UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023.
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File Number 1-32639
TG THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**36-3898269**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3020 Carrington Mill Blvd, Suite 475	
Morrisville, North Carolina	**27560**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (212) 554-4484

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock, par value $0.001	TGTX	Nasdaq Capital 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 Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was $3.4 billion as of June 30, 2023, based on the closing sale price of such stock as reported on the NASDAQ Capital Market.

There were 154,420,772 shares of the registrant's common stock, $0.001 par value, outstanding as of February 23, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

Auditor Name: KPMG LLP Auditor Location: New York, NY Auditor Firm ID: 185

TG THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the captions "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (Securities Act), and the Securities Exchange Act of 1934, as amended (Exchange Act), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would" or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words.

All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about:

- our ability to obtain and maintain regulatory approvals for our product candidates, including TG-1701, TG-1801, and Azercabtagene Zapreleucel (azer-cel), as well as any other product candidates, and our ability to maintain regulatory approval of BRIUMVI® (ublituximab) for the treatment of relapsing forms of multiple sclerosis (RMS) in the United States (U.S.), the European Union (EU) and the United Kingdom (UK);
- our ability to adapt and expand our commercial infrastructure to successfully launch, market and sell BRIUMVI and our other product candidates;
- our ability to maintain a reliable supply of our products that meets market demand;
- the success of the ongoing commercialization of BRIUMVI or any future products or combinations of products, including the anticipated rate and degree of market acceptance and pricing and reimbursement;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials;
- our ability to advance drug candidates into, and successfully complete, clinical trials;
- our ability to develop, formulate, manufacture and commercialize our product candidates;
- our ability to establish and maintain contractual relationships and partnerships, on commercially reasonable terms, with third parties for manufacturing, distribution, marketing and supply and a range of other support functions for our clinical development and commercialization efforts;
- the implementation of our business model and strategic plans for our business and drug candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product and product candidates;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations and enter into strategic arrangements, if desired;
- our ability to meet any of our financial projections or guidance, including without limitation short and long-term revenue projections or guidance and changes to the assumptions underlying those projections or guidance;
- our ability to obtain sufficient capital to fund our planned operations;
- our financial performance and cash burn management;
- our ability to maintain or obtain adequate product liability and other insurance coverage; and
- developments relating to our competitors and our industry.

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risks, the risk factors in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission (SEC).

Risks Related to Commercialization

- If we are unable to maintain current approval of BRIUMVI, our business will be materially harmed.
- We cannot predict when or if we will obtain regulatory approval to commercialize our product candidates, including TG-1701 and TG-1801 in B-cell disorders or azer-cel in non-oncology indications.
- We have limited experience operating as a commercial company, and, as a result, the marketing and sale of BRIUMVI for the treatment of RMS may be less successful than anticipated.
- If BRIUMVI or any of our future product candidates (if approved) do not achieve broad market acceptance among physicians, patients, payors or the medical community, the revenues that we generate from product sales will be limited.
- If the market opportunities for BRIUMVI and any future products for which we may receive approval, including TG-1701 or TG-1801 in B-cell disorders or azer-cel in non-oncology indications, are smaller than we estimate or if any approval we obtain is based on a narrower patient population or the labeling includes warnings or limitations that are not acceptable to patients or healthcare providers, our revenue will be adversely affected.
- We face substantial competition for treatments for our target indications, including from companies with greater resources than we have, which may result in others commercializing drugs before or more successfully than we do, which could result in the reduction or elimination of our commercial opportunity.
- If we are unable to generate sufficient revenue, we may need to raise substantial additional capital to sustain our business.
- Product liability lawsuits could cause us to incur substantial liabilities and limit product commercialization.

Risks Related to Drug Development and Regulatory Approval

- If we are unable to obtain or maintain regulatory approval for our product or product candidates and ultimately cannot commercialize one or more of them, or if we experience significant delays in doing so, our business will be materially harmed
- Our product and product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or significantly limit their commercial profile following marketing approval, if any, or result in withdrawal from the market if approved
- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials. Moreover, interim, "top-line," and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed.
- Any products or product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays, or prevent the receipt of the required approvals.

Risks Related to Governmental Regulation of the Pharmaceutical Industry

- We are subject to extensive regulation, including new legislative and regulatory proposals, including efforts to control, set or cap pricing for approved drugs, which may increase our costs and adversely affect our ability to market our products, obtain collaborators and raise capital.
- If we fail to comply with various healthcare laws and regulations, we may incur losses or be subject to liability.
- If we fail to comply with regulatory requirements, any product candidate may fail to receive regulatory approval and any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties.

Risks Related to our Dependence on Third Parties

- Our reliance on third parties for commercial and clinical supply of raw materials and our product and product candidates increases the risk that we will not have sufficient quantities of our product or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.
- If the third parties on which we rely to conduct our clinical trials and generate clinical, preclinical, and other data necessary to support our regulatory applications do not perform their services as required, we may not be able to obtain regulatory approval for or commercialize our product or product candidates when expected or at all.
- Because we have in-licensed our product and product candidates from third parties, any dispute with, or non-performance by our licensors will adversely affect our ability to develop and commercialize the applicable product.

Risks Related to Intellectual Property

- Our success depends upon our ability to obtain and protect our intellectual property, and if the scope of our patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.
- Our patent protection could be reduced or eliminated for non-compliance with various procedural and other requirements imposed by governmental patent agencies.
- We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.
- If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming to defend against such lawsuits, and an unfavorable outcome in any such lawsuit would have a material adverse effect on our business.
- If we are unable to protect the confidentiality of our trade secrets, our business may be significantly harmed.

Risks Related to our Financial Position and Need for Additional Capital

- We have incurred significant operating losses since our inception, and we may incur losses in the future.
- While we do not expect to need to raise additional capital, we may need to do so. If we are unable to raise capital, if needed, we may be required to delay, limit, reduce or eliminate some of our drug development programs or commercialization efforts.
- Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

General Risk Factors

- Public health issues including an epidemic or global pandemic, including the pandemic caused by COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.
- Patients and healthcare providers have raised concerns that immunosuppressive products, like anti-CD20 antibodies and other B-cell targeted agents, may increase the risk of acquiring COVID-19 or lead to more severe complications upon infection. These concerns may impact the commercial potential for BRIUMVI and other immunosuppressive products that we have in development.
- We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion.
- Our ability to continue our clinical development and commercialization activities will depend on our ability to attract and maintain key management and other personnel.
- Certain of our executive officers, directors and other stockholders own more than 5% of our outstanding common stock and may be able to influence our management and the outcome of matters submitted to shareholders for approval.
- Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition more difficult, which could limit the price investors might be willing to pay for our common stock.
- Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit and could subject us to securities and shareholder derivative litigation.
- Significant disruptions of information technology systems, breaches of data security or unauthorized disclosures of sensitive data could harm our business and subject us to liability or reputational damage.

The foregoing is only a summary of some of our risks. These and other risks are discussed more fully in the section entitled "Risk Factors" in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K (our Risk Factors).

PART I

Unless the context requires otherwise, references in this report to "TG," "Company," "we," "us" and "our" refer to TG Therapeutics, Inc. and our subsidiaries. Our name, logo and BRIUMVI are trademarks or tradenames of TG Therapeutics, Inc. All other trademarks, service marks or other tradenames appearing in this Annual Report on Form 10-K are the property of their respective owners.

ITEM 1. BUSINESS.

OVERVIEW

TG Therapeutics is a fully-integrated, commercial stage, biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell mediated diseases. In addition to a research pipeline including several investigational medicines, TG has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI® (ublituximab-xiiy) for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in adults, as well as approval by the European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features in Europe and the United Kingdom (UK), respectively. We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

Business Highlights

FDA Approval and U.S. Launch of BRIUMVI

On December 28, 2022, we announced that the FDA granted approval of ublituximab, now referred to as BRIUMVI, for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. BRIUMVI is an anti-CD20 monoclonal antibody approved for patients with RMS that can be administered in a one-hour infusion following the starting dose. Approval was granted for this indication based on data from the ULTIMATE I & II Phase 3 trials, which demonstrated superiority over teriflunomide in significantly reducing the annualized relapse rate (ARR, the primary endpoint), the number of T1 Gd-enhancing lesions and the number of new or enlarging T2 lesions. Results from the ULTIMATE I & II trials were published in August 2022 in *The New England Journal of Medicine.*

On January 26, 2023, we announced the commercial launch of BRIUMVI, making it available to physicians and patients. We are committed to helping patients access BRIUMVI through the BRIUMVI Patient Support Program, which we launched following the approval, additional information can be found at www.briumvi.com.

Ex-U.S. Commercialization of BRIUMVI

On June 1, 2023, we announced that the EC granted approval of BRIUMVI for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features.

On August 1, 2023, we announced an agreement with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm), a leading European specialty pharmaceutical company focused on the treatment of central nervous system (CNS) disorders, for the ex-U.S. commercialization of BRIUMVI.

On November 1, 2023, we announced that we also received approval by the MHRA for BRIUMVI to treat adult patients with RMS with active disease defined by clinical or imaging features in the UK.

On February 26, 2024, we announced the commercial launch of BRIUMVI in the European Union (EU) by Neuraxpharm, with BRIUMVI made available for commercial sale in Germany, with additional EU markets expected to follow.

Pipeline Expansion

On January 9, 2024, we entered into an agreement with Precision BioSciences, Inc. (Precision) to acquire a worldwide license to Precision's Azercabtagene Zapreleucel (azer-cel), an allogeneic CD19 CAR T cell therapy program for autoimmune diseases and all other non-oncology indications. Azer-cel is an allogeneic (off the shelf) CAR T program, and the Company has near term plans to evaluate the program in multiple autoimmune indications.

CORPORATE INFORMATION

We were incorporated in Delaware in 1993. Our executive offices are located at 3020 Carrington Mill Blvd, Suite 475, Morrisville, North Carolina, 27560. Our telephone number is 1-877-575-TGTX(8489), and our e-mail address is info@tgtxinc.com.

We maintain a website with the address www.tgtherapeutics.com and maintain various social media accounts, including but not limited to X (formerly Twitter) and LinkedIn. We also maintain websites related to BRIUMVI, including but not limited to www.BRIUMVI.com, and www.BRIUMVIPATIENTSUPPORT.com. We make available free of charge through our corporate website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website or our social media accounts as a part of, nor incorporating either by reference into, this report. The SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

In addition, we intend to use our corporate website, SEC filings, press releases, public conference calls and webcasts as well as social media to communicate with our subscribers and the public. It is possible that the information we post on social media could be deemed to be material information. Therefore, in light of the SEC's guidance, we encourage investors, the media and others interested in us to review the information we post on the U.S. social media channels listed on our website.

STRATEGY

As a fully-integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B cell mediated diseases, our key corporate objectives include:

- Successfully commercializing BRIUMVI in the U.S. for relapsing forms of multiple sclerosis;
- Building upon the BRIUMVI approval to evaluate other uses for BRIUMVI in additional MS indications and/or other autoimmune diseases;
- Continuing to expand our pipeline with mechanisms of importance to B-cell mediated diseases;
- Evaluating potential strategic collaborations to maximize the value of our programs and B-cell directed platform; and
- Maintaining our "patient first" culture as we grow our business.

Our Approach and Platform

Our approach to drug development is centered on developing therapies for B-cell mediated diseases. Our process begins by identifying validated targets against B-cell mediated diseases, and then searching for and, ideally, acquiring what we believe to be "best-in-class" compounds with complementary mechanisms against these targets.

Our preference is to identify targets for which there is human clinical proof of concept that the mechanism is active in B-cell mediated diseases and then to identify drug candidates that effectively modulate the desired molecular target. We identify these drug candidates at academic centers of excellence or in development at biotech companies or pharmaceutical companies globally. Our current drug candidates were acquired through license agreements, collaborations, or joint ventures with biopharmaceutical companies located globally. This approach enables us to minimize target risk while looking for the best available drug candidates around the world. By focusing on B-cell mediated diseases and targets with a known activity profile, we believe that we can quickly identify the patients most likely to respond, resulting in a more efficient development path with the potential for a greater likelihood of success.

Our approach is enabled by our clinical development platform which includes an internal team with a deep understanding of B-cell mediated diseases and significant experience successfully obtaining FDA approval for innovative treatments for these complex diseases.

AUTOIMMUNE DISEASE OVERVIEW

An autoimmune disease occurs when the body's immune system attacks and destroys healthy body tissue by mistake. There are currently more than 80 types of autoimmune disorders that have been identified. Some of these diseases may result from inappropriate production of antibodies from the B-cells. These antibodies cannot discriminate "self" from "non-self," and inadvertently mount a disabling immune response against normal organs. Some of these diseases may not be antibody mediated but may still result from aberrant activity of B-cells. Examples of common and very debilitating autoimmune disorders for which abnormally functioning B-cells have been implicated include multiple sclerosis (MS) and rheumatoid arthritis (RA).

The Company's current focus is on MS.

Multiple Sclerosis Overview

RMS is a chronic demyelinating disease of the central nervous system (CNS) and includes people with relapsing-remitting multiple sclerosis (RRMS) and people with secondary progressive multiple sclerosis (SPMS) who continue to experience relapses. RRMS is the most common form of MS and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. MS is the most prevalent chronic inflammatory disease of the CNS. It is estimated that nearly 1 million people are living with MS in the United States and over 2.3 million people world-wide are living with MS.

OUR PRODUCTS

We currently license worldwide development and commercial rights, subject to certain limited geographical restrictions, for all of our products under development. The following table summarizes the current status for our lead drug candidates as of February 2024.

Clinical Drug Candidate: (molecular target)	**Initial Target Disease**	**Stage of Development (trial name)**
Ublituximab (anti-CD20 mAb)	Relapsing Forms of Multiple Sclerosis (RMS)	APPROVED
TG-1701 (BTK inhibitor)	B-cell disorders	Phase 1 trial
TG-1801 (anti-CD47/CD19 bispecific mAb)	B-cell disorders	Phase 1 trial
Azer-cel	Auto-immune disorders	Phase 1 (pending)

BRIUMVI (ublituximab-xiiy) Overview

BRIUMVI is the first and only anti-CD20 monoclonal antibody approved for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, that can be administered in a twice a year one-hour infusion following the starting dose.

Late-Stage Clinical Development of Ublituximab-xiiy

ULTIMATE I & II Trials Evaluating Single Agent Ublituximab in RMS: ULTIMATE I and ULTIMATE II are two independent Phase 3 trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study evaluating the efficacy and safety/tolerability of ublituximab-xiiy (450mg dose administered by one hour intravenous infusion every six months, following a Day 1 infusion of 150mg over four hours, and a Day 15 infusion of 450mg over one hour) to teriflunomide (14mg oral tablets taken once daily) in subjects with RMS. The primary endpoint for each study was ARR following 96 weeks of treatment. This program was led by Lawrence Steinman, MD, George A. Zimmermann Professor and Professor of Pediatrics, Neurology and Neurological Sciences at Stanford University.

In December 2020, we announced positive topline results from the ULTIMATE I & II trials. Both studies met their primary endpoint of significantly reducing ARR over a 96-week period ($p<0.005$ in each study) with ublituximab-xiiy demonstrating an ARR of <0.10 in each of the studies. Relative reductions of approximately 60% and 50% in ARR over teriflunomide were observed in ULTIMATE I & II, respectively. Key secondary magnetic resonance imaging (MRI) endpoints were also met.

On August 22, 2022, the full results from the ULTIMATE I & II trials were published in the New England Journal of Medicine.

ENHANCE Phase 3b Trial: On October 11, 2023, we presented the first data from the ENHANCE Phase 3b trial evaluating BRIUMVI in patients with RMS who switch from another anti-CD20 therapy to BRIUMVI. The presentation occurred at the 2023 European Committee for Treatment and Research in Multiple Sclerosis Annual Meeting. In this study, patients with low levels of B-cells as pre-specified in the protocol are eligible to proceed directly to a full dose of BRIUMVI 450mg without receiving a 150 mg loading dose. As of the presentation, 13 patients switched from Ocrevus to BRIUMVI 450mg as a 2-hour infusion with no infusion related reactions reported and no unexpected side effects. An additional 2 patients switched from Ocrevus to BRIUMVI 450mg as a 1-hour infusion again with no infusion related reactions reported and no unexpected side effects. The study has continued to enroll patients at 450mg as a 1-hour infusion and additional data is expected to be reported during the course of 2024.

U.S. Commercialization of BRIUMVI (ublituximab-xiiy)

On December 28, 2022, we announced the FDA approval of BRIUMVI (ublituximab-xiiy) for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, primarily based on results from the ULTIMATE I & II Phase 3 trials, and on January 26, 2023, we announced the U.S. commercial launch of BRIUMVI, making it available to physicians and patients. On July 1, 2023, the permanent J-Code for BRIUMVI (J2329) became effective.

Ex-U.S. Commercialization of BRIUMVI

On June 1, 2023, we announced that the EC granted approval of BRIUMVI for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features. With this approval, the centralized marketing authorization is valid in all EU member states, Iceland, Norway and Liechtenstein.

On August 1, 2023, we announced an agreement with Neuraxpharm, a leading European specialty pharmaceutical company focused on the treatment of CNS disorders, for the Ex-US commercialization of BRIUMVI. Under the terms of the commercialization agreement, we received an upfront payment of $140 million, and are eligible to receive an additional $12.5 million upon launch in the first EU country and up to an additional $492.5 million in milestone-based payments on achievement of certain launch and commercial milestones. The total deal is valued at up to $645 million in upfront and milestone payments. In addition, we will receive tiered double-digit royalties on net product sales up to 30%. In exchange, Neuraxpharm will have the exclusive right to commercialize BRIUMVI in certain territories outside the United States, Canada and Mexico, the commercialization rights for which had been previously retained by TG, thus excluding certain Asian countries subject to previously existing partnerships. We retain an option to buy back all rights under the commercialization agreement for a period of two years in the event of a change in control of TG.

On November 1, 2023, we announced that we also received approval by the MHRA for BRIUMVI to treat adult patients with RMS with active disease defined by clinical or imaging features in the UK.

On February 26, 2024, we announced the commercial launch of BRIUMVI in the European Union (EU) by Neuraxpharm, with BRIUMVI made available for commercial sale in Germany, with additional EU markets expected to follow.

TG-1701 (BTK inhibitor) Overview

TG-1701 is a novel, orally available and covalently-bound Bruton's tyrosine kinase (BTK) inhibitor that exhibits strong selectivity to BTK in *in vitro* kinase screening.

B-cell receptor (BCR) signaling is crucial for normal B-cell development and supports the survival and growth of B-cells.

We are currently evaluating TG-1701 in a Phase 1, multi-center, dose-escalation clinical trial in patients with B-cell malignancies. Data from this trial was last presented at the 2021 American Society of Hematology (ASH) annual meeting.

TG-1801 (anti-CD47/anti-CD19 bispecific monoclonal antibody) Overview

TG-1801 is a potentially first-in-class, bispecific CD47 and CD19 antibody. It is the first therapy to target both CD19, a B-cell specific marker widely expressed across B-cell malignancies, and CD47, the "don't eat me" signal used by both healthy and tumor cells to evade macrophage mediated phagocytosis.

