately and will expire once exercised in full.

Pursuant to the 2025 Purchase Agreement, for each Share and each 2025 Pre-Funded Warrant issued, the Company agreed to issue to each purchaser an accompanying common warrant (the “2025 Common Warrants” and, together with the 2025 Pre-Funded Warrants, the “2025 Warrants”) to purchase shares of Common Stock (or 2025 Pre-Funded Warrants in lieu thereof), exercisable for an aggregate of 4,418,292 shares of Common Stock (or 2025 Pre-Funded Warrants in lieu thereof). Each 2025 Common Warrant is exercisable for one share of Common Stock at an exercise

price of \$3.395 per share (or one 2025 Pre-Funded Warrant at an exercise price of \$3.3949 per share in lieu thereof), will be immediately exercisable and will expire on the earlier of (i) the 60th day after the date the FDA approves the new drug application (“NDA”) for GTx-104 and (ii) September 25, 2028. The 2025 Common Warrants were offered and sold at a purchase price of \$0.125 per 2025 Common Warrant, which purchase price is included in the offering price per Share and 2025 Pre-Funded Warrant issued in the 2025 Private Placement.

The 2025 Private Placement included the issuance of Common Stock, 2025 Pre-Funded Warrants, and 2025 Common Warrants to related parties namely (i) Shore Pharma LLC, an entity held in a trust for the benefit of immediate family members of Vimal Kavuru, the Chair of the Company’s Board of Directors and (ii) ADAR1 Partners, LP, AIGH Investment Partners, LP, and SS Pharma LLC, each a beneficial owner of more than 5% of the Common Stock prior to the 2025 Private Placement, resulting in proceeds of \$5,694 in 2025.

The Company has paid TD Securities (USA) LLC, the placement agent, customary placement fees in its capacity as placement agent for the sale of the Company’s securities to certain of the investors in the 2025 Private Placement.

The 2025 Private Placement closed on February 11, 2025 (the “Closing Date”). The net proceeds to the Company were \$13,705, after deducting fees and expenses.

Both 2025 Pre-funded Warrants and 2025 Common Warrants are presented under additional paid-in capital in the equity section of the consolidated balance sheet as of March 31, 2025.

During the twelve months period March 31, 2025, 24,742 of the 2025 Pre-Funded Warrants were exercised into 24,742 shares of Common Stock.

### ***2023 Private Placement***

In September 2023, the Company entered into the Purchase Agreement with certain institutional and accredited investors in connection with the 2023 Private Placement. Pursuant to the Purchase Agreement, the Company offered and sold 1,951,371 Common Shares, at a purchase price of \$1.848 per Common Share and 2023 Pre-Funded Warrants to purchase up to 2,106,853 Common Shares at a purchase price equal to the purchase price per Common Share less \$0.0001. Each 2023 Pre-Funded Warrant is exercisable for one Common Share at an exercise price of \$0.0001 per Common Share, is immediately exercisable, and will expire once exercised in full. Pursuant to the Purchase Agreement, the Company also issued, to such institutional and accredited investors, 2023 Common Warrants to purchase Common Shares exercisable for an aggregate of 2,536,391 Common Shares. Under the terms of the Purchase Agreement, for each Common Share and each 2023 Pre-funded Warrant issued in the 2023 Private Placement, an accompanying five-eighths (0.625) of a 2023 Common Warrant was issued to the purchaser thereof. Each whole 2023 Common Warrant is exercisable for one Common Share at an exercise price of \$3.003 per Common Share, is immediately exercisable, and will expire on the earlier of (i) the 60<sup>th</sup> day after the date of the acceptance by the FDA of an NDA for the Company’s product candidate GTx-104 and (ii) five years from the date of issuance. The 2023 Private Placement closed on September 25, 2023. The net proceeds to the Company from the 2023 Private Placement were \$7,338, after deducting fees and expenses.