In the first quarter of 2019, we commenced a Phase 1 first-in-human, dose-escalation study of TG-1801 in patients with B-cell lymphoma. In December 2022, preliminary results from this first-in-human Phase 1 study were presented at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition. TG-1801 was well tolerated as monotherapy and in combination with ublituximab with no maximum tolerable dose (MTD) identified and exhibited preliminary signs of efficacy in a variety of relapsed or refractory B-cell lymphomas.

In the first half of 2021, we commenced a second Phase 1 study of TG-1801 in the U.S. to continue dose optimization as monotherapy.

Azercabtagene Zapreleucel (azer-cel)

Azer-cel is an allogeneic (off-the-shelf) CD19 CAR T cell therapy program for autoimmune diseases and all other non-oncology indications. Made from donor-derived T cells modified using a proprietary ARCUS genome editing technology, azer-cel recognizes the well characterized B-cell surface protein CD19, an important and validated target in several B-cell cancers and autoimmune diseases. Azer-cel is designed to avoid graft-versus-host disease (GvHD), a significant complication associated with other donor-derived, cell-based therapies. The Company has near term plans to evaluate the program in autoimmune indications.

INTELLECTUAL PROPERTY AND PATENTS

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge, trade secrets, proprietary information and experience we call "know-how." To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees and consultants. There can be no assurance, however, that we can prevent unauthorized disclosure or use of our trade secrets, know-how and proprietary information despite the existence of confidentiality agreements.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity or are effectively maintained as trade secrets. We have a number of issued patents and pending patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our issued patents and pending patent applications or that we were the first to file patent applications covering such inventions. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Therefore, we cannot predict the breadth of claims that may be ultimately allowed from our pending patent applications, cannot predict whether the claims in our issued patents will be invalidated or modified through the district courts, Patent Trial and Appeal Board (PTAB) proceedings, or reexamination proceedings at the United States Patent and Trademark Office (USPTO), and thus cannot predict the enforceability of the claims in our issued patents or the claims that may ultimately issue from our pending patent applications. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us in a pending patent application or issued patent, we may have to participate in interference proceedings to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability to be extended through the patent restoration program, although any such extension could still be minimal. If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of litigation involving a third-party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need

to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

Moreover, physicians may prescribe such a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent or prosecute.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of any FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the term of certain types of patents for up to five years as compensation for patent term lost during the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an Investigational New Drug (IND) application and the submission date of a New Drug Application (NDA) or BLA plus the time between the submission date of an NDA or BLA and the approval of that application. The calculation is subject to several subtractions for any portion of the regulatory review process that occurred before the date the patent was issued and any portion during which the FDA determined a lack of due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent, and within 60 days of a product's approval. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Following the approval of BRIUMVI in the U.S., we have applied for patent term extensions for certain of our issued U.S. patents covering our product and/or their methods of use. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug and have been filed for in certain European Patent (EP) countries.

Also, under the Hatch-Waxman Act, drugs that are new chemical entities (NCEs) are eligible for a five-year period of marketing exclusivity in the United States. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The Hatch-Waxman Act also provides three years of marketing exclusivity for a drug product that contains an active moiety that has been previously approved, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations. During this period, FDA will not approve an application filed by a third party for the protected conditions of use that relies on any of the data from the new clinical investigations that was submitted by the innovator company. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA that does not rely on the innovator company's data.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated pathway for companies to bring biologic drugs to market that are biosimilar to previously approved branded reference products by relying on clinical studies that were performed by the reference product sponsor. The BPCIA also created a 12-year period of data exclusivity for innovator biologics, whereby the FDA cannot approve a biological license application (BLA) for a biosimilar product relying on data for a specific reference product until 12 years after the reference product is first licensed. BLA supplements are not eligible for any additional exclusivity. The objectives of the BPCIA are conceptually similar to those of the Hatch-Waxman Act described above. The implementation of an abbreviated approval pathway for biosimilar products is under the direction of the FDA. Since the enactment of the BPCIA, the FDA has issued guidance on biosimilars, addressing scientific, quality and procedural issues relevant to an abbreviated application for a biosimilar product. As of December 2022, the FDA had approved 40 biosimilar products.

Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

We, or those companies from which we have licensed our drug candidates, file patent applications directed to our drug candidates in an effort to establish intellectual property positions regarding these new chemical entities as well as uses of these new chemical entities in the treatment of diseases. We also file patent applications directed to novel combinations of our drugs together and with drugs developed by others. The intellectual property portfolios for our most advanced drug candidates as of February 2024 are summarized below. Each of these portfolios contains one or more pending patent applications covering our products and product candidates and uses and combinations thereof. For those patents, prosecution is in progress. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO is often significantly narrowed by the time they issue, if they issue at all. This may be the case with respect to our pending patent applications referred to below.

BRIUMVI (ublituximab-xiiy)

Pursuant to our license for ublituximab with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, we have the exclusive commercial rights to a series of patents and patent applications in the U.S. and in multiple countries around the world, as well as a non-exclusive license to additional background patent rights. These patents and patent applications include composition of matter patents relating to the structure and mechanism of action for ublituximab, as well as method of use patents which cover use of ublituximab in combination with various agents and for various therapeutic indications.

Our earliest in time patent families relate to compositions of matter for ublituximab, which has been issued in the U.S., Europe and other jurisdictions, including Australia, Canada, China, Japan, Korea and India. The expected expiration for the composition of matter patent is 2029 in the U.S. and 2025 in Europe and other non-U.S. jurisdictions, exclusive of patent term extensions, which could result in later expiration dates. We also have a method of use patent on the combination of UKONIQ and ublituximab, which has been issued in the U.S., Europe, and other jurisdictions, including Australia, China, Korea, and Japan, and is pending in other territories.

Our most recently filed patent family relates to compositions of matter comprising ublituximab, methods of manufacturing those compositions and methods for treating multiple sclerosis using those compositions. This family includes three issued U.S. patents and one recently allowed U.S. application. We also have patent applications pending in this family in the U.S., Argentina, the EU and Taiwan. The Patent Cooperation Treaty application , from which further national phase applications may be filed, is also pending. Patents issuing from this family may first begin to expire as early as 2042.

In the U.S., the Biologics Price Competition and Innovation Act provides that BRIUMVI is eligible for 12 years of market exclusivity from the date of BRIUMVI's U.S. approval. During this 12 year period a biosimilar product that references our BRIUMVI product, cannot be approved.

TG-1701 (BTK inhibitor)

Pursuant to our license agreement with Jiangsu Hengrui Medicine Co. (Hengrui), we have the exclusive commercial rights in the treatment of hematologic cancers to a patent family which covers the composition of matter and proposed methods of use for various therapeutic indications in the U.S. and certain other countries. Patents directed to the compound have granted in the U.S., Europe, and other jurisdictions, including Australia, Canada, Japan, China, and Korea and are expected to expire no sooner than October 2034. Applications are pending in other jurisdictions.

TG-1801 (anti-CD47/anti-CD19 bispecific antibody)

Pursuant to our joint venture and license option agreement with Novimmune SA (Novimmune), we maintain an exclusive option, exercisable at specific times during development, to license the commercial rights to a series of global patent applications and patents, and the non-exclusive right to certain technology patent applications. Patents directed to a bispecific antibody have issued in Australia, China, Europe, Japan, and Russia and are pending in other jurisdictions including the U.S. Any patents maturing from these pending applications are expected to expire no sooner than December 2033.

Azer-Cel (allogeneic CD19 CAR T)

Pursuant to our license agreement with Precision, we have an exclusive license to develop and commercialize Precision's azer-cel for the treatment of autoimmune and other non-oncology diseases and conditions as well as a non-exclusive license to manufacture azer-cel. The license agreement includes non-exclusive rights to a series of patents and patent applications in the U.S. and in multiple countries around the world, as well as non-exclusive rights to additional background patent rights. These patents and patent applications include composition of matter patents relating to azer-cel, as well as method of use patents which cover use of azer-cel.

Limitations on Patent Rights and Trade Secrets

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market these product candidates. See "*Item 1A – Risk Factors -- Risks Related to the Company's Intellectual Property.*" In addition, the limited patent protection may adversely affect the value of our products or product candidates and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

Proof of direct infringement by a competitor for method of use patents can prove difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, proof that a competitor contributes to or induces infringement of a patented method of use by another can also prove difficult because an off-label use of a product could prohibit a finding of contributory infringement, and inducement of infringement requires proof of intent by the competitor.

LICENSING AGREEMENTS AND COLLABORATIONS

We have formed strategic alliances with a number of companies for the manufacture and commercialization of our products. Our current key strategic alliances are discussed below.

BRIUMVI (ublituximab-xiiy)

LFB Biotechnologies S.A.S, GTC Biotherapeutics, LFB/GTC LLC.

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the LFB License Agreement). Under the terms of the LFB License Agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. As of December 31, 2022, we have incurred expenses of approximately $25.0 million related to milestones in accordance with the terms of the LFB License Agreement, $12.0 million of which was incurred in December of 2022 related to a milestone associated with receiving approval of BRIUMVI by the FDA. LFB Group is eligible to receive future payments of approximately $6.0 million, upon our successful achievement of certain regulatory milestones, in addition to royalty payments on net sales of ublituximab at a royalty rate in the high-single digits. The license will terminate on a country-by-country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by LFB if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party.

Ildong Pharmaceutical Co. Ltd.(Ildong)

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of ublituximab in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize ublituximab in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar. To date, we have received $2 million in the form of an upfront payment from Ildong and are eligible to receive sales-based milestone payments up to an aggregate of $5 million and royalty payments on net sales of ublituximab at a royalty rate that escalates from mid-teens to high-teens upon approval in South Korea and/or Southeast Asia. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by Ildong if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party.

Neuraxpharm

In August 2023, we entered into an agreement with Neuraxpharm, for the ex-U.S. commercialization of BRIUMVI. Under the terms of the commercialization agreement, we received an upfront payment of $140 million and are eligible to receive an additional $12.5 million upon launch in the first EU country and up to an additional $492.5 million in milestone-based payments on achievement of certain launch and commercial milestones. The total deal is valued at up to $645 million in upfront and milestone payments. In addition, we will receive tiered double-digit royalties on net product sales up to 30%. In exchange, Neuraxpharm will have the exclusive right to commercialize BRIUMVI in certain territories outside the United States, Canada and Mexico, the commercialization rights for which had been previously retained by TG, thus excluding certain Asian countries subject to previously existing partnerships. We retain an option to buy back all rights under the commercialization agreement for a period of two years in the event of a change in control of TG.

TG-1701 (BTK inhibitor)

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui, to acquire worldwide intellectual property rights, excluding Asia but including Japan, and for the research, development, manufacturing, and commercialization of products containing or comprising of any of Hengrui's Bruton's Tyrosine Kinase inhibitors containing the compounds of either TG 1701 (SHR1459 or EBI1459) or TG1702 (SHR1266 or EBI1266). Hengrui is eligible to receive milestone payments totaling approximately $350 million upon and subject to the achievement of certain milestones. Various provisions allow for payments in conjunction with the agreement to be made in cash or our common stock, while others limit the form of payment. In July 2020, we paid Hengrui $2.0 million as part of a milestone in accordance with the license agreement. Royalty payments in the low double digits are due on net sales of licensed products and revenue from sublicenses.

The term of the agreement expires after the expiration of the last royalty term to expire with respect to any of the patent rights under the agreement. We or Hengrui may terminate the agreement upon notice to the other upon breach without remedy or upon insolvency. In addition, either party may terminate the agreement upon a material breach, after providing the other party with adequate notice and allowing 45 days to cure.

TG-1801 (anti-CD47/anti-CD19 bispecific antibody)

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune to collaborate on the development and commercialization of Novimmune's novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG 1801 (previously NI 1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies. We serve as the primary responsible party for the development, manufacturing and commercialization of the product. Milestone payments will be paid based on early clinical development, and the Company will be responsible for the costs of clinical development of the product through the end of the Phase 2 clinical trials, after which the Company and Novimmune will be jointly responsible for all development and commercialization costs. The Company and Novimmune will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TG 1801, in which case Novimmune is eligible to receive additional milestone payments totaling approximately $185 million as well as tiered royalties on net sales in the high single to low double digits upon and subject to the achievement of certain milestones.

Azer-Cel (allogeneic CD19 CAR T)

In January 2024, we, through our wholly-owned subsidiary, TG Cell Therapy, Inc., entered into a global exclusive license agreement with Precision to develop and commercialize azer-cel for autoimmune diseases and all other non-oncology indications. Pursuant to such license Agreement, the Company made an upfront payment to Precision of $7.5 million, consisting of (i) $5.25 million in cash and (ii) $2.25 million as an equity investment. The Company will make an additional deferred payment of $2.5 million to Precision as an equity investment to Precision within 12 months at a pre-specified premium. Upon achievement of certain near-term clinical or time-based milestones, the Company will make a further $7.5 million payment to Precision, a portion of which will also be an equity investment in Precision's common stock at a pre-specified premium. Precision will be eligible to receive up to $288 million in additional milestone payments based on the achievement of certain clinical, regulatory and commercial milestones. In addition, the Company is obligated to pay Precision high-single-digit to low-double-digit royalties on net sales of the licensed product on a country-by-country basis until the latest to occur of patent expiration, loss of regulatory exclusivity or a period of ten years following the first commercial sale of the licensed product in such country. The Company has also agreed to make certain payments to Precision's licensors during the term of our license agreement with Precision.

UKONIQ (umbralisib)

In September 2014, we exercised our option to license the global rights to umbralisib, thereby entering into an exclusive licensing agreement (the Umbralisib License) with Rhizen Pharmaceuticals, S A (Rhizen) for the development and commercialization of umbralisib. Rhizen is eligible to receive approval and sales-based milestone payments in the aggregate of approximately $175 million. Additionally, Rhizen receives tiered royalties that escalate from high single digits to low double digits on any net sales of umbralisib. The license will terminate on a country-by-country basis upon the expiration of the last licensed patent right or any other exclusivity right in such country, unless the agreement is earlier terminated (i) by us for any reason, or (ii) by either party due to a breach of the agreement.

Cosibelimab

In March 2015, we entered into a global collaboration (the Collaboration Agreement) with Checkpoint Therapeutics, Inc. (Checkpoint) for the development and commercialization of Checkpoint's anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies with an option to acquire rights in autoimmune diseases. In September 2023, we terminated this agreement and have no remaining obligations or commitments under the Collaboration Agreement.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. The resulting changes in standard of care can impact the likelihood of regulatory accelerated approval opportunities for our drug candidates.

For BRIUMVI, there are a number of established therapies with which we will compete:

- We expect BRIUMVI will primarily compete against other iv CD20-targeted agents, while the group of CD20-targeted agents will also compete broadly against a number of already approved MS therapies. Currently, there is one other approved intravenously delivered anti-CD20 monoclonal antibody ocrelizumab (Roche Holdings AG). In addition, while we believe not directly competitive, there is also a subcutaneous anti-CD20 monoclonal antibody approved for MS, ofatumumab (Novartis AG).

TG-1701, TG-1801 and azer-cel, if approved will also face competition from drugs on the market and under development in the same therapeutic class as each of those drugs.

Additional information can be found under Item "1A - Risk Factors – Other Risks Related to Our Business" within this report.

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities of our own. We have established a contract manufacturing relationship for the commercial supply of BRIUMVI with Samsung Biologics. As with any supply program, obtaining materials of sufficient quality and quantity to meet the requirements of the market demand for BRIUMVI and our ublituximab development programs cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

To the extent possible and commercially practicable, we plan to develop back-up strategies for raw materials, manufacturing and testing services for our commercial products. Given the long lead times and cost of establishing additional commercial manufacturing sites we expect that we will rely on single contract manufacturers to produce our commercial products under current Good Manufacturing Practice, or cGMP, regulations for many years. Our commercial manufacturing partners have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration if applicable, and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations. Where manufactured products are globally registered, similar regulatory inspection burdens are applicable from each and every marketed territory. If our manufacturing partners are inspected and deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies may need to approve these new manufacturers in advance, which will involve testing, regulatory submissions, and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATION

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our product candidates, as well as our ongoing research and development activities. We, along with our third-party contractors, will be required to navigate the various pre- and post-approval requirements of the governing regulatory agencies of the jurisdictions in which we wish to conduct clinical studies or market our product candidates. None of our product candidates, except BRIUMVI, are approved for sale in any market in which we have marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory review and approval process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA) and, in the case of biologics, the Public Health Service Act. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, quality control and assurance, record keeping, pharmacovigilance and adverse event reporting, packaging, labeling, storage, advertising, promotion, import and export, sale and distribution of biopharmaceutical products. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Product Development and Applications for Marketing Authorization

The regulatory review and approval process is lengthy, expensive, and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources, and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

For purposes of clinical development and to pursue NDA or BLA approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1:* The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.
- Phase 2: Studies are conducted on more patients to assess the product's efficacy, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- *Phase 3:* Studies establish safety and efficacy in an expanded patient population.
- *Phase 4:* The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted. In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the drug candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.

In December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan (DAP) for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, DAPs must include the sponsor's goals for enrollment, the underlying rationale for those goals and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

For clinical trials that are intended to form the basis of a new drug or biologics license application for approval, sponsors of drugs may apply for a Special Protocol Assessment (SPA) from the FDA, by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols. While obtaining an SPA provides some assurance the design of a trial should be sufficient for approval, the final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its expedited drug development programs. A sponsor can apply for Fast Track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application, or NDA. To receive Fast Track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition; and
- that nonclinical or clinical data demonstrate the potential to address an unmet medical need.

The FDA must respond to a request for Fast Track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a Fast Track development program must continue to meet the criteria for Fast Track designation. Sponsors of products in Fast Track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in Fast Track drug development programs are also permitted to submit portions of an NDA or BLA to the FDA on a rolling basis where the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application.

In addition, sponsors may also apply to the FDA for Breakthrough Therapy Designation (BTD). The procedures and requirements for BTD are similar to those required for Fast Track such that the Breakthrough Therapy Designation is intended to expedite the development and review of a potential new drug for serious or life-threatening diseases, however, with BTD, there is a further requirement that the sponsor present "preliminary clinical evidence" which "indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a drug as a Breakthrough Therapy was enacted as part of the 2012 Food and Drug Administration Safety and Innovation Act.

Sponsors of drugs granted Fast Track or breakthrough therapy designation also may seek approval under the FDA's accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. To obtain accelerated approval a sponsor must be able to demonstrate the drug candidate treats a serious condition, provides a meaningful advantage over other available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. Many companies have filed for accelerated approval and have subsequently failed to obtain such approval for a variety of reasons. To the extent a product does obtain an accelerated approval, such approval will be subject to the requirement that the applicant study the drug further in a post-marketing confirmatory clinical trial to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Accelerated approval is sometimes referred to as conditional approval because if the results of these confirmatory clinical trials fail to verify clinical benefit, the FDA has the right to remove the drug from the market and has done so in the recent past. Post-marketing confirmation studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing confirmation studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing confirmation studies with due diligence. Completing the required post-approval clinical studies as designed can be difficult, especially as the treatment landscape evolves.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of an NDA/BLA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

The NDA and BLA review process also generally includes a pre-approval inspection, or PAI, to assess the manufacturing facilities and relevant processes and data for compliance, and readiness for commercial manufacture in accordance with cGMPs. Among the conditions of approval is the requirement that a manufacturer's quality systems and manufacturing procedures conform to cGMP. Even when product approval is received, manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic surveillance inspections to monitor the manufacturing process and drug quality and evaluate whether the manufacturers are in compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure. Many drug approvals have been delayed due to issues at contract manufacturing facilities. If we were to experience any such delay that would negatively impact our business and timeline to commercialization of any of our drug candidates affected by such manufacturing issue.

Post-Approval Requirements

Any products for which we receive FDA approval are subject to continuing regulation by the FDA and other federal and state regulators on a wide range of matters, including, among other things cGMPs and product quality, pharmacovigilance and reporting of adverse events, product distribution requirements, fulfilling post-marketing or confirmatory study or REMS commitments, and complying with FDA promotion and advertising requirements. Violations of the FDCA or other post-approval regulatory requirements may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

The FDA promotion and advertising requirements applicable to marketed products include, among other things, standards for direct-to-consumer advertising, restrictions against promoting products for uses or in patient populations that are not either described in the product's approved indications and uses or otherwise consistent with the FDA-approved product labeling, limitations on industry-sponsored scientific and educational activities, rules regarding communication of health care economic information regarding biopharmaceutical products to payors and formularies, and requirements for promotional activities involving the internet. Drugs whose review was accelerated may carry additional requirements on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA.

After product approval, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements. FDA regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMPs. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments and list their products with the FDA and certain state agencies. Manufacturers and their third-party contractors may be subject to periodic unannounced inspections by the FDA and certain state agencies for assessment of compliance with cGMPs and other applicable laws. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain quality control and manufacturing compliance. Discovery of problems with a product after approval may result in restrictions on a product, including, among other things, withdrawal of approval, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval or notification before being implemented. Other types of changes to the approved product, such as adding new indications and claims to the product labeling, are also subject to further FDA review and approval.

Marketed products must meet the requirements of the Drug Supply Chain Security Act, or DSCSA, which regulates the commercial distribution of prescription drug products at the federal level. The DSCSA sets certain standards for federal or state registration, requires tracing of products through the pharmaceutical distribution supply chain, and imposes other requirements on entities in the supply chain, including manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in per the DSCSA implementation timeline established by the FDA.

In addition, the post-marketing discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance documents, and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Should we wish to market our products outside the U.S., we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. Importantly, the level of evidence of efficacy and safety necessary to apply for marketing authorization for a drug candidate differs from country to country. In particular, clinical trial endpoints, and the level of clinical evidence that may support, for example, an accelerated approval filing with the FDA, may be insufficient to file for marketing applications outside of the U.S. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the European Union, centralized registration procedures are available to companies wishing to market a product across the European Union member states. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Coverage and Reimbursement

Sales of our drugs will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical drugs and services. In addition, the containment of healthcare costs has become a priority of foreign and U.S. federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, importation, and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, enacted in March 2010, has had a significant impact on the health care industry. The Affordable Care Act expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the Affordable Care Act, among other things, created a new average manufacturer price definition under the Medicaid Drug Rebate Program for drugs that are inhaled, infused, instilled, implanted or injected and not generally dispensed through the retail channel, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period (subsequent legislation increased this to 70% effective as of January 1, 2019), as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since the enactment of the Affordable Care Act, certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Although litigation and legislation over the Affordable Care Act are likely to continue, with unpredictable and uncertain results, we expect that the Biden administration may seek to expand and strengthen the Affordable Care Act.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the Act), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. Specifically, the Act authorizes and directs the Department of Health and Human Services (the DHHS) to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs selected on August 29, 2023, and the first year of maximum price applicability to begin in 2026. The Act further authorizes the DHHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. Finally, the Act creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending at $2,000 beginning in 2025. We cannot be sure whether additional or related legislation or rulemaking will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control prescription drug pricing, including price and marketing cost disclosure and transparency measures, and, in some cases, authorizing importation of prescription drugs from other countries. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products or put pressure on our product pricing. We expect that additional state healthcare reform measures will be adopted in the future, which could limit the amounts that state governments will pay for healthcare products and services and result in additional pricing pressures.

In addition, in some foreign countries, the proposed pricing for a prescription drug must be approved before the drug may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the United Kingdom and many European Union member states have robust health technology assessment processes to determine pricing and reimbursement for pharmaceuticals through their national health insurance system. Many European Union members states also include either direct or indirect price referencing, or other price control mechanisms, in determining the price of a pharmaceutical in their market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical drugs will allow favorable reimbursement and pricing arrangements for any of our products. Historically, drugs launched in the European Union do not follow price structures of the U.S. and generally tend to be significantly lower.

Other U.S. Healthcare Laws

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation: state and federal anti-kickback, fraud and abuse, false claims, privacy and security laws; laws governing interactions with healthcare professionals and related transparency requirements (such as the federal Sunshine Act and a range of state biopharmaceutical marketing and transparency laws); and requirements for manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs. The compliance and enforcement landscape is informed by government enforcement precedent and settlement history, Advisory Opinions, and Special Fraud Alerts. The risks we face and our approach to compliance may evolve over time in light of these types of developments. The potential safe harbors available for, example, relative to the Anti-Kickback Statute, are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or paying remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on research, consulting and other financial arrangements with physicians that the government alleged were not based on the provision of bona fide services and were intended as an inducement or reward. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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 False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, the civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, (HIPAA), also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposes reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit annual reports to the Centers for Medicare & Medicaid Services, which publicly posts the data on its website. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, (HITECH), and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, according to the U.S. Federal Trade Commission, (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data 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 improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required under HIPAA.

In addition, we may be subject to state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Protection Act, (CCPA), which went into effect on January 1, 2020, established a privacy framework for covered businesses by creating an expanded definition of personal information, data privacy rights for consumers in California, and a potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The CCPA was recently amended by the California Privacy Rights Act (CPRA), expanding certain consumer rights such as the right to know. It remains unclear what, if any, additional modifications will be made to these laws by the California legislature or how these laws will be interpreted and enforced. The potential effects of the CCPA and CPRA are significant and may cause us to incur substantial costs and expenses to comply.

Rest of the World Healthcare Regulation

For other countries outside of the U.S. and the European Union, the requirements governing the conduct of clinical trials, drug licensing, sales and marketing, pricing and reimbursement vary from country to country. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

European Union member states, the United Kingdom, Switzerland, and other foreign jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the European Union and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR, together with national legislation, regulations and guidelines of the European Union member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the European Union or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business to ensure full compliance. Furthermore, European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the European Union or United Kingdom.

Human Capital

As of February 26, 2024, we had 264 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage.

We believe that our future success largely depends upon our continued ability to attract and retain a diverse workforce of highly skilled and dedicated employees. We pride ourselves on being an equal opportunity employer and strictly prohibit unlawful discrimination based on color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital and veteran status.

We expect to continue to grow our organization to support the commercialization of BRIUMVI and to enhance our overall development capabilities for current or future products under development. As part of that process, we will continue to evaluate the business needs and market opportunities, balancing in-house expertise and core competencies with outsourced capacity.

Drug development and commercialization requires deep expertise across a broad array of disciplines. Pharmaceutical companies of all sizes compete for a limited number of qualified applicants to fill specialized positions. To attract qualified candidates, the Company offers an attractive total rewards package, consisting of base salary, cash bonus, a comprehensive benefit package, equity compensation, and 401(k) plan. Bonus opportunities and equity compensation increase as a percentage of total compensation based on level of responsibility, and actual bonus awards are based on performance.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risk factors and the other information contained elsewhere in this Annual Report before making an investment in our securities. If any of the following risks occur, our business, financial condition or operating results could be materially harmed. An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. The risks described below are not the only ones that our business faces. Additional risks not currently known to us or that we currently deem to be immaterial may adversely impact our business in the future.

Risks Related to Commercialization

If we obtain U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approval for a product candidate and do not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from product sales will be limited.

We currently have one marketed product, BRIUMVI, which received approval from the FDA on December 28, 2022, for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Additionally, BRIUMVI received approval from the European Commission (EC) on June 1, 2023, and later in 2023, from the Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of adult patients with RMS who have active disease defined by clinical or imaging features in the EU and UK, respectively.

While we have initiated the commercial launch of BRIUMVI in the U.S., we have limited experience as a commercial company, and our ability to successfully overcome the risks associated with commercializing drugs in the biopharmaceutical industry, including the risk that our products do not achieve an adequate level of acceptance, remains uncertain. BRIUMVI, as well as other drugs that we may bring to the market in the future, may not gain market acceptance by physicians, patients, third-party payors and others in the healthcare community. As a result, we may not generate significant revenues or meet our revenue projections or guidance and may not become profitable. The degree of market acceptance of BRIUMVI, as well as any future product candidates for which we may receive marketing approval, will depend on a number of factors, including:

- the timing of our receipt of marketing approvals, the terms of such approvals, and the countries in which such approvals are obtained;
- the efficacy, safety and tolerability as demonstrated in clinical trials and as compared to alternative treatments;
- the timing of market introduction of BRIUMVI and any of our product candidates, as well as competitive products;
- the indications for which our products are approved, and other aspects of the approved labeling for such products;
- acceptance by physicians, advanced practitioners, major operators of neurology clinics, and patients of our products as safe, tolerable and effective treatments;
- the potential and perceived advantages or disadvantages of our products compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the availability of adequate reimbursement by third-party payors and government authorities;
- the extent of patient cost-sharing obligations, including copays and deductibles;
- changes in regulatory requirements by government authorities for our products;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of our sales and marketing efforts, as well as those of any current or future partners;
- protecting our rights in our intellectual property portfolio;
- our ability to maintain a reliable supply of our products that meets market demand; and
- favorable or unfavorable publicity relating to our products or relating to the Company.

In addition, global health concerns such as the COVID-19 pandemic could impact commercialization of BRIUMVI. Patients and healthcare providers have raised concerns that immunosuppressive products like anti-CD20 antibodies and other B-cell targeted agents may increase the risk of acquiring viruses such as COVID-19 or lead to more severe complications or outcomes upon infection, including death. These or other similar concerns may impact the commercial potential for BRIUMVI and other immunosuppressive products that we have in development.

If BRIUMVI, or any future product candidates for which we receive regulatory approval, do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become or remain profitable, which would have a material adverse effect on our business.

We may be subject to limitations on the indicated uses or requirements to fulfill certain post-marketing requirements to the satisfaction of regulatory authorities or may be unable to maintain marketing approval for BRIUMVI or future products that we may bring to market.

Regulatory approvals for our product or any of our product candidates may be subject to conditions and limitations on the approved indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the approved product candidate. For example, with respect to the FDA's approval of BRIUMVI for RMS, the approval is subject to certain post-marketing requirements and commitments, including long-term safety studies, as well as studies to evaluate the effects of BRIUMVI in pregnant women and pediatric populations, among others. Similar post-approval studies are required by other regulatory authorities outside of the U.S., including but not limited to, the EMA in the EU and the MHRA in the United Kingdom (UK). These studies are highly specialized in their design and conduct and are associated with considerable expenses, and based on the outcome, could result in further labeling restrictions that could impair or restrict the way in which we are able to market BRIUMVI, or negatively impact its overall clinical profile.

In addition, with respect to BRIUMVI and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices (cGMPs), with Good Clinical Practices (GCPs), for any clinical trials that we conduct post-approval, and with Good Laboratory Practices (GLPs), for any nonclinical studies. Later discovery of previously unknown problems with a product or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things, restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, mandatory safety labeling changes or product recalls, suspension or revocation of product approvals, product seizure or detention, refusal to permit the import or export of products, and injunctions or the imposition of civil or criminal penalties, all of which would adversely affect our business, prospects and ability to achieve or sustain profitability.

BRIUMVI, and any of our product candidates for which we in the future obtain approval, may, after approval, be found to cause undesirable side effects that could result in significant negative consequences following commercialization.

As BRIUMVI or any future approved products are used more widely or for a longer duration after being brought to market, data may emerge from clinical studies, including confirmatory or other post-marketing studies, or from adverse event reporting, that may affect the commercial potential of our products. For example, as additional patients are exposed for longer durations to a product in the commercial and clinical settings, it is unknown whether greater frequency and/or severity of adverse events are likely to occur or whether an acceptable safety and tolerability profile will continue to be demonstrated. If we or others identify unexpected side effects caused by BRIUMVI or other products or product candidates within the RMS space following introduction into the market, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval or limit the approved indications for use of such products;
- regulatory authorities may require the addition of new or different labeling statements, including warnings or boxed warnings, precautions, or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way such drug candidates are distributed or administered, or to conduct additional clinical trials;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy (REMS), a plan to mitigate risks, which could include a Medication Guide, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug candidates from the marketplace;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products; and
- our reputation may suffer.

Any one or a combination of these events could prevent us from maintaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the affected product, which in turn could significantly impact our ability to successfully commercialize our drug candidates and generate revenues.

The incidence and prevalence for target patient populations of BRIUMVI and our product candidates, including TG-1701 and TG-1801 in B-cell disorders and azer-cel in non-oncology indications, have not been established with precision. If the market opportunities for BRIUMVI and our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected.

The precise incidence and/or prevalence of RMS are unknown. Our projections for BRIUMVI in RMS are based on estimates and our current knowledge and understanding of the disease. These estimates are typically based on one-on-one and group interactions with target physicians and other sources available at the time we make the estimates, including the scientific literature, healthcare utilization databases and market research. Although we believe our estimates are reasonable, many factors may limit their accuracy. For example, the sources we use to make the estimates may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases and the number of patients may turn out to be lower than expected.

The total addressable market opportunity for BRIUMVI and our product candidates, if approved, ultimately depends upon, among other things, the approved prescribing information, acceptance by the medical community, patient access, and drug pricing and reimbursement. The number of patients in major markets, including the number of addressable patients in those markets, may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, new patients may become increasingly difficult to identify or gain access to, patients and physicians may choose to utilize competitive products or reimbursement may be unfavorable, all of which would adversely affect our results of operations and our business.

We face substantial competition, which may result in others commercializing drugs before or more successfully than we do resulting in the reduction or elimination of our commercial opportunity.

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and commercialization resources. Large pharmaceutical companies have extensive experience commercializing products and may have significant existing relationships with customers and more resources available to them to promote their products. Many are active in the same diseases that we are, including within the neurological and immunological fields, some in direct competition with us. We may also compete with these organizations to recruit commercial and other key personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are more effective, have fewer or less severe side effects, are more convenient or are priced or contracted differently than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. In a competitive environment, a company's communications may also be subject to heightened scrutiny from regulators and competitors, under laws, regulations, and guidance about promotional communications (advertising and promotional labeling) and non-promotional communications (e.g., certain educational and scientific exchange); and with regard to potential competitor actions under federal law (the Lanham Act) and congruous state law, which protect businesses against the unfair competition of misleading advertising or labeling.

The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic or biosimilar competition and the availability of reimbursement from government and other third-party payors.

New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. These developments may render our product or product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- pharmaceutical development, clinical trial and pharmaceutical commercialization experience;
- experience and expertise in exploitation of intellectual property rights; and
- capital resources.

We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites, patient registration for clinical trials, and in identifying and in-licensing new products and product candidates.

BRIUMVI, as well as any products that we are able to commercialize in the future, may become subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products, even if more of our product candidates obtain marketing approval. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent. On April 27, 2023, we received a product-specific J-Code for BRIUMVI (J2329), which became effective July 1, 2023 and is expected to help reduce reluctance by physicians to prescribe BRIUMVI based on reimbursement concerns. However, some third-party payors may nevertheless still require documented proof that patients meet certain eligibility criteria in order to be reimbursed for BRIUMVI.

Our ability to commercialize any product successfully also will depend in part on the extent to which coverage and reimbursement for our products and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement and co-payment levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by restricting coverage and limiting the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs, examining the cost effectiveness of drugs in addition to their safety and efficacy. Third-party commercial payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Payors may restrict coverage of some products by using formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payor more expensive for patients, and utilization management controls, such as requirements for prior authorization or failure first on another type of treatment. Payors may target higher-priced drugs for imposition of these obstacles to coverage, and consequently our products may be subject to payor-driven restrictions. Additionally, in countries where patients have access to insurance, as in the U.S., insurance co-payment amounts or other benefit limits may represent a barrier to obtaining or continuing use of our products that receive regulatory approval. If we are unable to obtain or maintain coverage, or coverage is reduced in one or more countries, our product sales may be lower than anticipated and our financial condition could be harmed.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices. In the United States, for example, we must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, such as the Medicaid Drug Rebate Program, the 340B drug pricing program and the Medicare Part D Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program and Medicare Part B. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose us to penalties.

If we are unable to expand our commercialization operations, we may not be successful in commercializing BRIUMVI or any product candidate, if and when such product candidates are approved, and we may not be able to generate revenue.

Commercialization of pharmaceutical products is an extremely complex and highly capital and resource-intensive process. Even for established companies with existing infrastructure and significantly greater resources than we have, challenges have occurred.

We have made and continue to make significant investments in our commercial organization and infrastructure. We built processes and systems to support the commercialization of BRIUMVI following its commercial launch on January 26, 2023. There are risks involved with establishing our own commercialization capabilities. For example, if we are unable to recruit and retain adequate numbers of effective personnel to support the ongoing commercialization of BRIUMVI, we may not be successful in marketing and selling the product.

Additional factors that may inhibit our efforts to commercialize BRIUMVI and our other product candidates on our own, or through partnership, and generate product revenues include:

- the costs and time associated with the initial and ongoing training of commercialization personnel on the applicable disease states, products, competitors, and legal and regulatory compliance matters;
- the inability of commercialization personnel to obtain access to physicians or to effectively promote or provide education about BRIUMVI and any future approved products;
- the lack of complementary drugs to be offered by the Company, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- decisions by third-party payors to deny reimbursement of or delay coverage decisions regarding BRIUMVI or following approval of any product candidates;
- our inability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring;
- our inability to establish and maintain commercial partnerships outside the U.S.;
- our inability, or the inability of a third party with whom we have partnered, to maintain the necessary regulatory approvals required to operate in markets outside of the U.S.;
- the timing of product availability for commercial sale following approval and continued product supply; and
- unforeseen costs and expenses associated with creating a commercialization organization.

In addition, we have entered into a commercialization agreement, and may enter into additional agreements in the future, that facilitate commercialization of BRIUMVI and/or future products that receive approval in markets outside the U.S. through partnerships. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any products or product candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product or product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

We believe there is potential market opportunity for BRIUMVI outside of the U.S., including in the EU. We have entered into a commercialization agreement for the sale of BRIUMVI in certain territories outside the U.S., Canada and Mexico, the commercialization rights for which had been previously retained by TG, thus excluding certain Asian countries subject to previously existing partnerships, and we also may enter into certain collaboration and/or commercialization agreements with third parties in the future to facilitate market expansion. To the extent we do expand into other markets outside of the U.S. in which we are responsible for building and maintaining a commercial infrastructure, we expect to incur significant expenses in establishing an infrastructure to commercialize our drug products. Depending on the expenses incurred, it could have a negative impact on our cash resources.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any drug candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and an even greater risk in connection with the commercialization of BRIUMVI and any other products for which we may receive marketing authorization in the future. If we cannot successfully defend ourselves against claims that BRIUMVI or any of our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products that we may commercialize;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation, including the risk that any individuals who may face such related litigation may in turn seek to recover from us;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products or product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception, and we may incur losses in the future.