The 2023 Private Placement included the issuance of Common Shares, 2023 Pre-Funded Warrants, and 2023 Common Warrants to related parties namely (i) Shore Pharma LLC, an entity that was controlled by Vimal Kavuru, the Chair of the Company’s Board of Directors, at the time of the 2023 Private Placement and (ii) SS Pharma LLC, the beneficial owner of 5.5% of Common Shares outstanding prior to the 2023 Private Placement, resulting in proceeds of \$2,500 in 2023. As of March 31, 2025 and 2024, the balance of derivative warrant liabilities from related parties was \$ 952 and \$1,453, respectively.

During the twelve months period March 31, 2025, 1,041,851 of the 2023 Pre-Funded Warrants were exercised into 1,041,828 Common Shares or Common Stock, as applicable. There were no 2023 Common Warrants exercised during the twelve months ended March 31, 2024.

### **Warrants**

As further discussed above, on September 25, 2023, the Company issued the 2023 Pre-Funded Warrants and the 2023 Common Warrants exercisable for 4,643,244 Common Shares in the 2023 Private Placement pursuant to the terms of the Purchase Agreement entered into with certain institutional and accredited investors.

The 2023 Common Warrants issued as a part of the 2023 Private Placement are derivative warrant liabilities given the 2023 Common Warrants did not meet the fixed-to-fixed criteria and that the 2023 Common Warrants are not

indexed to the Company's own stock. Proceeds were allocated amongst Common Shares, 2023 Pre-Funded Warrants, and 2023 Common Warrants by applying the residual method, with fair value of the 2023 Common Warrants determined using the Black-Scholes model, resulting in initial derivative warrant liabilities of \$1,631 and issuance costs of \$45 allocated to 2023 Common Warrants. Accordingly, \$2,822 and \$3,047 of the gross proceeds were allocated to the Common Shares and the 2023 Pre-Funded Warrants, respectively, and \$78 and \$84 of issuance costs were allocated to the Common Shares and the 2023 Pre-Funded Warrants, respectively.

The derivative warrant liabilities are measured at fair value at each reporting period and the reconciliation of changes in fair value is presented in the following table:

	<u>March 31, 2025</u>	<u>March 31, 2024</u>
	\$	\$
Beginning balance . . . . .	4,359	—
Issued during the year . . . . .	—	1,631
Change in fair value . . . . .	<u>3,218</u>	<u>2,728</u>
Ending balance . . . . .	<u>1,141</u>	<u>4,359</u>

The warrant liability was determined based on the fair value of warrants at the issue date and the reporting dates using the Black-Scholes model with the following weighted-average assumptions will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of a NDA for the Company's product candidate GTx-104 and (ii) five years from the date on issuance.

	<u>March 31, 2025</u>	<u>March 31, 2024</u>
Risk-free interest rate . . . . .	4.18%	4.69%
Share price . . . . .	\$ 2.28	\$ 3.43
Expected warrant life . . . . .	1.14	2.03
Dividend yield . . . . .	0%	0%
Expected volatility . . . . .	74.26%	85.94%

The weighted-average fair values of the 2023 Common Warrants were determined to be \$0.45 and \$1.72 per 2023 Common Warrant as of March 31, 2025 and 2024, respectively. The risk-free interest rate at the issue date and on the reporting date of March 31, 2025 was based on the interest rate corresponding to the U.S. Treasury rate issue with a remaining term equal to the expected term of the 2023 Common Warrants. The expected volatility was based on the historical volatility for the Company.

At March 31, 2025, the Company had outstanding 2023 Common Warrants to purchase 2,536,391 shares of Common Stock, with an exercise price of \$3.003, all of which were classified as derivative warrant liabilities. At March 31, 2025, the Company had outstanding 2023 Pre-funded Warrants to purchase 1,065,002 shares of Common Stock, with an exercise price of \$0.0001, all of which were classified within stockholders' equity.

At March 31, 2025, the Company had outstanding 2025 Common Warrants to purchase 4,418,292 shares of Common Stock, with an exercise price of \$3.395, all of which were classified within stockholders' equity. At March 31, 2025, the Company had outstanding 2025 Pre-funded Warrants to purchase 1,141,418 shares of Common Stock, with an exercise price of \$0.0001, all of which were classified within stockholders' equity.