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in January 2012. To date, our operations have been limited primarily to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential drug candidates, undertaking pre-clinical studies and clinical trials, commercializing UKONIQ (withdrawn from sale) and launching and commercializing BRIUMVI. We are transitioning from a company with a research and development focus and commercialization capabilities in oncology to a company capable of supporting commercial activities in neurology and immunology in the U.S. and outside the U.S. This transition involves a wide variety of risks, and we may not be successful in such transition.

Since inception, we have focused our efforts and financial resources on clinical trials, manufacturing of our product and product candidates and preparing to support a commercial product. To date, we have financed our operations primarily through public offerings of our common stock and debt financing. Since inception, we have incurred significant operating losses. Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our prior losses, combined with expected future losses, have had, and will continue to have an adverse effect on our stockholders' deficit and working capital. BRIUMVI is currently our only marketed product. We expect to continue to incur significant research and development expenses, and we expect to continue to incur significant commercialization and outsourced-manufacturing expenses as we commercialize BRIUMVI. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

To become and remain profitable, we must succeed in developing (or in-licensing) and commercializing our products or product candidates that generate significant revenue. It is uncertain when and if we will generate any significant revenue from the sale of our product or any product candidates, if approved, in the future. Furthermore, no assurance can be given that we will meet revenue projections or guidance with respect to BRIUMVI or our product candidates, if approved. To obtain significant and sustained revenues and meet our revenue projections or guidance, we must succeed, either alone or with others, in (i) obtaining and maintaining regulatory approval for our product and product candidates; and (ii) manufacturing and marketing our product and product candidates. Our ability to generate sustained revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete clinical trials that meet their clinical endpoints;
- initiate and successfully complete all safety, pharmacokinetic, biodistribution, and non-clinical studies required to obtain U.S. and foreign marketing approval for our product and product candidates;
- obtain approval from the FDA and foreign equivalents to market and sell our product and product candidates, and maintain FDA and EMA approvals of BRIUMVI for RMS;
- establish and maintain commercial manufacturing capabilities with third parties that are satisfactory to the regulatory authorities, cost effective, and that are capable of providing commercial supply of our product and product candidates;
- expand on our commercialization infrastructure to commercialize BRIUMVI, and/or entering into collaborations with third parties; and
- achieve market acceptance of BRIUMVI and any other products for which we may receive regulatory approval in the medical community and with third-party payors.

If we are unable to generate significant and sustained revenues, we will not become profitable and we will be unable to continue our operations without continued funding.

While we do not expect to need to raise additional capital, we may need to do so. If we are unable to raise capital, if needed, we may be required to delay, limit, reduce or eliminate some of our drug development programs or commercialization efforts.

The development of pharmaceuticals is capital-intensive. We are also continuing to generate additional clinical data for BRIUMVI to support and potentially expand commercial adoption, including assessing long-term tolerability in an Open-Label Extension of the Phase 3 ULTIMATE I and II trials and Phase 4 clinical studies necessary to satisfy post-approval commitments for regulatory authorities or those undertaken voluntarily by the Company to evaluate the use of BRIUMVI in alternate settings or with alternate methods of administration. Moreover, now that we have launched BRIUMVI, we will need to expend substantial resources on maintaining approvals and continuing commercialization, manufacturing and distribution over the foreseeable future. Additionally, we expect to commence a trial evaluating azer-cel in autoimmune disease in 2024. We are also currently advancing our early-stage drug candidates, TG-1701 and TG-1801 in ongoing Phase 1 studies to identify tolerable and efficacious doses.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to, the following:

- the success of the commercialization of BRIUMVI and any other products for which we receive regulatory approval;
- the costs and timing of clinical and commercial manufacturing supply arrangements for each product and product candidate;
- the costs of expanding our sales, distribution, and other commercialization capabilities;
- the costs and timing of regulatory approvals;
- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable under our license agreements;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the costs involved in enforcing or defending patent claims or other intellectual property rights; and
- the extent to which we in-license or invest in other indications or product candidates.

As a result, significant additional funding may be required. Additional sources of financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we could be forced to discontinue product development, reduce or forego commercialization efforts that are required for successful commercialization of BRIUMVI or any of our product candidates and otherwise forego attractive business opportunities. Any additional sources of financing may involve the issuance of our equity securities, which would have a dilutive effect to stockholders. Currently, other than BRIUMVI, our products are investigational and have not been approved by the FDA or any foreign regulatory authority for sale. For the foreseeable future, we will have to fund all our operations and capital expenditures from sales of BRIUMVI, cash on hand and amounts raised in future offerings or financings. Accordingly, our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of commercial operations and the competitive environment in which we operate.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates and occupy valuable management time and resources.

Until such time, if ever, as we can generate substantial revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances, licensing agreements or other arrangements. We do not have any committed external source of funds, other than funds already borrowed under the loan and security agreement that we entered into with Hercules in February 2019, amended and restated in December 2021 and amended on March 31, 2023 (*see* Note 7 to our consolidated financial statements for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. We may also seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or products and product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, which could limit our ability to expand our business operations and could harm our overall business prospects.

Additionally, fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. Dislocations in the financial markets have generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. Moreover, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline.

Due to limited resources, we may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for a product candidate could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing, sale or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. If any of the aforementioned events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

In February 2019, we entered into a Loan and Security Agreement, with Hercules Capital, Inc., a Maryland corporation (Hercules), and on December 30, 2021 (the Amendment Closing Date), the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules. Under the Amended Loan Agreement, Hercules increased the aggregate principal amount of the loan, available at the Company's option, from $60.0 million to $200.0 million. On March 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended Loan Agreement (the First Amendment) with Hercules. An advance of $25.0 million was drawn at the First Amendment Effective Date (*see* Note 7 to our consolidated financial statements for more information). We have the option to request additional loan advances in an aggregate principal amount of up to $85.0 million under the First Amendment.

All obligations under the Amended Loan Agreement, as amended, are secured by substantially all our existing property and assets, excluding intellectual property. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing its outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- we will need to repay the indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the restrictive covenants in the Amended Loan Agreement, as amended, could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce its security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

We may not have cash available in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Failure to satisfy our current and future debt obligations under the Amended Loan Agreement, as amended,, or the breach of any of its covenants, subject to specified cure periods with respect to certain breaches, could result in an event of default and, as a result, Hercules could accelerate all the amounts due. In the event of an acceleration of amounts due under the Amended Loan Agreement, as amended, as a result of an event of default, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the term loan for its benefit, which collateral includes substantially all our property other than intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

The Amended Loan Agreement, as amended, imposes operating and other restrictions on the Company. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- dispose of certain assets;
- change its lines of business;
- engage in mergers, acquisitions or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make contributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

The breach of any of these restrictive covenants could have a material adverse effect on our business and prospects.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

On March 10, 2023, the Federal Deposit Insurance Corporation (FDIC) announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation, and on March 12, 2023, Signature Bank was closed by the New York State Department of Financial Services, and the FDIC was named receiver. Although we did not maintain any bank accounts with Silicon Valley Bank or Signature Bank, we regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Any failure of a depository institution to return any of our deposits, or any other adverse conditions in the financial or credit markets affecting depository institutions, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

Risks Related to Drug Development and Regulatory Approval

If we are unable to obtain and maintain regulatory approval for our product and product candidates and ultimately cannot successfully commercialize our product or product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our ability to generate revenues from product sales will depend largely on the successful commercialization of BRIUMVI. Each of our product candidates will require additional non-clinical or clinical development, regulatory approval, and sufficient clinical and commercial supply. The success of our development programs and achievement of regulatory approval of our product candidates will depend on several factors, including, among others, the following:

- successful completion of our clinical programs with positive results that support a finding of effectiveness and an acceptable safety profile of our product candidates in the intended populations within the timeframes we have projected;
- Investigational New Drugs (INDs) and clinical trial applications (CTAs), being cleared/approved such that our product candidates can commence clinical trials;
- successful initiation and completion of preclinical studies and successful initiation of, enrollment in, and completion of clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for our product candidates;
- establishing commercially viable arrangements with third-party manufacturers for clinical supply and commercial manufacturing; and
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our clinical programs and regulatory submission timelines and may not be able to obtain regulatory approval for our product candidates.

Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, "***top-line,***" ***and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed.***

Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate, through adequate and well-controlled clinical trials, that our product candidates are effective with a favorable benefit-risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising pre-clinical results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

Individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. In addition, larger scale Phase 3 studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region or country to country basis, which could materially adversely affect the outcome of the study or the opinion of the validity of the study results by applicable regulatory agencies.

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data from the particular study or trial, including all endpoints and safety data. As a result, top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline, interim, or preliminary data we previously published. When providing top-line results, we may disclose the primary endpoint of a study before all secondary endpoints have been fully analyzed. A positive primary endpoint does not translate to all, or any, secondary endpoints being met. As a result, top-line and preliminary data should be viewed with caution until the final data are available, including data from the full safety analysis and the final analysis of all endpoints.

Further, from time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, time-to-event based endpoints such as duration of response (DOR) and progression-free survival (PFS), and continuously observed data such as annualized relapse rate (ARR) have the potential to change with longer follow-up. In addition, as patients continue on therapy, there can be no assurance given that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions we have reached, our ability to obtain approval for, or successfully commercialize, our product or product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Many of the results reported in our early clinical trials rely on local investigator-assessed efficacy outcomes which may be subject to greater variability or subjectivity than results assessed in a blinded, independent, centrally reviewed manner, often required of later phase, adequate and well-controlled registration-directed clinical trials. If the results from our registration-directed trials are different from the results found in the earlier studies, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. It is impossible to predict when or if our product candidates will prove effective and safe in humans, will receive regulatory approval or will have a differentiated safety and tolerability profile. A failure of one or more clinical trials can occur at any stage of testing. Accordingly, our ongoing trials and future clinical trials may not be successful. Even if our clinical trials produce positive results, there can be no guarantee that the positive outcomes will be replicated in future studies either within the same indication as previously evaluated or in alternate indications and settings.

Successful completion of our clinical trials is a prerequisite to submitting a New Drug Application (NDA) or a Biologics License Application (BLA) to the FDA and a Marketing Authorization Application (MAA) to the EMA for each product candidate and, consequently, the ultimate approval and commercial marketing of our product candidates. We do not know whether any of our ongoing or future clinical trials for our product candidates will be completed on schedule, if at all.

Whether or not and how quickly we complete clinical trials depends in part upon the rate at which we are able to engage clinical research/trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same diseases that we are studying. We may experience unforeseen events, such as the COVID-19 pandemic, that could delay or prevent our ability to complete current clinical trials, initiate new trials, receive marketing approval or commercialize our product candidates, including:

- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- the FDA or other regulatory authorities or institutional review boards (IRBs) or ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or in a country; we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations (CROs), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional pre-clinical studies or clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, and enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors, including our clinical trial sites, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to or regulatory authorities or IRBs or ECs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including, without limitation, as a result of disruptions to our supply chains caused by global health crises, such as the COVID-19 pandemic, international conflicts such as the Russian invasion of Ukraine or the Israel-Hamas war, economic instability, or natural disasters;
- regulatory authorities may revise the requirements applicable to our product candidates, or such requirements may not be as we anticipate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities, IRBs or ECs to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other therapies in the same or a similar class that raise safety or efficacy concerns about our product candidates.

We also could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data and Safety Monitoring Board (DSMB) for such trial or by the FDA or other regulatory authorities. Such regulatory authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition to the FDA, the DSMB for our clinical trials may recommend modification to the study design or closure of the study entirely based on the DSMB's interpretation of the benefit-risk of the study. While we develop charters that guide the nature of the DSMB meetings, their analysis and interpretation of study data occurs independently from us and is wholly within their control. Even if the DSMB finds no safety concerns and recommends no modifications to the ongoing study, this does not mean the safety profile reported in the study may support a marketing approval or commercial acceptance if marketing approval is granted. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Negative or inconclusive results from the clinical trials we conduct, unanticipated adverse medical events, or changes in regulatory policy could cause us to have to delay, repeat or terminate the clinical trials. If we are required to repeat or conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements or post-marketing commitments;
- be subject to increased pricing pressure; or
- have the drug removed from the market after obtaining marketing approval.

In addition, changes in regulatory policy could cause us to have to repeat or conduct additional clinical trials or change our clinical development strategy. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. If we are not able to adhere to these new requirements, our ability to conduct clinical trials may be delayed or halted. Our drug development costs will also increase if we experience delays in testing or regulatory approvals. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower-than-expected event rates. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. Any delays in our pre-clinical or future clinical development programs may harm our business, financial condition and prospects significantly. We may also incur additional costs if enrollment is increased.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site or the FDA's acceptance of such data, may be jeopardized.

Biologics carry unique risks and uncertainties, which could have a negative impact on our business.

The successful development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited, and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture. Failure to successfully, develop, manufacture and sell BRIUMVI could adversely affect our business.

Our product or product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or impact their availability and commercial potential after approval.

Unexpected or undesirable adverse events caused by BRIUMVI or any of our product candidates that we take into clinical trials could cause either a DSMB or regulatory authorities to interrupt, delay, modify or suspend clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Even if a product candidate has obtained marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. This could prevent us from commercializing the affected product candidate and generating revenues from its sale.

As is the case with all drugs, it is likely that there will be side effects associated with the use of our drug candidates. Results of our trials could reveal a higher than expected and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to discontinue an ongoing trial or deny approval of our drug candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, data may emerge, from confirmatory or other post-marketing studies, or from pharmacovigilance reporting, as products are used more widely, or for a longer duration, after approval that may affect the commercial potential of our products. Any of these occurrences may harm our business, financial condition and prospects significantly.

Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. Further, early clinical trials by their nature utilize a small sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and serious side effects of our drug candidates may only be uncovered when a significantly larger number of patients are exposed to the drug candidate in Phase 3 or registration-directed trials or when the drug candidate is on the market. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale, or even if approved for sale may lack differentiation from competitive products, which could have a material adverse impact on our business and operations. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of BRIUMVI or our other product candidates may only be uncovered with a significantly larger number of patients exposed to the product.

Any products or product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, and pharmacovigilance and adverse event reporting of our product or product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable regulatory authorities worldwide. In the United States, we are not permitted to market a product candidate until we receive approval of a BLA or NDA from the FDA. The process of obtaining a BLA or NDA approval is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, approval policies or regulations may change over time. If we fail to gain approval to commercialize our product candidates from the FDA and other foreign regulatory authorities in the timelines we project or at all, we may be unable to generate the revenues that we may project or generate revenues at levels sufficient to sustain our business.

The FDA and foreign regulatory authorities have complete control over the pharmaceutical product approval process, including substantial discretion to delay, limit or deny approval of a product candidate for many reasons. During the regulatory review process, the FDA or other regulatory authorities may disagree with or not accept our clinical trial design, may have questions about the potential impact of our study design on conclusions that can be drawn from the data, may interpret results differently than we do, may apply the results of our trials in one disease to the review of a regulatory application for a different disease even if the doses and therapeutic areas are distinct, and may change its view on the criteria that must be met for approval. This could happen even for a protocol used to support a trial that is subject to an SPA agreement with the FDA. There is no guarantee that the FDA will not delay, limit or deny approval of our product candidates in the future.

Furthermore, some of our clinical trials may be conducted as open-label studies, meaning that trial participants, investigators, site staff, some employees of our CROs, and our field-level employees (e.g., clinical research associates and monitors), among others, have knowledge of treatment arm assignments on a patient-level, which has the potential to introduce bias into study conduct. Further, even when our clinical trials are double-blind, double-dummy studies, unblinding of treatment arm assignment may occur from time to time, for example, on the occurrence of unexpected safety events which may necessitate understanding of study treatment. While we believe we have put in place adequate firewalls to prevent inappropriate unblinding of study data consistent with standard industry practice for these types of studies, no assurance can be given that issues related to study conduct will not be raised. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the study design or data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee in evaluating (among other things) clinical data and safety and effectiveness considerations prior to making its final decision. These issues could cause a delay in the FDA's review, lead the FDA to deny approval, or lead the Company to withdraw a regulatory application.

Other reasons that the FDA or regulatory authorities around the world may delay, limit or deny approval of a product candidate, include:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is tolerable and effective for an indication;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care or the patient population, is potentially different from that of the United States;
- the results of clinical trials 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 product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies and/or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other marketing authorization submission to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may identify issues related to the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators currently contract for clinical supplies and plan to contract for commercial supplies; during the course of review, the FDA or foreign regulatory authorities may raise issues and request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC), or other data and information, and the development and provision of these data and information may be time consuming. We may not be able to generate the data within the time period necessary to obtain approval within the established regulatory review timelines, such as by a PDUFA goal date or at all to satisfy the FDA or foreign regulatory authorities;
- the approval processes of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; or
- interruptions or delays in the operations of the FDA and foreign regulatory authorities as a result of global health or economic crises, such as the COVID-19 pandemic, international conflict, or national disasters may negatively impact review, inspection, and approval timelines.

Even if we succeed in obtaining regulatory approval for a product candidate, the FDA may require post-marketing studies, including additional clinical trials such as those necessary to assess drug interactions or activity of a product in specific populations, which may be costly. The outcomes of post-marketing studies may impact product labeling and therefore, there can be no guarantee that the product attributes contained in the initial prescribing information will be maintained as future studies produce data. This includes, without limitation, additional results from studies evaluating drug-drug interactions and patients with certain comorbidities that may restrict the use of an approved product in select populations or introduce dose modifications or contraindicated concomitant medications that have the potential to impact the utility of a product or its perceived product profile among prescribers. Post-marketing studies may also lead to the introduction of new warnings in the product prescribing information. The FDA may require adoption of a REMS program requiring prescriber training or a post-marketing registry or may restrict the marketing and dissemination of our products. Finally, failure to complete a post-marketing commitment by the applicable post-marketing milestone date may lead to withdrawal of the product or indication. Any requirements to conduct post-approval studies or fulfill special post-approval requirements could impact our ability to commercialize our product or product candidates and increase our costs.

A Breakthrough Therapy or Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek Breakthrough Therapy or Fast Track designation for some of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition, and the drug demonstrates the potential to address an unmet medical need for this condition, the Sponsor may apply for Fast Track designation or Breakthrough Therapy designation, the latter of which has more significant requirements. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular drug candidate is eligible for such a designation, we cannot be sure that the FDA would decide to grant it. Even if we receive Breakthrough Therapy or Fast Track designation for a drug candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A drug that receives Fast Track designation is eligible for more frequent interactions with the FDA, priority review if relevant criteria are met, and rolling submission of the BLA or NDA. Even if rolling review is allowed, there is no guarantee that the FDA will have commenced or completed review of the BLA or NDA modules submitted earlier in the rolling review process. Neither Breakthrough Therapy nor Fast Track designation guarantees Priority Review of an NDA or BLA application.

We may seek orphan drug designation for some of our drug candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States, the European Union, and the United Kingdom, may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. Orphan drug designations are required to be maintained through annual reporting and are subject to re-evaluation. Based on the evolving data and development plans for our product candidates and changing incidence and prevalence rates for our intended indications, there can be no guarantee that we will be able to successfully maintain orphan drug designations that we have for certain of our drug candidates or that we will be successful in obtaining orphan designation for other drug candidates in the future.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes FDA or EMA from approving another marketing application for the same drug or biologic for that time period. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another product that meets the definition of a “same drug” under 21 C.F.R. 316.3 for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA exercises its authority to revoke orphan drug designation, which it may do on a variety of grounds, including that the request contained an untrue statement of material fact or omitted material information, or that the drug in fact was not eligible for orphan drug designation. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to seek orphan drug designation for our other drug candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations or obtain orphan drug exclusivity. In addition, the U.S. Orphan Drug Act may be subject to amendments that could reduce the period of marketing exclusivity or change the qualifications for orphan drug designation, which could adversely impact our products or product candidates that have or may be eligible for orphan drug designation.

We are conducting clinical trials and anticipate conducting additional clinical trials for our product and product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or clinical trial activities in such locations may be impacted by political conditions, including international conflict.

Many of our clinical trials utilize international clinical research sites. We work with what we believe are reputable CROs and clinical research sites in conducting our studies internationally. Nevertheless, there can be heightened challenges to monitoring and oversight of global clinical trials and sponsors are subject to the risk that fraud, misconduct, incompetence, unexpected patient variability and other issues affecting the reliability, quality, and outcome of studies. The geographic variability of the COVID-19 pandemic also introduces increased risk in the conduct of clinical research in certain countries and territories where vaccination rates and available standard of care anti-viral therapy varies significantly. Such problems, if they were to occur, could negatively impact trial results, and depending on the circumstances and scope of concerns could potentially even prevent a trial from being useful or acceptable for regulatory approval. If such events were to occur with respect to any of our trials (and in particular with respect to registration-directed studies), they would have a substantial negative impact on our business.

In addition, our clinical studies with sites outside the United States may be adversely impacted by international conflict. For example, in February 2022, Russia initiated a full-scale military invasion of Ukraine. In one or both countries, as well as neighboring countries that may be impacted by this conflict (e.g. Poland, Slovakia, Belarus, Georgia), we have clinical trial sites for our RMS and/or oncology programs. While no clinical trials are actively enrolling patients in these territories, there are a number of trial subjects in long-term treatment and follow-up. The political and physical conditions in Russia and Ukraine have disrupted our ability to supply investigational drug product to impacted sites; impacted patients' ability to partake in our clinical trials and our ability to gather data on those patients, including long-term follow-up data; and resulted in suspension of clinical trial activities at impacted sites. Furthermore, the United States and its European allies have imposed significant sanctions against Russia and Belarus, including regional embargoes, full blocking sanctions, and other restrictions targeting major Russian financial institutions. Specifically, such sanctions have included, among other things, a prohibition on doing business with certain Russian companies, officials, and oligarchs; a commitment by certain countries and the European Union to remove selected Russian banks from the Society for Worldwide Interbank Financial Telecommunications (SWIFT) electronic banking network that connects banks globally; and restrictive measures to prevent the Russian Central Bank from undermining the impact of the sanctions. Our ability to conduct clinical trials in Russia, Belarus, Ukraine and elsewhere in the region may also become restricted under applicable sanctions laws. The conflict, as well as government responses, has resulted in global economic instability, which could affect our supply chain and commercialization efforts. While we do not believe this conflict will have a material impact on product development or our overall business, given the rapidly evolving situation and the potential to expand beyond Ukraine and Russia, the full impact of the conflict remains uncertain.

Approval of one of our product candidates in the United States would not assure approval of that candidate in foreign jurisdictions.

We intend to seek additional product approvals in certain countries outside of the United States. The approval procedures for pharmaceuticals vary among countries and obtaining approval in one jurisdiction does not guarantee approval in another jurisdiction. For example, even if the FDA grants approval of a product candidate comparable regulatory authorities in foreign jurisdictions may not approve the same product candidate, or the same indications for use for the product candidate, or may require additional evidence for approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. In many countries outside the United States, the product must be approved for reimbursement before it can be marketed. As a general matter, however, the foreign regulatory approval process involves a lengthy and challenging process with risks similar or identical to the risks associated with the FDA approval discussed above. Therefore, we cannot guarantee that we, or future collaborators, will obtain approvals of our product and product candidates in any foreign jurisdiction on a timely basis, if at all. Failure to receive approval in certain foreign markets could significantly impact the full market potential of our product and product candidates and may negatively impact the regulatory process in other countries. Furthermore, if we obtain regulatory approval for a product or product candidate in a foreign jurisdiction, we will be subject to the burden of complying with complex regulatory, legal, and other requirements that could be costly and could subject us to additional risks and uncertainties.

We have product candidates still under development and are also engaging manufacturing partners in commercial manufacturing activities, and as such clinical and commercial manufacturing site additions and process improvements implemented in the production of our product and product candidates may affect their timely delivery or quality.

We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities of our own. We have established a contract manufacturing relationship for the commercial supply of BRIUMVI with Samsung Biologics. As with any supply program, obtaining materials of sufficient quality and quantity to meet the requirements of the market demand for BRIUMVI and our development programs cannot be guaranteed and we cannot ensure that we will be successful in these endeavors.

To the extent possible and commercially practicable, we plan to develop back-up strategies for raw materials, manufacturing and testing services for our commercial products. Given the long lead times and cost of establishing additional commercial manufacturing sites we expect that we will rely on single contract manufacturers to produce our commercial products under current Good Manufacturing Practice, or cGMP, regulations for many years. Our commercial manufacturing partners have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for our development programs and any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration, if applicable, and corresponding state agencies to ensure strict compliance with cGMP requirements and other state and federal regulations. Where manufactured products are globally registered, similar regulatory inspection burdens are applicable from each and every marketed territory. If our manufacturing partners are inspected and deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers either before or after commercialization, the FDA and corresponding foreign regulatory agencies may need to approve these new manufacturers in advance, which will involve testing, regulatory submissions, and additional inspections to ensure compliance with FDA and other regulations and standards, and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

Some of our product and product candidates are currently manufactured in relatively small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity and/or analytical profile of the product or product candidates, which may affect the safety and efficacy of the products. It is possible that additional and/or different adverse events may appear among patients exposed to drug product manufactured under one process compared to the other, or that adverse events may arise with greater frequency, intensity and duration among patients exposed to drug product manufactured under one process compared to the other.

Further, no assurance can be given that the material manufactured from any future optimized processes, if any, for BRIUMVI or any of our product candidates will perform comparably to the product or product candidates as manufactured to date which could result in an unexpected safety or efficacy outcome as compared to the data published or presented to date. Similarly, following each round of process improvements, if any, for any of our drug candidates, future clinical trial results conducted with the new material will be subject to uncertainty related to the effects, if any, of those additional process improvements that were made.

Risks Related to Governmental Regulation of Pharmaceutical Industry and Legal Compliance Matters

We are subject to new legislation, regulatory proposals and third-party payor initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes or proposed changes to the healthcare system, many of which have focused on prescription drug pricing and lowering overall healthcare costs, that could impact our ability to sell our products profitably and support future innovation. We expect prescription drug pricing and other healthcare costs to continue to be subject to intense political and social pressures on a global basis.

In the United States, the President, federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of healthcare and addressing public concern over access and affordability of prescription drugs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) was enacted in 2010 and made significant changes to the U.S. healthcare system. ACA changes included expanding healthcare coverage through Medicaid expansion and implementation of the individual health insurance mandate; changing coverage and reimbursement of drug products under government healthcare programs; imposing an annual fee on manufacturers of branded drugs; and expanding government enforcement authority. Although the ACA has been the subject of a number of legislative and litigation challenges since it passed, it is expected that the Biden Administration will seek to strengthen and expand the ACA. We cannot predict what effect, if any, further changes to the ACA would have on our business.

Beyond the ACA, there has been increasing legislative, regulatory and enforcement interest with respect to prescription drug pricing practices. Proposals that may garner bipartisan legislative support or become legislation through reconciliation include adding a cap on out-of-pocket spending under Medicare Part D, authorizing Medicare to negotiate certain drugs covered by Medicare Parts D and B directly with manufacturers, and imposing limits on increases in drug prices. In addition, President Biden may take executive action to introduce new drug pricing models and other drug pricing initiatives. The Biden Administration also may propose substantial changes to the U.S. healthcare system, including expanding government-funded health insurance options. We are uncertain of the impact or outcome of potential Executive Orders, rescission of rules and policy statements, or new legislation, especially any relative impact on the healthcare regulatory and policy landscape, or the impact they may have on our business. We expect drug pricing will continue to be a focus of the Biden Administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, limit price increases, evaluate the relationship between pricing and manufacturer patient programs, and reform government health care program reimbursement methodologies for prescription drugs. For example, the Bipartisan Budget Act of 2018 (the BBA) increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70% effective as of January 1, 2019, ultimately increasing the liability for brand drug manufacturers. We expect that health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased manufactured financial liability and additional downward pressure on the price that we may receive for any of our product candidates, if approved. Any reduction in reimbursement from Medicare or other government health care programs may result in a similar reduction in payments from private payors.

There continue to be efforts to lower drug prices through increased competition, with policy proposals seeking to facilitate generic and biosimilar approval and marketing authorization. For example, in 2018, the FDA announced the Biosimilar Action Plan and sought input on how the agency can best facilitate greater availability of biosimilar products, including input on whether changes to an approved biologic (e.g., a new indication) would be protected by the remainder of the statutory 12-year exclusivity period (commonly referred to as umbrella exclusivity). In the event there is a modification to the biologic exclusivity period or other steps taken to facilitate biosimilar or generic approvals, we could experience biosimilar/generic competition of any products for which we receive FDA approval at an earlier time than currently anticipated.

Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the Act), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. Specifically, the Act authorizes and directs the Department of Health and Human Services (DHHS) to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs selected on August 29, 2023, and the first year of maximum price applicability to begin in 2026. On October 3, 2023, the Centers for Medicare & Medicaid Services announced that all manufacturers of the initially selected drugs opted to participate. The Act further authorizes the DHHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. Finally, the Act creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending at $2,000 beginning in 2025. We cannot be sure whether additional or related legislation or rulemaking will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

At the state level, individual states are experiencing significant economic pressure within their respective Medicaid programs and responding to public concern over the cost of healthcare. States, including California, Florida, Nevada and Maine, among others, have responded to these pressures with a range of legislative enactments and policy proposals designed to control prescription drug prices by, for example, allowing importation of pharmaceutical products from jurisdictions outside the U.S., imposing price controls on state drug purchases, consolidating state drug purchasing to a single purchaser, and imposing transparency measures around prescription drug prices and marketing costs. These measures, which vary by state, could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing.

In addition, other legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' or product candidates' commercial success. More broadly, the Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2030 (except May 1, 2020 to December 31, 2020). Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues.

Furthermore, legislative and regulatory proposals have been made to expand post-approval requirements, make changes the Orphan Drug Act and related guidance, reform the 340B Drug Pricing Program, and restrict sales and promotional activities for drugs. With respect to the 340B Drug Pricing Program recent legislative proposals as well as judicial challenges to DHHS's policies present both opportunities and challenges for drug manufacturers participating in the program. Further, we cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In many international markets, including the European Union, the government regulates prescription drug prices, patient access, and/or reimbursement levels to control the biopharmaceutical budget of their government-sponsored healthcare system. The European Union and some individual countries have announced or implemented measures and may in the future implement new or additional measures, to reduce biopharmaceutical costs to contain the overall level of healthcare expenditures. These measures vary by country and may include, among other things, non-coverage decisions, patient access restrictions, international price referencing, mandatory discounts or rebates, and cross-border sales of prescription drugs. These measures may adversely affect our ability to generate revenues or commercialize our product or product candidates in certain international markets.

There likely will continue to be pressure on prescription drug prices globally and legislative and regulatory proposals, including at the federal and state levels in the U.S., directed at broadening the availability of health care and containing or lowering the cost of health care products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, health insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect, among other things:

- our ability to generate revenues and achieve or maintain profitability;
- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

Our relationships with customers and third-party payors are subject to applicable fraud and abuse laws, false claims laws, transparency and disclosure laws, health information and security laws, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

With the FDA and EMA approval of BRIUMVI, we are subject to additional extensive healthcare statutory and regulatory requirements and oversight by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our past, current and future relationships, arrangements and interactions with these professionals and entities, as well as with patients and patient advocacy organizations expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product and product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute or the Federal Food, Drug, and Cosmetic Act (FDCA) constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the Physician Payments Sunshine Act under section 6002 of the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to monitor and report certain information related to payments and other transfers of value to and the ownership and investment interests of physicians and certain other healthcare providers as well as teaching hospitals to the federal government for redisclosure to the public;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- a wide range of federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers including those related to privacy;
- the FDCA and its implementing regulations, which among other things, strictly regulate drug product marketing and prohibit manufacturers from promotion and marketing of products prior to approval or for uses inconsistent with the FDA-required labeling;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
    - the Drug Supply Chain Security Act (DSCSA), which imposes obligations on entities in the commercial product supply chain, including manufacturers, to identify and track prescription drugs as they are distributed in the U.S.; and
- state law equivalents of some of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

As we continue commercialization of BRIUMVI, we are taking steps to provide patient support services to help patients access the product. Our patient support programs are administered in conjunction with a patient support program vendor and other third parties. There has been heightened governmental scrutiny over the scope of patient support programs and the manner in which drug manufacturers and their vendors operate such programs. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws, regulations, or evolving government guidance on patient support programs. A government investigation, regardless of its outcome, could impact our business practices, harm our reputation, divert attention of management, increase our expenses and reduce availability of assistance to patients. If we or our vendors are deemed to fail to comply with relevant laws, regulations or government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will 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. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Advisory Opinions, and Special Fraud Alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the federal Anti-Kickback Statute are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations.

If we violate applicable data privacy and security laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, reputation harm and the curtailment or restructuring of our operations.

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store 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 with the potential to affect our business.

Within the United States, various federal and state laws regulate the privacy and security of personal information and so may affect our business operations. For example, at the federal level, our operations may be affected by the data privacy and security provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations. HIPAA affects the ability of healthcare providers and other entities with which we may interact, including clinical trial sites, to disclose patient health information to us. Under Section 5(a) of the Federal Trade Commission Act (FTCA), the Federal Trade Commission (FTC) expects a company's data 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 improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements. For example, the California Consumer Privacy Act (CCPA), went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information. Colorado, Connecticut, Utah, Virginia and Iowa have also enacted data privacy statutes, and both California and Colorado are also undergoing or have undergone rulemaking procedures to finalize regulatory regimes to supplement their privacy statutes.

Numerous other jurisdictions regulate the privacy and security of personally identifiable data. For example, the processing of personal data in the European Economic Area (EEA), is subject to the General Data Protection Regulation (GDPR), which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected individuals, as well as how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the EC to lack an adequate level of data protection, such as the United States. In July 2020, the Court of Justice of the European Union invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S., which decision may lead to increased scrutiny on data transfers from the EEA to the U.S. generally and increase our costs of compliance with data privacy legislation.

If our operations are found to be in violation of any data privacy and security laws, rules or regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, rules or regulations, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated, particularly because the requirements and government interpretations of the requirements in this space are constantly evolving. Any action against us for violation of these laws, rules or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

If we fail to adequately understand and comply with the local laws and customs as we expand into new international markets, these operations may incur losses or otherwise adversely affect our business and results of operations.

We expect to operate a portion of our business in certain countries through subsidiaries or through supply, marketing, and distributor arrangements. In those countries where we have limited experience in operating subsidiaries and in reviewing equity investees, we will be subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and multiple and possibly overlapping tax laws. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries or with international operations generally. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees hired in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries, and it may adversely affect our business and results of our operations. In all interactions with foreign regulatory authorities and other government agencies, we are exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

Any product for which we obtain marketing approval, including BRIUMVI, could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products.

Any regulatory approvals that we receive for our drug candidates may be subject to limitations on the indicated uses for which the drug may be marketed or to conditions of approval that may require potentially costly post-marketing clinical trials or surveillance to monitor safety and efficacy of the drug candidate. In addition, any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA, EMA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding promotional interactions with healthcare professionals.

Failure to comply with these regulatory requirements or later discovery of previously unknown problems with products, manufacturers, or manufacturing processes, may result in actions such as:

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or other advisory actions;
- request for withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we or our subsidiaries submit;
- recalls;
- suspension or termination of ongoing clinical trials;
- fines, restitutions, or disgorgement of profits or revenues;
- refusal to permit the import or export of products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA's or EMA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We also cannot predict the likelihood, nature, or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad.

If we, or our respective suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we, our subsidiaries, or our respective collaborators may be subject to the actions listed above, including losing marketing approval for products, resulting in decreased revenue from milestones, product sales or royalties.

If we or any of our contract manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

Our third-party manufacturers, suppliers, and we are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, release, disposal of, and exposure to, hazardous and regulated materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures, and those of our third-party manufacturers, for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future releases.

Risks Related to Our Dependence on Third Parties

We rely on third parties to generate clinical, preclinical and other data necessary to support the regulatory applications needed to conduct clinical trials and submit for marketing approval. We rely on third parties to help conduct our planned clinical trials. If these third parties do not perform their services as required, we may not be able to obtain regulatory approval for or commercialize our product or product candidates when expected or at all.

In order to submit an IND, BLA, or NDA to the FDA and maintain these applications, it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. Clinical trial applications and marketing authorization applications for foreign regulatory bodies have substantially similar requirements. We rely on our third-party contractors and our licensing partners to provide portions of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs and commercialization efforts.

Additionally, we use CROs to assist in the conduct of our current clinical trials and expect to use such services for future clinical trials and we rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and appropriate regulations. Our current and future CROs, investigators and other third parties play a significant role in the conduct of our trials and the subsequent collection and analysis of data from the clinical trials. There is no guarantee that any CROs, investigators and other third parties will devote adequate time and resources to our clinical trials or perform as contractually required. If any third parties upon whom we rely for administration and conduct of our clinical trials fail to meet expected deadlines, fail to adhere to its clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated, and we may not be able to commercialize our product or product candidates. In addition to the third parties identified above, we are also heavily reliant on the conduct of our patients enrolled to our studies by our third-party investigators. We rely on our clinical trial sites and investigators to properly identify and screen eligible candidates for our clinical trials, and for them to ensure participants adhere to our clinical protocol requirements. The majority of our clinical trial conduct occurs in the outpatient setting, where patients are expected to continue to adhere to our study protocol specified requirements. The ability of our enrolled patients to properly identify, document, and report adverse events; take protocol specified study drugs at the correct quantity, time, and setting, as applicable; avoid contraindicated medications; and comply with other protocol specified procedures such as returning to the trial site for scheduled laboratory and disease assessments, is wholly out of our control. Deviations from protocol procedures, such as those identified previously, could materially affect the quality of our clinical trial data, and therefore ultimately affect our ability to develop and commercialize our drug candidates. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. If any of our clinical trial sites is required by the FDA or IRB to close down due to data management or patient management or any other issues, we may lose clinical trial subjects.