In connection with the Continuance and the Domestication, the Company continues its obligations under the Purchase Agreement and the 2023 Warrants. At effectiveness of the Continuance, each outstanding 2023 Warrant exercisable for Common Shares remained exercisable for an equivalent number of common shares of Acasti British Columbia for the equivalent exercise price per share without any action by the holder. At effectiveness of the Domestication, each outstanding warrant exercisable for common shares of Acasti British Columbia remained exercisable for an equivalent number of shares of Common Stock for the equivalent exercise price per share without any action by the holder.

## 9. Stock-based compensation

### 2024 Equity Incentive Plan

At the Annual and Special Meeting of Shareholders on September 30, 2024, the Company's shareholders approved the Grace Therapeutics, Inc. 2024 Equity Incentive Plan (the "2024 Plan") which became effective on the date of the

Domestication. The 2024 Plan replaced the Acasti Pharma Inc. Stock Option Plan and the Acasti Pharma Inc. Equity Incentive Plan (the “Prior Plans”). The 2024 Plan provides for the grant of awards of stock options, stock appreciation rights, restricted stock, restricted stock units, deferred stock units, unrestricted stock, dividend equivalent rights, performance-based awards and other equity-based awards to eligible persons as defined under the 2024 Plan. Any of these awards may, but need not, be made as performance incentives to reward the holders of such awards for the achievement of performance goals in accordance with the terms of the 2024 Plan. Stock options granted under the 2024 Plan may be non-qualified stock options or incentive stock options, as provided in the 2024 Plan.

In connection with the Continuance and the Domestication, the Company continues its obligations under the Prior Plans and all of the outstanding equity awards under the Prior Plans. Upon effectiveness of the Continuance, each outstanding option exercisable for and restricted share unit settleable into Common Shares remained exercisable for or able to be settled into, as applicable, an equivalent number of common shares of Acasti British Columbia for the equivalent exercise price per share (if applicable), without any action by the holder. Upon effectiveness of the Domestication, each outstanding option exercisable for and restricted share unit settleable into common shares of Acasti British Columbia remained exercisable for or able to be settled into, as applicable, an equivalent number of shares of Common Stock for the equivalent exercise price per share (if applicable), without any action by the holder.

Following the Effective Date of the 2024 Plan, no awards shall be made under the Prior Plans. However, Common Shares reserved under the Prior Plans to settle awards which were made under the Prior Plans may be issued and delivered following the Effective Date to settle such awards.

The 2024 Plan is administered by a committee designated from time to time, by resolution of the Company’s Board of Directors. The committee will also be responsible for determining, among others, the key terms of the awards including their grant dates, pricing, basis for fair value determination, vesting terms, restrictions, and terminations. The Board has designated its Compensation Committee to administer the 2024 Plan. The 2024 Plan authorizes a total of 1,350,000 shares of Common Stock available for issuance. As of March 31, 2025, there were 1,335,000 shares available for issuance under the 2024 Plan.

The 2024 Plan will terminate automatically ten years after the Effective Date and may be terminated on any earlier date as provided by the 2024 Plan.

The following table summarizes information about activities within the 2024 Plan and Prior Plans for the year ended March 31, 2025:

	Number of options	Weighted-average exercise price \$	Weighted-average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, March 31, 2024 . . . . .	721,793	3.68	9.08	527
Granted . . . . .	213,130	2.98		
Outstanding, March 31, 2025 . . . . .	<u>934,923</u>	<u>3.52</u>	<u>8.26</u>	<u>24</u>
Exercisable, March 31, 2025 . . . . .	<u>586,478</u>	<u>3.96</u>	<u>8.08</u>	<u>20</u>

The weighted-average grant date fair value of awards for options granted during the year ended March 31, 2025 was \$2.53. The fair value of options granted was estimated using the Black-Scholes option pricing model, resulting in the following weighted-average assumptions for the options granted:

	March 31, 2025 Weighted- average	March 31, 2024 Weighted- average
Exercise price . . . . .	\$ 2.98	\$ 2.50
Share price . . . . .	\$ 2.98	\$ 2.50
Dividend . . . . .	—	—
Risk-free interest . . . . .	4.42%	3.95%
Estimated life (years) . . . . .	5.81	5.62
Expected volatility . . . . .	114.19%	117.94%

Compensation expense recognized under the 2024 Plan is summarized as follows:

	<u>March 31, 2025</u>	<u>March 31, 2024</u>
	<u>\$</u>	<u>\$</u>
Research and development expenses .....	216	198
General and administrative expenses .....	<u>514</u>	<u>715</u>
	<u>730</u>	<u>913</u>

As of March 31, 2025, there was \$302 of total unrecognized compensation cost, related to non-vested stock options, which is expected to be recognized over a remaining weighted-average vesting period of 1.27 years.

## 10. Loss per share

The Company has generated a net loss for all periods presented. Therefore, diluted loss per share is the same as basic loss per share since the inclusion of potentially dilutive securities would have had an anti-dilutive effect. All currently outstanding options and warrants could potentially be dilutive in the future.

The Company excluded the following potential Common Stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	<u>March 31, 2025</u>	<u>March 31, 2024</u>
Options outstanding .....	934,923	721,793
2023 Common Warrants .....	2,536,391	2,536,391
2025 Common Warrants .....	4,418,292	—

Basic and diluted net loss per share is calculated based upon the weighted-average number of shares of Common Stock outstanding during the year. Common Stock underlying the 2025 Pre-Funded Warrants and 2023 Pre-Funded Warrants are included in the calculation of basic and diluted earnings per share.

## 11. Income taxes

Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due. Deferred taxes relate to differences between the basis of assets and liabilities for financial and income tax reporting which will be either taxable or deductible when the assets or liabilities are recovered or settled.

The provision for income taxes consisted of the following:

	<u>March 31, 2025</u>	<u>March 31, 2024</u>
	<u>\$</u>	<u>\$</u>
Current Provision		
Federal .....	—	2
State .....	<u>3</u>	<u>—</u>
Total Current Provision .....	<u>3</u>	<u>2</u>
Deferred Provision		
Federal .....	(2,392)	(1,834)
State .....	<u>(810)</u>	<u>—</u>
Total Deferred Provision .....	<u>(3,202)</u>	<u>(1,834)</u>
Total Provision for Income Taxes .....	<u>(3,199)</u>	<u>(1,832)</u>

For the years ended March 31, 2025 and 2024, the income/(loss) before income taxes was \$ (12,767) and (\$14,685), respectively. The Company had an effective tax rate of 25.06% and 12.47% for the years ended March 31, 2025 and 2024, respectively.

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended March 31, 2025 and 2024 were as follows:

	For the year ended			
	March 31, 2025	March 31, 2025	March 31, 2024	March 31, 2024
	\$		\$	
U.S. statutory rate. . . . .	(2,681)	21.00%	(3,084)	21.00%
State taxes, net of federal . . . . .	(770)	6.03%	(341)	2.32%
Difference in foreign tax rates. . . . .	(105)	0.82%	(543)	3.69%
Return to provision. . . . .	(1)	0.00%	—	0.00%
Change in valuation allowance . . . . .	2,347	(18.39)%	1,635	(11.13)%
Change in tax rates. . . . .	—	0.00%	(486)	3.31%
Non-deductible stock-based compensation . . . . .	—	0.00%	242	(1.65)%
Non-deductible transaction costs. . . . .	—	0.00%	723	(4.92)%
Tax credits . . . . .	(1,583)	12.40%	—	0.00%
Change in fair value of warrant liabilities . . . . .	(876)	6.86%	—	0.00%
Other permanent differences . . . . .	468	(3.67)%	23	(0.16)%
Total tax (benefit) expense. . . . .	<u>(3,199)</u>	<u>25.06%</u>	<u>(1,832)</u>	<u>12.47%</u>

The rate reconciliation was previously presented using the Canadian statutory tax rate. However, following the Company's redomiciliation from Canada to the U.S. during the year, the reconciliation now reflects the U.S. statutory tax rate. For consistency and comparison, the rate reconciliation for the year ended March 31, 2024, has been recalculated based on the U.S. statutory tax rate.