Whether conducted through a CRO or through our internal staff, we are solely responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or other enforcement actions that may include civil penalties or criminal prosecution. We and our CROs are required to comply with regulations, including GCP guidelines for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drug candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, clinical investigators, CROs, institutional review boards, and non-clinical laboratories. If we, our CROs, our investigators or other third parties fail to comply with applicable GCPs, 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, the FDA will determine that our current or future clinical trials comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMP regulations. Our failure or the failure of our CROs or CMOs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register most ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, e.g., ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

CROs play an important role in the conduct of our clinical trials, especially outside of the United States. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current or future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our drug candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our drug candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product or product candidates. As a result, we believe that our financial results and the commercial prospects for our product or product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of BRIUMVI for commercial supply, as well as all of our clinical product supply, and we expect to continue to do so. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture, testing, packaging and labeling of any products that we commercialize and our product candidates for pre-clinical development and clinical testing. For example, we currently rely on Samsung Biologics for clinical and commercial supply of BRIUMVI. In addition, we utilize multiple vendors who provide testing services. Our reliance on third parties increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by contract manufacturers to manufacture, test, package, and label our product and product candidates typically undergo periodic inspections by the FDA or a comparable foreign regulatory authority to verify compliance with applicable cGMP regulations. Additional inspections may be conducted after we submit our marketing applications to or receive marketing approval from the FDA or a comparable foreign regulatory authority. Although the FDA and other regulators impose requirements regarding our selection, qualification, oversight, and monitoring of our contract manufacturers and hold us responsible for the ultimate compliance of our products, we do not directly control the manufacturing process of our third-party contract manufacturers and are subject to risks associated with their ability to comply with cGMPs in connection with the manufacture of our products and product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others and the compliance concerns cannot be resolved, remediated, or otherwise addressed to the FDA's or others' satisfaction in a timely manner during the review of any marketing applications that we submit, it may negatively impact our ability to obtain regulatory approval for our drug candidates or obtain approval within projected timelines. We cannot guarantee the ability of our third-party manufacturers to maintain compliance with cGMP regulations, including having adequate quality control, quality assurance and qualified personnel. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products or product candidates.

Our reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing, supply or quality agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Moreover, our current long-term supply agreement for BRIUMVI contains certain minimum purchases in what are commonly referred to as a "take or pay" provision, and it is possible that future supply agreements could contain such provisions. To the extent our demand does not meet the minimum supply required amounts, we would be forced to pay more than desired. This could create a situation where we are spending more than required and could impact our on-going operations and entail curtailing other important research and development or commercialization efforts, all of which could have a material adverse effect on the Company. In negotiating our supply agreement for BRIUMVI, there is no guarantee that we have foreseen all eventualities or that our third-party manufacturer will be able to accommodate unforeseen changes in business direction in a timely fashion or at all. Scheduling of manufacturing at our third-party manufacturer is governed by contractual terms that require us to make investments in inventory of materials, with limited shelf-life, in advance of regulatory approval and based on preliminary commercial forecasting, and such inventory may not be used if timelines and supply needs shift.

Our drug candidates and any drugs that we may develop may compete with other drug candidates and approved drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any third-party manufacturer with which we contract will have other clients, and our relative importance as a customer may adversely impact contractual terms or the performance of services in a satisfactory manner or on a timely basis.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval or interrupt commercial distribution. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement. If a new contract manufacturer is not successful in replicating the product or experiences delays, or if regulatory authorities impose unforeseen requirements with respect to product comparability from multiple manufacturing sources, we may experience delays in clinical development or an interruption in our commercial supply. No assurance can be given that any new manufacturer will be successful or that material manufactured by a new manufacturer will perform comparably to product manufactured by the previous manufacturer or that the relevant regulatory agencies will agree with our interpretation of comparability. Any significant delays or gaps in supply of commercial or clinical products may adversely affect our clinical development program, our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis, and our future profit margins.

We also rely on other third parties to store and distribute drug supplies for our clinical trials and for commercial demand for BRIUMVI and expect to continue to do so for any other potential commercial products. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any future product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

The third parties upon whom we rely for the supply of starting materials, intermediates, active pharmaceutical ingredient (API)/drug substance, drug product, and other materials used in our drug candidates are our sole source of supply, and the loss or disruption of any of these suppliers could significantly harm our business.

The starting materials, intermediates, API/drug substance, and drug product used in many of our drug candidates are currently supplied to us from single-source suppliers. Our ability to successfully develop our drug candidates, supply our drug candidates for clinical trials and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain starting materials, intermediates, API/drug substance, and drug product for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. It is expected that many of our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Various raw materials, components, and testing services required for our product and product candidates may also be single sourced. We are not certain that our single-source suppliers will be able to supply sufficient quantities of their products or on the timelines necessary to meet our needs, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers, our relative importance as a customer to those suppliers, international political conflicts that may impact trade or the supply chain within a particular region, public health emergencies such as the COVID-19 pandemic or natural disasters that may cause those suppliers to stop work for a period of time or lead to a sudden increase in demand for selected materials resulting in short-term unavailability of such materials. If any of our suppliers ceases operations for any reason or is unable or unwilling to supply starting materials, intermediates, API/drug substance, and drug product in sufficient quantities or on the timelines necessary to meet our needs, it could significantly and adversely affect our business, the supply of our drug products and drug candidates and our financial condition. In addition, if our current or future supply of any of our products or product candidates should fail to meet specifications during its stability program there could be a voluntary or mandatory product recall if the product is approved and, even in the absence of a recall, there could be significant interruption of our supply of drug, which would adversely affect the clinical development and commercialization of the product.

We continually evaluate our supply chains to identify potential risks and needs for additional manufacturers and other suppliers for the production of our products and product candidates. Establishing additional or replacement suppliers for the API/drug substance, drug product, and certain raw materials, if required, may not be accomplished quickly, or at all, and may involve significant expense. If we are able to find a replacement supplier, we would need to evaluate and qualify such replacement supplier and its ability to meet quality and compliance standards. Any change in suppliers or the manufacturing process could require additional regulatory approval and result in operational delays. While we seek to maintain adequate inventory of materials necessary for the production of our products and product candidates, any supply interruption or delay, or our inability to identify alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our commercialization and development efforts, which could harm our business, results of operations, financial condition and prospects.

Because we have in-licensed BRIUMVI and our product candidates from third parties, any dispute with or non-performance by our licensors will adversely affect our ability to develop and commercialize the applicable product or product candidate.

Because we license BRIUMVI and our product candidates from third parties and we expect to continue to in-license additional product candidates, if there is any dispute between us and our licensor regarding our rights under a license agreement, our ability to develop and commercialize the applicable product or product candidate may be adversely affected. Disputes may arise with the third parties from whom we license our products and product candidates for a variety of reasons, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships and obligations associated with sublicensing;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license BRIUMVI and our product candidates from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations, or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of our licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product or product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If conflicts arise between us and our future collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for any future product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm any future product development efforts.

We are dependent upon our relationships with collaboration and commercialization partners to further develop, fund, manufacture and commercialize our drug products and our product candidates. If such relationships are unsuccessful, or if a collaboration or commercialization partner terminates its collaboration or commercialization agreement with us, it could negatively impact our ability to conduct our business and generate net product revenue. Failure by a collaboration or commercialization partner to perform its duties under its collaboration or commercialization agreement with us (e.g. financial reporting or internal control compliance) may negatively affect us.

On July 28, 2023, we entered into a commercialization agreement (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm), pursuant to which Neuraxpharm has the right to commercialize BRIUMVI in certain markets outside of the U.S. In addition to the Commercialization Agreement, we may enter into collaboration arrangements with other collaboration and commercialization partners.

We are subject to a number of risks associated with our dependence on our relationships with our collaboration and commercialization partners, including:

- our collaboration and commercialization partners may terminate their collaboration or commercialization agreements with us for reasons specified in the collaboration or commercialization agreements, including our breach;
- the need for us to identify and secure on commercially reasonable terms the services of third parties to perform key activities, including development and commercialization activities, currently performed by our collaboration or commercialization partners in the event that a collaboration or commercialization partner terminates its agreement with us;
- adverse decisions by a collaboration or commercialization partner regarding the amount and timing of resource expenditures for the commercialization, distribution, and sale of our drug products;
- failure by a collaboration or commercialization partner to perform its duties under its agreement with us (e.g., its failure to comply with regulatory requirements which may disrupt its performance of its obligations under the agreement with us);
- failure by a collaboration or commercialization partner to timely deliver accurate and complete financial information to us or to maintain adequate and effective internal control over its financial reporting may negatively affect our ability to meet our financial reporting obligations as required by the SEC;
- failure by a collaboration or commercialization partner to timely deliver accurate and complete medical or clinical information to us or to maintain adequate and effective internal control over its pharmacovigilance activities and reporting may negatively affect our ability to meet our reporting obligations as required by the FDA and other regulatory bodies;
- collaboration or commercialization partners' and their affiliates' development and commercialization of products that compete directly or indirectly with our products or product candidates;
- decisions by a collaboration or commercialization partner to prioritize others of its current or future products more highly than our drug products or our product candidates when it performs its duties;
- possible disagreements with a collaboration or commercialization partner as to the timing, nature and extent of our development plans or distribution and sales and marketing plans; and
- the financial returns to us, if any, under our collaboration agreement with Neuraxpharm depends in large part on the achievement of milestones and generation of product sales, and if Neuraxpharm fails to perform or satisfy its obligations under the collaboration agreements, the development and commercialization of our drug products could be delayed, hindered or may not occur, and our business and prospects could be materially and adversely affected.

While the Commercialization Agreement contains provisions that allow for dispute resolution, arbitration, and/or termination of the agreement by the Company in the event of a breach by Neuraxpharm, there can be no assurance that the Company and Neuraxpharm will agree on a cure for such a breach, and in the event of termination, there can be no assurance that the Company would be appropriately compensated and/or recover any losses sustained. Due to these factors and other possible disagreements with our collaboration and commercialization partners, we may be delayed or prevented from further developing, manufacturing or commercializing our drug products or our product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

If any collaboration or commercialization partner were to terminate our relationship with it unilaterally, we would need to undertake development, commercialization or distribution or sale activities for our drug products and product candidates solely at our own expense, and/or seek one or more other partners for some or all of these activities in the U.S. or worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements, might limit the indications we are able to pursue for our drug products and our product candidates, and could prevent us from effectively commercializing our drug products and our product candidates. If we sought to find one or more other pharmaceutical company partners for some or all of these activities, we may not be successful in such efforts, or they may result in collaborations that have us expending greater funds and efforts than our relationships with our current collaboration and commercialization partners.

We may seek to establish additional collaborations, and if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may be restricted under our collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue from their sales.

Risks Relating to Our Intellectual Property

Our success depends upon our ability to obtain and protect our intellectual property and proprietary technologies. If the scope of our patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success in part depends on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to any product we commercialize, including BRIUMVI, our product candidates, their formulations and uses and the methods we use to manufacture them, as well as successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. Because we in-license our products and product candidates, we also rely on our licensors to protect the patent and other intellectual property rights necessary for commercialization.

We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed. The degree of patent protection we require to successfully commercialize our products and product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect any of our products. In addition, the laws of foreign countries may not protect our patent rights to the same extent as the patent laws of the United States.

Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our product or product candidates, including generic versions of such drugs.

Currently, we have several granted patents in the United States and EU, among other countries, and several pending patent applications that have not yet been issued or have been issued in certain jurisdictions but not all jurisdictions in which such applications have been filed. There can be no guarantee that any pending patent applications, nor any patent applications filed in the future will be granted in any or all jurisdictions in which they were filed, or that all patent claims initially submitted for examination in such patent applications will be allowed in the patent that is eventually granted, if at all. The patent prosecution process is subject to numerous risks and uncertainties, and there can be no assurance of the scope of patent claims that will ultimately be allowed, if at all, and no assurance that we or our partners will be successful in protecting our product and product candidates by obtaining and defending patents.

These risks and uncertainties include the following:

- the patent applications that we or our licensors file may not issue as patent;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage;
- as of March 16, 2013, the United States converted from a first-to-invent to a first-to-file system. If we do not win the filing race, we will not be entitled to inventive priority;
- our competitors, many of whom have substantially greater resources than we do, and many of whom have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to file new patent applications covering our products, or make, use, and/or sell our products either in the United States or in international markets;
- there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns, which could limit our ability to fully monetize our intellectual property rights; and
- countries other than the United States may have less restrictive patent laws than those of the United States, allowing foreign competitors to exploit such less restrictive patent laws to make, use, and/or sell competing products in their respective jurisdictions.

If we are not able to obtain patents that protect our product and product candidates, it could have a material adverse effect on our financial condition and results of operations.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to some of the pending patent applications covering our drug candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the United States Patent and Trademark Office (USPTO) can be significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of our patent applications may change or be modified throughout the patent prosecution process, leaving our product(s) or process(es) without patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, that cover technology licensed from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or we fail to appropriately prosecute and maintain patent protection or trade secret protection for one or more products or product candidates, our ability to develop and commercialize such drugs may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to our product and product candidates could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability, which would have a material adverse effect on our financial condition and results of operations. Furthermore, should we enter into other collaborations, including out-licensing, joint development projects, partnerships, or strategic alternatives, we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of patents licensed or developed under such collaborations. Therefore, such patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. The patent laws of foreign countries may not protect our patent rights to the same extent as the laws of the United States, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States patent law does. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a thirdparty.

In addition, U.S. patent laws may change, which could prevent or limit us, our subsidiaries, or our licensors from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include the transition from a first-to-invent system to a first-to-file system and changes to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents.

The patents or patent applications owned or filed by us, or by our licensors or other collaborators, may be affected by third-party pre-issuance submissions of prior art to the USPTO, or by opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by patents and patent applications for our drug candidates is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products or product candidates.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with enough rights to exclude others from commercializing products similar or identical to ours.

Even if our patent applications issue as patents, and they are unchallenged, our issued patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our products or product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products or product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our products or product candidates could be negatively affected, which would harm our business.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we have entered into agreements with many of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology for the purpose of assigning or granting similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and drug candidates. Such challenges may also result in our inability to manufacture or commercialize our products and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our drugs or procedures, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our products or product candidates, which would have a material adverse effect on our business.

If we do not obtain patent term extensions under the Hatch-Waxman Act and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business may be materially harmed.

Depending on the timing, duration, and specifics of any FDA regulatory approval for our drug candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval by the FDA, and only one patent covering the approved product may be extended.

The application for a patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of the patent protection afforded could be less than what we request. If we are unable to obtain patent term extension or any term of such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

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

Filing, prosecuting and defending patents on drug candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe.

Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our resources and attention from other aspects of our business. Moreover, such proceedings 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 meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which typically are very expensive, time-consuming and disruptive to our day-to-day business operations. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging invalidity of our or certain of our subsidiaries' patents or that we infringe their patents; or provoke those parties to petition the USPTO to institute inter parties review against the asserted patents, which may lead to a finding that all or some of the claims of the asserted patents are invalid. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our pending patents at risk of being invalidated, held unenforceable, or interpreted narrowly.

In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with the prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid.

Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong as in the United States. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a material adverse effect on our business.

In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Furthermore, adverse results on United States patents may affect related patents in our global portfolio. The adverse result could also put related pending patent applications at risk of not issuing. Additionally, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or pending patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. The costs of these proceedings could be substantial. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our respective licensors' patent rights are highly uncertain. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we or our partners 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 depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology, including interference proceedings before the USPTO.

Our competitors or other third parties may assert infringement claims against us, alleging that our drugs are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product or product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product or product candidates of which we are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions.

We are aware of certain patents that may pose issues for our commercialization of our product and product candidates. If we decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, as courts or patent offices in the United States and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we are unable to do so, we may be forced to delay the launch of our product candidates or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

If a third-party claims that we or any collaborators of ours infringe their intellectual property rights, we may have to defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or drug candidates. In addition, we could be found liable for monetary damages, including treble damages and attorney's fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business.

No assurance can be given that patents issued to third parties do not exist, have not been filed, or could not be filed or issued, which contain claims covering their products, technology or methods that may encompass all or a portion of our products and methods. Given the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a risk that third parties may allege they have patent rights encompassing our products or methods.

Other products or product candidates that we may in-license or acquire could be subject to similar risks and uncertainties.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties, whom may or may not be interested in granting such a license, on commercially reasonable terms, in which case our business could be harmed, possibly materially. For example, we engage extensively with third parties, including academic institutions, to conduct non-clinical and clinical research on our product and product candidates. While we seek to ensure all material transfer and service agreements governing this research provide us with favorable terms covering newly generated intellectual property, a general principle under which much of this research with academic institutions is conducted provides third-party ownership of newly generated intellectual property, with an exclusive option available for us to obtain a license to such intellectual property. Through the conduct of this research, it is possible that valuable intellectual property could be developed by a third party, which we will then need to license in order to better develop or commercialize our products. No assurance can be given that we will be able to successfully negotiate such a license on commercially reasonable terms, or at all. Further, should we fail to successfully negotiate a license to such intellectual property, most institutions are then free to license such intellectual property to any other third party, including potentially direct competitors of ours. Should we fail to adequately secure a license to any newly generated intellectual property, our ability to successfully develop or commercialize our products may be hindered, possibly materially.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our proprietary compound library, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' drugs, our competitive position could be adversely affected, as could our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. 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 could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our drug candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates, which would have an adverse effect on our business, results of operations and financial condition.

Risks Related to Our Business Organization and Governance, Strategy, Employees and Growth Management

If we fail to attract and keep key management, commercial, and clinical development personnel, we may be unable to successfully develop or commercialize our product and product candidates.

We are highly dependent on the research and development, commercialization, manufacturing, quality, financial and legal expertise of our senior management team as well as the other principal members of our management. Although we have entered into an employment agreement with our chief executive officer and employment letters with our senior managers, each of our executive officers may terminate their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and medical affairs, and commercial personnel, particularly in MS, will be critical to our success. The loss of the services of our chief executive officer or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital, and our ability to implement our business strategy.

We will need to develop and expand our business, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We may attempt to expand our business by acquiring additional businesses or drugs, forming strategic alliances or creating joint ventures with third parties. We may encounter numerous difficulties in developing, manufacturing, and marketing any new products resulting from any such arrangement or transaction that may delay or prevent us from realizing their expected benefits. If we are unable to successfully integrate such acquired businesses with our existing operations and company culture, we may never realize the benefits of such acquisitions or strategic alliances. We cannot assure you that, following any such transaction, we will achieve the expected synergies to justify the transaction.

As of February 26, 2024, we had 264 full-time employees. To manage our anticipated future growth and focus in neurology and immunology, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these activities. Due to our limited resources, we may not be able to effectively manage the expansion and shift of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our transition to a strategy primarily focused on neurology and immunology, our expenses may increase more than expected our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and changes to our business.

Additionally, to help manage the evolving needs, we may utilize the services of outside vendors or consultants to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development, chemistry, manufacturing, controls, and other pharmaceutical development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on a substantial number of consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors when needed, we may be unable to successfully implement the tasks necessary to achieve our research, development and commercialization goals.

Certain anti-takeover provisions in our governing documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Certain provisions in our amended and restated certificate of incorporation and restated bylaws may make it more difficult for a third party to acquire us or discourage a third party from attempting to acquire or control us and may limit the price that certain investors might be willing to pay in the future for shares of our common stock. For example, our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders, the issuance of which could decrease the amount of earnings and assets available for distribution to, or affect the rights and powers, including voting rights, of our common stockholders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. In addition, our restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

On July 18, 2014, the Board of Directors declared a distribution of one right for each outstanding share of common stock. The rights may have certain anti-takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the Board of Directors unless the offer is conditioned on a substantial number of rights being acquired. However, the rights should not interfere with any merger, statutory share exchange or other business combination approved by the Board of Directors since the rights may be terminated by us upon resolution of the Board of Directors. Thus, the rights are intended to encourage persons who may seek to acquire control of the Company to initiate such an acquisition through negotiations with the Board of Directors. However, the effect of the rights may be to discourage a third party from making a partial tender offer or otherwise attempting to obtain a substantial equity position in the equity securities of, or seeking to obtain control of, the Company. To the extent any potential acquirers are deterred by the rights, the rights may have the effect of preserving incumbent management in office.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2023, we had federal net operating loss carryforwards of approximately $1.4 billion, and our ability to utilize those net operating loss carryforwards could be limited by an ownership change as described above, which could result in increased tax liability to us. In addition, pursuant to the Tax Act, we may not use net operating loss carry-forwards to reduce our taxable income in any year by more than 80%, and we may not carry back any net operating losses to prior years. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed by President Trump. Certain provisions of the CARES Act alter the rules regarding net-operating losses for such losses arising in 2018, 2019 and 2020. Such losses may be carried back for five years. We cannot assure you, however, of our ability to utilize these favorable offset rules within the applicable time period. These rules apply regardless of the occurrence of an ownership change.

Certain of our executive officers, directors, principal stockholders and their affiliates maintain the ability to exercise significant influence over our company and all matters submitted to stockholders for approval.

Certain of our executive officers, directors and stockholders own more than 5% of our outstanding common stock and, together with their affiliates and related persons, beneficially own a significant percentage of our capital stock. If these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Our internal information technology systems, or those of our third-party CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug candidates' development programs and our commercialization of any products for which we receive regulatory approval.

Despite the implementation of security measures, our internal information technology systems and those of our third-party CROs, CMOs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks or cyber-intrusions over the Internet, natural disasters, terrorism, war and telecommunication and electrical failures. Although we have been the targets of cyber-attacks and cyber-intrusions, the impact on our operations and financial condition has not been material. We expect such cybersecurity threats to continue and become more sophisticated, even more so due to the conflict between Russia and Ukraine. A significant cyber-attack or cyber-intrusion could cause our systems to fail, leakage of confidential information, or business interruption, which could result in a material disruption of our operations, financial loss, or reputational harm. For example, the loss of clinical trial data for our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We have invested in protections and monitoring practices of our data and information technology systems to reduce these risks and expect to continue do so as our information technology systems increase in magnitude and complexity. However, there can be no assurance that our efforts and investments will prevent breakdowns or breaches in our systems that could adversely affect our business.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Key national economies, including the United States, have been affected from time to time by economic downturns or recessions, supply chain constraints, rising inflation, restricted credit, poor liquidity, reduced corporate profitability, debt, equity and foreign exchange market volatility, bankruptcies, rising interest rates, unemployment rates and overall uncertainty with respect to the economy. Increasing interest rates in the United States to respond to inflationary pressures and market volatility, as well as the government closures of Silicon Valley Bank and Signature Bank and liquidity concerns at other financial institutions, could negatively impact our results of operations and financial condition. In addition, increased interest rates or a general economic downturn or recession could reduce our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, supply disruptions or international trade disputes could also strain our third-party suppliers, possibly resulting in supply disruption.

Likewise, the capital and credit markets may be adversely affected by the conflicts between Russia and Ukraine and Israel and Hamas, the possibility of wider European, Middle Eastern or global conflicts, and the global sanctions imposed in response thereto. Other international events such as trade disputes, separatist movements, leadership changes and political and military conflicts could also adversely affect global financial activity and markets and could negatively affect the U.S. economy. These conditions could result in decreased economic activity, heightened risk of cyberattacks and inflation, as well as impact our ability to raise capital. Additionally, the Federal Reserve Board (FRB) and other major central banks have been consistently removing or reducing monetary accommodation, increasing the risk of recession and also potentially negatively impacting asset values and credit spreads that were boosted by extraordinary monetary stimulus. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our marketed product and services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions, could adversely impact our business.

Our employees, principal investigators, CROs, CMOs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, principal investigators, CROs, CMOs, and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics applicable to all of our employees and have implemented a compliance program, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity 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 or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, regardless of the outcome, our reputation and our business may suffer. If we are not successful in defending ourselves or asserting our rights, those actions could lead to 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.

We may acquire businesses or drugs, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result

in an increase in our, or our stockholders, tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

On December 22, 2017, legislation commonly referred to as the Tax Act was signed into law and is generally effective after December 31, 2017. The Tax Act makes significant changes to the United States federal income tax rules for taxation of individuals and business entities. Most of the changes applicable to individuals are temporary and apply only to taxable years beginning after December 31, 2017 and before January 1, 2026. For corporations, the Tax Act reduces the top corporate income tax rate to 21% and repeals the corporate alternative minimum tax, limits the deduction for net interest expense, limits the deduction for net operating losses and eliminates net operating loss carrybacks, modifies or repeals many business deductions and credits, shifts the United States toward a more territorial tax system, and imposes new taxes to combat erosion of the U.S. federal income tax base. The Tax Act makes numerous other large and small changes to the federal income tax rules that may affect potential investors and may directly or indirectly affect us. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the Tax Act on us, whether adverse or favorable, is uncertain, and may not become evident for some period of time. This document does not discuss such legislation or the manner in which it might affect us or purchasers of our common stock. Prospective investors are urged to consult with their legal and tax advisors with respect to the Tax Act and any other regulatory or administrative developments and proposals, and their potential effects on them based on their unique circumstances.

General Risks

Risks Related to Our Common Stock and Being a Publicly Traded Company

Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

The trading price of our common stock has been and is likely to continue to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include, among others:

- reception and success of BRIUMVI in the U.S. market;
- the anticipated launch of BRIUMVI in European markets;
- publicity regarding actual or potential clinical results relating to our product or products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by us or our competitors;
- any delay in our regulatory review for products and product candidates we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation a change to the projected approval date, scheduling of an advisory committee meeting or issuance of a "refusal to file" letter;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors such as the disruptions in the global economy caused by the COVID-19 pandemic, the conflict between Russia and Ukraine, and the Israel-Hamas war;
- period-to-period fluctuations in our revenues and other results of operations;
- failure to meet our revenue projections or guidance;
- changes in financial estimates by securities analysts; and
- sales of our common stock by us.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares.

We are subject to risks related to corporate social responsibility and reputational matters.

Our reputation and the reputation of our brands, including the perception held by our customers, end-users, business partners, investors, other key stakeholders and the communities in which we do business are influenced by various factors. There is an increased focus from our stakeholders on Environmental, Social, and Governance (ESG) practices and disclosure - and if we fail, or are perceived to have failed, in any number of ESG matters, such as environmental stewardship, inclusion and diversity, workplace conduct and support for local communities, or if we fail, or are perceived to have failed, to effectively respond to changes in legal or regulatory requirements concerning climate change or other sustainability concerns, our reputation or the reputation of our brands may suffer. Such damage to our reputation and the reputation of our brands may negatively impact our business, financial condition and results of operations. In addition, negative or inaccurate postings or comments on social media or networking websites about the Company or our brands could generate adverse publicity that could damage our reputation or the reputation of our brands. If we are unable to effectively manage real or perceived issues, including concerns about product quality, safety, corporate social responsibility or other matters, sentiments toward the Company or our products could be negatively impacted, and our financial results could suffer.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will likely be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. However, any future determination relating to the use of our future earnings, if any, will be made at the discretion of the Board of Directors and will depend on a number of factors, including capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that the Board of Directors may deem relevant. In addition, under the Amended Loan Agreement, as amended, with Hercules, we are currently restricted from paying cash dividends, and we expect these restrictions to continue in the future. Furthermore, the terms of any future debt agreements may continue to preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be likely the sole source of gain for our stockholders for the foreseeable future.

An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid.

Although we have listed our common stock on the Nasdaq Capital Market, an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the price at which they acquired their shares or at the time that they would like to sell. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If equity research analysts do not publish research or reports about our business or if they publish negative evaluations of or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause our common stock price to decline.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, and the rules of any stock exchange on which we are listed. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our team has devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal control over financial reporting. These efforts to comply with Section 404 will require the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal control over financial reporting, which could have an adverse effect on the market price of our stock.

Volatility in the price of our common stock may subject us to securities and shareholder derivative litigation, which could cause us to incur substantial costs and divert management's attention, financial resources and other company assets.

In the past, securities class action and shareholder derivative litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. Past lawsuits and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend, and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits in which we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price.

Future sales of our common stock, including by us or our directors and executive officers or shares issued upon the exercise of currently outstanding options, could cause our stock price to decline.

A substantial portion of our outstanding common stock can be traded without restriction at any time. In addition, a portion of our outstanding common stock is currently restricted as a result of federal securities laws but can be sold at any time subject to applicable volume limitations. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock or impair our ability to raise adequate capital through the sale of additional equity securities. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the number, timing or size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to mitigate risks on a case-by-case basis from cybersecurity threats to our critical computer networks, third party-hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to patients and clinical trials (IT Assets). The potential consequences of a material cybersecurity incident could include reputational damage, litigation with third parties, regulatory criticism or proceedings and increased cybersecurity protection and remediation costs, which in turn could materially adversely affect our results of operations. The Company's information security program evaluates threats posed by internal and external factors and supports daily operational functions that prevent unauthorized access or compromise.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our IT Assets, including, for example: implementing policies and guidelines governing the individual use and protection of IT Assets by employees, employee training, and leveraging the capability of third-party service providers to support our internal cybersecurity processes. We will continue to monitor proposed cybersecurity disclosure rules from the SEC and alter our procedures accordingly.

Risks from cybersecurity threats have, to date, not materially affected us, our business strategy, results of operations or financial condition. For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the risk factor captioned "Our internal information technology systems, or those of our third-party CROs, CMOs, or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug candidates' development programs and our commercialization of any products for which we receive regulatory approval."

Governance

Our information technology (IT) team leads the Company's overall cybersecurity efforts and is responsible for the day-to-day management of risks we face, while our Board of Directors/management provides guidance on the oversight of risk management. Our Information Security Incident Response Plan is designed to escalate cybersecurity incidents, depending on the circumstances, to appropriate stakeholders as defined by internal Standard Operating Procedures. As part of such process, the corporate IT Security Team receives aggregate monthly reports from a third-party managed services organization contracted to monitor the TGTX IT environment. Additionally, the Vice President of IT receives regular reports from the corporate IT Security Team concerning the Company's significant cybersecurity threats and risks and the processes the Company has implemented to address them. Significant events are reported to the Chief Financial Officer.

ITEM 2. PROPERTIES.

We maintain corporate and executive space in Morrisville, North Carolina, New York, New York, and Edison, New Jersey. We are also currently leasing small office space in Boca Raton, Florida. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS.

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol "TGTX".

Holders

The number of record holders of our common stock as of February 23, 2024 was 214.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

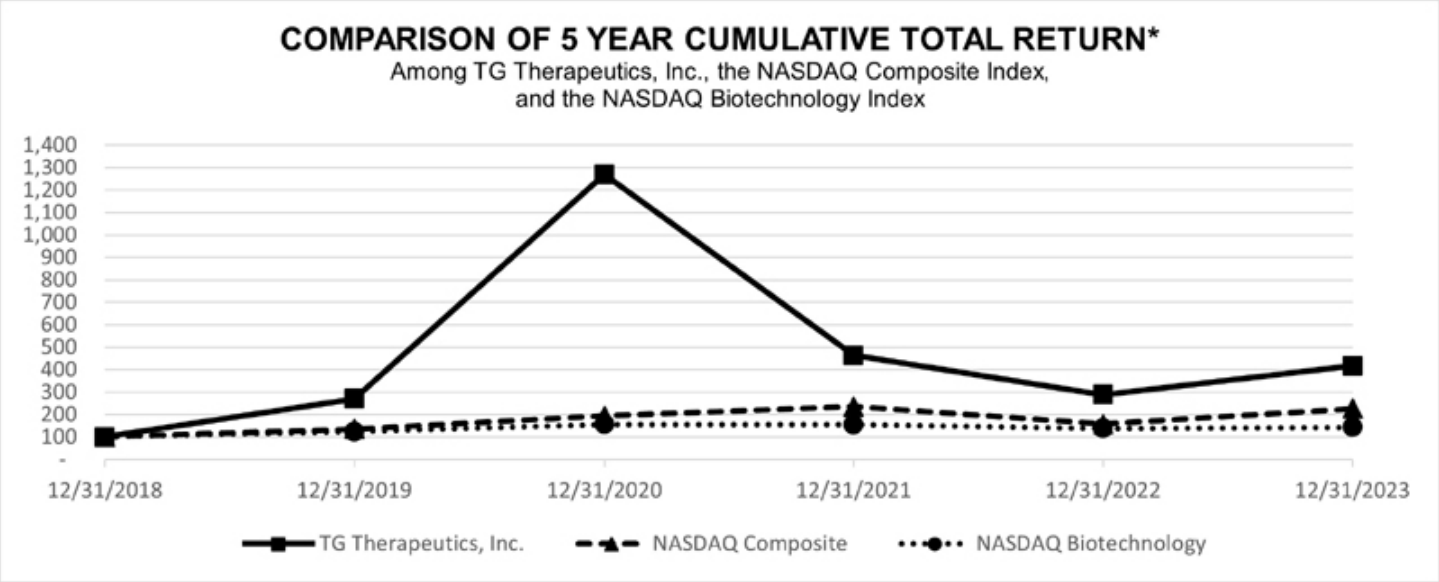
The following table provides information as of December 31, 2023, regarding the securities authorized for issuance under our equity compensation plans, the TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (the 2012 Incentive Plan) and the TG Therapeutics, Inc. 2022 Incentive Plan (the 2022 Incentive Plan). There were no additional shares available to be issued under the 2012 Incentive Plan.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 1)
Equity compensation plans approved by security holders	4,697,029	$ 6.98	8,751,892
Equity compensation plans not approved by security holders	—	—	—
Total	4,697,029	$ 6.98	8,751,892

For information about all of our equity compensation plans see Note 6 to our Consolidated Financial Statements included in this report.

COMMON STOCK PERFORMANCE GRAPH



The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2018 through December 31, 2023, with the cumulative total return over such period on (i) the U.S. Index of The Nasdaq Stock Market and (ii) the Biotechnology Index of The Nasdaq Stock Market. The graph assumes an investment of $100 on December 31, 2018, in our common stock (at the adjusted closing market price) and in each of the indices listed above, and assumes the reinvestment of all dividends. Measurement points are December 31 of each year.

*** $100 invested on December 31, 2018 in stock or index, including reinvestment of dividends. Fiscal Years ending December 31.**

ITEM 6. REMOVED AND RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with "Item 8. Financial Statements and Supplementary Data," and our consolidated financial statements beginning on page F-1 of this report.

Overview

TG Therapeutics is a fully-integrated, commercial stage, biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has received approval from the FDA for BRIUMVI (ublituximab-xiiy) for the treatment of adult patients with RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

On February 5, 2021, we announced that the FDA granted accelerated approval of umbralisib, the Company's PI3K delta inhibitor, then commercially referred to as UKONIQ, for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20 based regimen and adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapy. On April 15, 2022, we announced the voluntary withdrawal of UKONIQ from sale for the approved indications. During the year ended December 31, 2023, our only sources of product revenues were from the sales of BRIUMVI. Product revenues are recorded net of estimates of variable consideration. For further discussion of our revenue recognition policy, see "Critical Accounting Policies and Significant Judgements and Estimates" below.

Cost of revenue consists primarily of materials and third-party manufacturing costs, as well as freight and royalties owed to our licensing partner for BRIUMVI sales. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, a portion of the manufacturing costs of BRIUMVI units recognized as revenue during the year ended December 31, 2023 were expensed prior to receipt of FDA approval on December 28, 2022, and therefore are not included in costs of product revenue during the current period.

Our other research and development expenses consist primarily of expenses relating to the design, development, manufacture, testing and enhancement of our drug candidates and technologies, milestone expenses related to in-licensing of new product candidates, fees paid to consultants and outside service providers for clinical and laboratory development, personnel expenses and other facilities-related expenses. We expense our research and development costs as they are incurred. Research and development expenses for the years ended December 31, 2023, 2022 and 2021 were approximately $63.2 million, $112.1 million and $198.5 million respectively, excluding noncash compensation expenses related to research and development.

The following table sets forth the research and development expenses per project, exclusive of noncash compensation expenses, for the periods presented.

(in thousands)	2023	2022	2021
Ublituximab	$ 50,972	$ 59,307	$ 112,522
Umbralisib	5,925	38,468	63,033
Early Clinical Pipeline & Pre-Clinical	6,285	14,353	22,977
Total	$ 63,182	$ 112,128	$ 198,532

Our selling, general and administrative expenses consist primarily of expenses related to the commercial launch of our products, including salaries and related expenses for our commercialization team and commercial development activities. Other selling, general and administrative expenses consist of executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses.

Our results of operations include noncash compensation expenses as a result of the grants of restricted stock and stock options. Compensation expense for awards of restricted stock and stock options granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. The expense is included in the respective categories of expense in the consolidated statements of operations. We expect to continue to incur significant noncash compensation expenses.

We recognize all share-based payments to employees and non-employee directors (as compensation for service) as noncash compensation expense in the consolidated financial statements based on the fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes the results of operations for the years ended December 31, 2023 and 2022:

(in thousands)	2023	2022
Product revenue, net	$ 92,005	$ 2,633
License, milestone and other revenue	141,657	152
Total Revenue	$ 233,662	$ 2,785
Costs and expenses:		
Cost of revenue	14,131	265
Research and development:		
Noncash compensation	13,010	13,224
Other research and development	63,182	112,128
Total research and development	76,192	125,352
Selling, General and administrative:		
Noncash compensation	24,923	5,961
Other selling, general and administrative	97,783	64,046
Total selling, general and administrative	122,706	70,007
Total costs and expenses	213,029	195,624
Interest expense	12,615	10,191
Other income	(5,044)	(4,695)
Total other expense, net	7,571	5,496
Net income (loss) before taxes	13,062	(198,335)
Income taxes	390	
Net income (loss)	$ 12,672	$ (198,335)

Product Revenue, net. Product revenue, net increased for the year ended December 31, 2023 compared to the comparable period ended December 31, 2022 primarily due to an increase in net product revenues from sales of our sole commercial product, BRIUMVI, which was commercially launched in the U.S. in January 2023, following FDA approval. Product revenue, net for the year ended December 31, 2022, consisted of net product sales of UKONIQ, which was officially withdrawn from the market in May 2022.

License Revenue. License revenue was $140.2 million and $0.2 million for the years ended December 31, 2023 and December 31, 2022, respectively. License revenue for the year ended December 31, 2023 is predominantly comprised of recognition of license revenue from the one-time $140.0 million non-refundable upfront payment recognized in the third quarter of 2023 as part of the Commercialization Agreement with Neuraxpharm (see Note 2 for more information). License revenue for the year ended December 31, 2022 is comprised of recognition of a portion of the upfront payment from the ublituximab sublicense agreement with Ildong.

Other Revenue. Other revenue was $1.5 million and zero for the year ended December 31, 2023 and December 31, 2022, respectively. Other revenue for the year ended December 31, 2023 is comprised of consideration received for development and regulatory activities performed on behalf of Neuraxpharm in accordance with the Commercialization Agreement.