The table below presents the effects of temporary differences that gave rise to significant portions of deferred tax assets and liabilities as of March 31, 2025 and 2024:

	March 31, 2025	March 31, 2024
	\$	\$
Deferred income tax assets		
Tax losses carried forward. . . . .	43,049	40,659
Research and development expenses . . . . .	10,928	8,522
Property, plant and equipment. . . . .	—	523
Intangible assets. . . . .	206	328
Financing expenses . . . . .	—	169
Net federal investment tax credits. . . . .	2,882	2,882
Other accruals and other . . . . .	131	56
Orphan drug credit. . . . .	<u>1,583</u>	<u>—</u>
Total deferred income tax assets. . . . .	58,779	53,139
Valuation allowance. . . . .	<u>(49,530)</u>	<u>(47,284)</u>
Total deferred income tax assets, net of valuation allowance . . . . .	<u>9,249</u>	<u>5,855</u>
Deferred income tax liabilities		
Intangible assets. . . . .	<u>(11,561)</u>	<u>(11,369)</u>
Total deferred tax liabilities. . . . .	<u>(11,561)</u>	<u>(11,369)</u>
Net deferred tax liabilities. . . . .	<u>(2,312)</u>	<u>(5,514)</u>

The Company has U.S. Federal and State net operating loss carryforwards ("NOLs") of approximately \$18,621 and \$18,621 and Canadian Federal and Quebec NOLs of \$143,346 and \$141,851, respectively, as of March 31, 2025. The Company's U.S. Federal NOLs, generated after December 31, 2017, are available for indefinite carryforward; however, their utilization is limited to 80% of taxable income. State NOLs are subject to a 20-year carryforward period, with expirations beginning in 2038. The Company also has orphan drug tax credit totaling \$1,583, which may be carried forward for 20 years and are set to begin expiring in 2045. Canadian and Quebec NOLs are scheduled to

begin expiring in 2028, while scientific research and experimental development expenditures investment tax credit totaling \$3,922 are set to begin expiring in 2029. Additionally, the Company has research and development expenses of \$25,708 in Canada and \$27,887 in Quebec, both of which are available for indefinite carryforward.

The utilization of the Company’s NOLs and research tax credit carryovers could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), and similar state tax provisions, due to ownership change limitations that may have occurred previously or that could occur in the future. These ownership changes limit the amount of NOLs and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has not completed an analysis of an ownership change under Section 382 of the Code. To the extent that a study is completed and an ownership change is deemed to occur, the Company’s NOLs and tax credits could be limited.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a partial valuation allowance as of March 31, 2025 and March 31, 2024.

As a result of changes made by the Tax Cuts and Jobs Act of 2017, that became effective as of January 1, 2022, the Company is required to capitalize for tax purposes certain research and development expenses, and amortize domestic expenses over a 5-year period and foreign expenses over a 15-year period, resulting in a deferred tax asset for the capitalized amounts.

In accordance with ASC 740, *Income Taxes*, specifically related to uncertain tax positions, a company is required to use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company believes its income tax filing positions and deductions will be sustained upon examination, and accordingly, no reserves or related accruals for interest and penalties have been recorded as of March 31, 2025.

The Company is subject to taxation in the United States at both the federal level and within the state jurisdictions of New Jersey, Pennsylvania, and California. The Company is not currently under examination by any tax authority. The statute of limitations remains open for each tax year to the extent of the net operating losses generated in that year.

**Government assistance**

Government assistance is comprised of research and development investment tax credits receivable from the Quebec provincial government which relate to qualifiable research and development expenditures under the applicable tax laws. The amounts recorded as receivables are subject to a government tax audit and the final amounts received may differ from those recorded. For the years ended March 31, 2025 and 2024, the Company recorded (\$0) and (\$55), respectively, as a reduction of research and development expenses in the consolidated statements of operations and comprehensive loss.

	March 31, 2025	March 31, 2024
	\$	\$
Investment tax credit . . . . .	—	356

**12. Segment Information**

An operating segment is a component of an entity whose operating results are regularly reviewed by its chief operating decision maker (“CODM”) to make decisions about resources to be allocated to the segment and assess its performance. Factors used by the Company in determining the reportable segment include the nature of the Company’s operating activities, the organizational and reporting structure and the type of information reviewed by the CODM to allocate resources and evaluate financial performance.

The Company has one reportable operating segment: the development and commercialization of pharmaceutical applications of its patents and licensed rights. The Company’s CODM is its Chief Executive Officer. The accounting policies of the segment are those described in the summary of significant accounting policies within Note 2.

The CODM assesses the performance of the segment based on net loss, which is reported on the income statement as consolidated net loss. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

The Company has not generated any revenue and expects to continue to incur significant expenses and operating losses as it advances product candidates through all stages of development, and ultimately, receive regulatory approval. Accordingly, the CODM utilizes the cash budget and forecasts in assessing the entity-wide operating results and performance, and in deciding how to allocate resources across the organization and its segment. Net loss is used to monitor budgets against actual results, which then is used in assessing the performance of the segment.

The table below summarizes the significant expenses, by category regularly review by the CODM, for the years ended March 31, 2025 and 2024:

	<u>March 31, 2025</u>	<u>March 31, 2024</u>
	\$	\$
Clinical development programs . . . . .	(8,164)	(3,167)
Professional fees . . . . .	(3,707)	(3,475)
Salaries and benefits . . . . .	(2,840)	(2,028)
Stock-based compensation . . . . .	(730)	(913)
Government grants & tax credits . . . . .	—	(55)
Other general and administrative expenses <sup>(1)</sup> . . . . .	(1,238)	(1,729)
Other segment income (expense) <sup>(2)</sup> . . . . .	3,184	(2,708)
Interest income, net . . . . .	728	875
Restructuring costs . . . . .	—	(1,485)
Income tax benefit . . . . .	<u>3,199</u>	<u>1,832</u>
Segment and consolidated net loss . . . . .	<u>(9,568)</u>	<u>(12,853)</u>

1) Other general and administrative expenses include depreciation and loss on disposal, travel, and other administrative costs.

2) Other segment income includes change in fair value of derivative warrant liabilities, and foreign exchange (loss)/gain.

### 13. Commitments and contingencies

#### *Research and development contracts and contract research organizations agreements*

The Company utilizes contract manufacturing organizations (“CMOs”) for the development and production of clinical materials and contract research organizations (“CROs”) to perform services related to its clinical trials. Pursuant to the agreements with these CMOs and CROs, the Company has either the right to terminate the agreements without penalties or under certain penalty conditions. As of March 31, 2025, the Company has \$300 of commitments to CMOs and \$110 of commitments to CROs for the next twelve months.

#### *Legal proceedings and disputes*

In the ordinary course of business, the Company is at times subject to various legal proceedings and disputes. The Company assesses its liabilities and contingencies in connection with outstanding legal proceedings utilizing the latest information available. Where it is probable that the Company will incur a loss and the amount of the loss can be reasonably estimated, the Company records a liability in its consolidated financial statements. These legal contingencies may be adjusted to reflect any relevant developments on a quarterly basis. Where a loss is not probable or the amount of loss is not estimable, the Company does not accrue legal contingencies. While the outcome of legal proceedings is inherently uncertain, based on information currently available, management believes that it has established appropriate legal reserves. No reserves or liabilities have been accrued as at March 31, 2025.

### 14. Restructuring Costs

On May 8, 2023, the Company communicated its decision to terminate a substantial amount of its workforce as part of a plan that intended to align the Company’s organizational and management cost structure to prioritize resources to GTx-104, thereby reducing losses to improve cash flow and extend available cash resources. During the twelve months ended March 31, 2024, the Company incurred \$1,485 in costs primarily consisting of employee severance costs and legal fees. There was no restructuring costs incurred during the year ended March 31, 2025.

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