Cost of Revenue. Cost of revenue for the year ended December 31, 2023 increased compared to the comparable period ended December 31, 2022 due to increased product sales resulting from the commercial launch of BRIUMVI in the U.S. market which began in January 2023 following FDA approval. During the year ended December 31, 2023 the cost of revenue consisted primarily of third-party manufacturing, distribution, overhead costs and royalties on net sales of BRIUMVI owed to our licensing partner. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, a portion of the manufacturing costs of BRIUMVI units recognized as revenue during the year ended December 31, 2023 were expensed as research and development expenses prior to receipt of FDA approval, and therefore are not reflected in the cost of revenue. We expect the cost of revenue for BRIUMVI to increase in relation to product revenues as we deplete these inventories and we expect to use the remaining pre-commercialization inventory for product sales through the first half of 2025

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $13.0 million for the year ended December 31, 2023, as compared to $13.2 million during the comparable period in 2022.

Other Research and Development Expense. Other research and development expense decreased for the year ended December 31, 2023, by approximately $48.9 million to $63.2 million as compared to the prior year ended December 31, 2022. The decrease in other research and development expense during the year ended December 31, 2023 was primarily attributable to reduced manufacturing expense, a decrease in license milestones and reduced clinical trial related expenses. Prior to the approval of BRIUMVI, manufacturing costs pertaining to BRIUMVI were expensed to research and development expense in the period incurred, and following approval are reflected in inventory.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled $24.0 million for the year ended December 31, 2023, as compared to $6.0 million during the comparable period in 2022. The increase in noncash compensation expense was primarily due to vesting of milestone-based grants and a decrease in forfeitures during the year ended December 31, 2023 compared to the year ended December 31, 2022.

Other Selling, General and Administrative. Other selling, general and administrative expenses increased for the year ended December 31, 2023, by approximately $33.9 million to $97.8 million as compared to the prior year ended December 31, 2022. The increase was primarily due to other selling, general and administrative costs, including personnel and consultants, associated with the approval and commercialization of BRIUMVI, as well as increase in advisory fees pertaining to the Commercialization Agreement with Neuraxpharm during the year ended December 31, 2023.

Interest Expense. Interest expense for the year ended December 31, 2023 was $12.6 million compared to $10.2 million for the comparable period ended December 31, 2022. The $2.4 million increase is mainly due to greater interest expense related to First Amendment to the Amended Loan Agreement

Other Income. Other income increased by $0.3 million to $5.0 million for the year ended December 31, 2023, as compared to $4.7 million for the year ended December 31, 2022.

Income Taxes. Income tax increased by $0.4 million to $0.4 million for the year ended December 31, 2023, as compared to zero for the year ended December 31, 2022. The $0.4 million increase is due to state tax liabilities incurred during the year ended December 31, 2023.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes the results of operations for the years ended December 31, 2022 and 2021:

(in thousands)	2022	2021
Product revenue, net	$ 2,633	$ 6,537
License revenue	152	152
Total Revenue	$ 2,785	$ 6,689
Costs and expenses:		
Cost of product revenue	265	790
Research and development:		
Noncash compensation	13,224	24,047
Other research and development	112,128	198,532
Total research and development	125,352	222,579
General and administrative:		
Noncash compensation	5,961	37,227
Other selling, general and administrative	64,046	90,863
Total general and administrative	70,007	128,090
Total costs and expenses	195,624	351,459
Interest expense	10,191	5,638
Other income	(4,695)	(2,307)
Total other expense, net	5,496	3,331
Net Loss	$ (198,335)	$ (348,101)

Revenues. Total revenue for the year ended December 31, 2022 decreased compared to the comparable period ended December 31, 2021 due to a decrease in net product revenues resulting from the voluntary withdrawal from the U.S. market of our sole commercial product, UKONIQ.

Cost of Product Revenue. Cost of product revenue for the year ended December 31, 2022 decreased compared to the comparable period ended December 31, 2021 due to the stoppage of product sales resulting from the withdrawal from the U.S. market of our sole commercial product UKONIQ. During the year ended December 31, 2022 the cost of product revenue consists primarily of freight and royalties on net sales of UKONIQ owed to our licensing partner. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, the manufacturing costs of UKONIQ units recognized as revenue during the year ended December 31, 2022 were expensed as research and development expenses prior to receipt of FDA approval on February 5, 2021, and therefore are not included in costs of product revenue during the current period.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $13.2 million for the year ended December 31, 2022, as compared to $24.0 million during the comparable period in 2021. The decrease in noncash compensation expense was primarily due to forfeitures of restricted stock during the year ended December 31, 2022, as well as an overall decreased headcount during the year ended December 31, 2022 compared to the year ended December 31, 2021.

Other Research and Development Expense. Other research and development expense decreased for the year ended December 31, 2022, by approximately $86.4 million to $112.1 million as compared to the prior year ended December 31, 2021. The decrease in research and development expense is primarily attributable to reduced clinical trial related expenses, headcount, lower fees paid to consultants and outside service providers, license milestones and decreased manufacturing expense during the year ended December 31, 2022.

Noncash Compensation Expense (Selling, General and Administrative). Noncash compensation expense (selling, general and administrative) related to equity incentive grants totaled $6.0 million for the year ended December 31, 2022, as compared to $37.2 million during the comparable period in 2021. The decrease in noncash compensation expense was primarily due to forfeitures of restricted stock during the year ended December 31, 2022, as well as an overall decreased headcount during the year ended December 31, 2022 compared to the year ended December 31, 2021.

Other Selling, General and Administrative. Other selling, general and administrative expenses decreased for the year ended December 31, 2022, by approximately $26.8 million to $64.0 million as compared to the prior year ended December 31, 2021. The decrease was due primarily to lower other selling, general and administrative costs, as a result of our withdrawal of UKONIQ and decreased headcount, during the period ended December 31, 2022.

Interest Expense. Interest expense for the year ended December 31, 2022 was $10.2 million compared to $5.6 million for the comparable period ended December 31, 2021. The $4.6 million increase is mainly due to greater interest expense related to the Amended Loan Agreement entered into in December 2021.

Other Income. Other income increased by $2.4 million to $4.7 million for the year ended December 31, 2022, as compared to $2.3 million for the year ended December 31, 2021. The increase is mainly due to greater interest income, as well as a research & development tax credit refund received by our Australian subsidiary during the year ended December 31, 2022.

LIQUIDITY AND CAPITAL RESOURCES

Historically, we have incurred operating losses since our inception; however, the Company experienced a net profit during the twelve months ended December 31, 2023 due to a $140.0 million non-refundable upfront payment recognized as license revenue in the third quarter of 2023 as part of our Commercialization Agreement with Neuraxpharm (see Note 2 for more information). We expect to continue to incur operating losses in the near term and may never become profitable. As of December 31, 2023, we have an accumulated deficit of $1.5 billion.

Our major sources of cash have been proceeds from private placements and public offerings of equity securities, from our loan and security agreements executed with Hercules (see Note 7 for more information), and the upfront payment from the Commercialization Agreement (see Note 2 for more information). Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. As of December 31 2023, we had generated $92.0 million in product revenue from sales of BRIUMVI. BRIUMVI first became commercially available in the United States in January of 2023. Even with the commercialization of BRIUMVI and the possible future commercialization of our other drug candidates, we may not become profitable. Our ability to achieve profitability depends on our ability to generate revenue and many other factors, including our ability to successfully commercialize our drug candidates alone or in partnership; successfully complete any post-approval regulatory obligations and our ability to maintain or obtain regulatory approval for our drug candidates. We may continue to incur operating losses even now that we are generating revenues from BRIUMVI.

As of December 31, 2023, we had $217.5 million in cash and cash equivalents, and investment securities. We anticipate that our cash, cash equivalents, and investment securities as of December 31, 2023, combined with projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will provide sufficient liquidity for more than a twelve-month period from the date of filing this Annual Report on Form 10-K. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, our commercialization efforts for BRIUMVI, preparations for the potential commercialization of our other drug candidates, and the timing, design and conduct of clinical trials for our drug candidates as well as the costs associated with licensing or otherwise acquiring new product candidates. We may be dependent upon significant future financing to provide the cash necessary to execute our ongoing and future operations, including the commercialization of any of our drug candidates.

Discussion of Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2023 and 2022:

(in thousands)	2023	2022
Net cash used in operating activities	$ (31,413)	$ (176,170)
Net cash used in investing activities	$ (50,651)	$ (20,013)
Net cash provided by (used in) financing activities	$ 72,705	$ (391)

Cash used in operating activities for the year ended December 31, 2023 was $31.4 million as compared to $176.2 million for the year ended December 31, 2022. The decrease in cash used in operating activities was due primarily to the one-time upfront payment of $140.0 million from Neuraxpharm, as part of the Commercialization Agreement during the year ended December 31, 2023.

For the year ended December 31, 2023, net cash used in investing activities was $50.7 million as compared to $20.0 million for the year ended December 31, 2022. The increase in net cash used in investing activities was primarily due to greater investment in short-term securities during the year ended December 31, 2023.

For the year ended December 31, 2023, net cash provided by financing activities was $72.7 million as compared to net cash used in financing activities of $0.4 million for the year ended December 31, 2022. The increase in net cash provided by financing activities was primarily attributable to proceeds from debt financings and net proceeds from the issuance of common stock as part of our ATM program that took place during the year ended December 31, 2022.

ATM Program

On September 5, 2019, we filed an automatic "shelf registration" statement on Form S-3 (the 2019 WKSI Shelf) as a "well-known seasoned issuer" as defined in Rule 405 under the Securities Act, which registered an unlimited and indeterminate amount of debt or equity securities for future issuance and sale. The 2019 WKSI Shelf was declared effective in September 2019. In connection with the 2019 WKSI Shelf, we entered into an At-the-Market Issuance Sales Agreement (the 2020 ATM) with Jefferies LLC, Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (each a 2020 Agent and collectively, the 2020 Agents), relating to the sale of shares of our common stock. Under the 2020 ATM, we paid the 2020 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. In November 2020, we entered into an At-the-Market Issuance Sales Agreement (the 2021 ATM) with the same terms and agents (each a 2021 Agent and collectively, the 2021 Agents) as the 2020 ATM.

During the year ended December 31, 2021, we sold a total of 72,000 shares of common stock under the 2021 ATM for aggregate total gross proceeds of approximately $2.5 million at an average selling price of $34.25 per share, resulting in net proceeds of approximately $2.4 million after deducting commissions and other transactions costs.

On September 2, 2022, we filed an automatic "shelf registration" statement on Form S-3 (the 2022 WKSI Shelf) as a "well-known seasoned issuer" as defined in Rule 405 under the Securities Act, which registered an unlimited and indeterminate amount of debt or equity securities for future issuance and sale. The 2022 WKSI Shelf was declared effective in September 2022. In connection with the 2022 WKSI Shelf, we entered into an At-the-Market Issuance Sales Agreement (the 2022 ATM) with Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (each a 2022 Agent and collectively, the 2022 Agents), relating to the sale of shares of our common stock. Under the 2022 ATM, we will pay the 2022 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. The 2022 ATM has replaced the 2021 ATM as the only active ATM program.

During the year ended December 31, 2023, we sold a total of 1,385,700 shares of common stock under the 2022 ATM for aggregate total gross proceeds of approximately $47.1 million at an average selling price of $34.01 per share, resulting in net proceeds of approximately $46.3 million after deducting commissions and other transactions costs.

The 2022 WKSI Shelf is currently our only active shelf registration statement. We may offer any combination of the securities registered under the 2022 WKSI Shelf from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We may need to file additional shelf registration statements in the future to provide us with the flexibility to raise additional capital to finance our operations as needed.

Debt Financings

On February 28, 2019 (the Closing Date), we entered into a term loan facility of up to $60.0 million (Term Loan) with Hercules Capital, Inc. (Hercules), the proceeds of which were used for research and development programs and for general corporate purposes. The Term Loan is governed by a loan and security agreement, dated February 28, 2019 (the Loan Agreement), which provides for up to four separate advances. The first advance of $30.0 million was drawn on the Closing Date. An additional $30.0 million was available with different milestones and time points that have lapsed.

On December 30, 2021 (the First Amendment Closing Date), the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules Capital, Inc. The Amended Loan Agreement amended the terms of the Loan Agreement to, among other things, (i) increase the aggregate principal amount of the loan, available at the Company's option, from $60.0 million to $200.0 million (the Amended Term Loan), (ii) issue a first advance of $70.0 million drawn at the First Amendment Closing Date, a portion of which was used to refinance the current outstanding loan balance of approximately $7.8 million and pay for expenses incurred by the Lender in executing the agreements, (iii) change the draw amounts and dates available in Tranche 2 through Tranche 4 including increasing the amount available under Tranche 2 subject to the achievement of performance milestones from $10.0 million to $20.0 million, increasing the amount available under Tranche 3 subject to the achievement of performance milestones from $10.0 million to $45.0 million, and increasing the amount under Tranche 4 subject to the approval of Hercules' investment committee from $10.0 million to $65.0 million, (iv) extend the maturity date of the facility from the original March 1, 2022 to January 1, 2026, (v) reset and extend the interest only period from April 1, 2021 to February 1, 2025 and extendable to August 1, 2025 subject to the achievement of certain performance milestones, and (vi) modify the cash interest rate to be the greater of either (a) the "prime rate" as reported in The Wall Street Journal plus 2.15%, and (b) 5.40%. The performance milestones are based on achievement of certain U.S. Food and Drug Administration approvals and impact the potential extension of the interest only period, access to future advances under the Loan Agreement and minimum cash levels required under the Amended Loan Agreement.

On March 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended and Restated Loan and Security Agreement (the First Amendment) with Hercules. The First Amendment amended the terms of the Amended Loan Agreement to, among other things, (i) issue an advance of $25.0 million drawn at the First Amendment Effective Date (the Tranche 3A Advance), (ii) provide for the formal expiration of Tranche 2, (iii) change the draw amounts and dates available under subsequent tranches, including splitting the remaining balance of Tranche 3 into two additional advances in an aggregate principal amount of up to $20.0 million, in increments of $10.0 million (a Tranche 3B Advance and a Tranche 3C Advance), decreasing the amount available under Tranche 4 from $65.0 million to $60.0 million, and adding a Tranche 5 of $25.0 million, subject to the achievement of revenue related performance milestones, (iv) extend the interest only period from February 1, 2025 to August 1, 2025 and (v) modify the cash interest rate to be the greater of either (a) the "prime rate" as reported in The Wall Street Journal plus 1.20%, and (b) 8.95%. In addition to the cash interest rate, the principal balance will accrue paid-in-kind interest at a rate of 2.25%, which amount will be capitalized and added to the outstanding principal balance of the Amended Term Loan and payable at the maturity date of the Amended Loan Agreement, as amended, The Amended Loan Agreement, as amended, contains financial covenants that require the Company to maintain certain levels of unrestricted cash and additional financial covenants related to market capitalization. As of December 31, 2023, we are in compliance with all financial covenants.

The Amended Loan Agreement, as amended also contains warrant coverage of 2.95% of the total amount funded. A warrant (the Warrant) was issued by the Company to Hercules to purchase 115,042 shares of common stock with an exercise price of $17.95 for the initial amount funded at the Closing Date. The Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. Additionally, a warrant was issued by the Company to Hercules to purchase 50,172 shares of common stock with an exercise price of $14.70 for the amount funded pertaining to the Tranche 3A Advance (the First Amendment Warrant). The First Amendment Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the First Amendment Warrant either by (a) cash or check or (b) through a net issuance conversion.

In addition, the Company is required to pay a final payment fee equal to 5.95% of the aggregate principal amount of the Term Loan Advances (as defined in the Amended Loan Agreement, as amended)

The Company may, at its option, prepay the Amended Term Loan in full or in part, subject to a prepayment penalty equal to (i) 1.5% of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the First Amendment Effective Date, and (ii) 1.0% of the principal amount prepaid if the prepayment occurs on or after the first anniversary of the First Amendment Effective Date.

Leases

In October 2014, we entered into an agreement (the Office Agreement) with Fortress Biotech, Inc. (FBIO) to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of $1.8 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. Also in connection with this lease, we have pledged $1.3 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying condensed consolidated balance sheets.

Total rental expense was approximately $2.2 million, $2.7 million and $2.2 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Future minimum lease commitments as of December 31, 2023 total, in the aggregate, approximately $15.0 million through December 31, 2032. Our future minimum lease commitments include our office leases in New York, New Jersey and North Carolina as of December 31, 2023.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

Revenue Recognition. Pursuant to Topic 606, we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, Topic 606 includes provisions within a five-step model that includes i) identifying the contract with a customer, ii) identifying the performance obligations in the contract, iii) determining the transaction price, iv) allocating the transaction price to the performance obligations, and v) recognizing revenue when, or as, an entity satisfies a performance obligation.

At contract inception, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

Product Revenue, Net – The Company recognizes product revenues, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. The Company records product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components, which are described below: chargebacks, government rebates, trade discounts and allowances, product returns, and co-payment assistance.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is expected to be settled with a credit against the Company's customer account) or a liability (if the amount is expected to be settled with a cash payment). The Company's estimates of reserves established for variable consideration are calculated based upon a consistent application of the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. These estimates reflect the Company's current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment. For a complete discussion of the accounting for product revenue, see Note 1 – Organization and Summary of Significant Accounting Policies in the Notes to Consolidated Financial Statements.

License Revenue - Revenue recognized from license agreements will include royalties on sales, upfront, milestone and other payments, if any, under any current or future licensing agreements, including revenues related to the supply of our drug candidates or approved drugs to our various licensing partners under these types of contracts. For a complete discussion of the accounting for license revenue, see Note 1 – Organization and Summary of Significant Accounting Policies in the Notes to Consolidated Financial Statements.

Stock Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. For employee, director and consultant grants the value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock and our assessment of future volatility; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, because some of the options, restricted stock and warrants issued to employees, consultants and other third parties vest upon the achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestones becomes probable.

Accrued Research and Development Expenses. As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include:

- fees paid to contract research organizations (CROs) in connection with clinical studies;
- fees paid to contract manufacturing organizations (CMOs);
- fees paid to trial sites in connection with clinical studies; and
- fees paid to vendors associated with licenses/milestones.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to an initial negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing certain service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

RECENTLY ISSUED ACCOUNTING STANDARDS

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company’s financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We currently invest in government and investment-grade corporate debt in accordance with our investment policy, which we may change from time to time. The securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of December 31, 2023, our portfolio of financial instruments consists of cash equivalents and short-term interest-bearing securities, including government debt and money market funds. The average duration of all of our held-to-maturity investments held as of December 31, 2023, was less than 24 months. Due to the relatively short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and the notes thereto, included in Part IV, Item 14(a), part 1, are incorporated by reference into this Item 8.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2023, management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (Exchange Act)). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive and Chief Financial Officers concluded that, as of December 31, 2023, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our management used the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework. Our management has concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on these criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2023 was audited by KPMG LLP, our independent registered public accounting firm, as stated in their report.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

ITEM 9B. OTHER INFORMATION.

Securities Trading Plans of Directors and Executive Officers

During the three months ended December 31, 2023, none of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) for the purchase or sale of the Company's securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c).

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2024 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2024 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2024 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2024 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2024 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

1. Consolidated Financial Statements

The following consolidated financial statements of TG Therapeutics, Inc. are filed as part of this report.

2. Consolidated Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. Exhibits

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc. dated April 26, 2012 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2012).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc. dated June 9, 2014 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2014).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc. dated June 16, 2021 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 21, 2021).
3.4	Amended and Restated Bylaws of TG Therapeutics, Inc. dated July 18, 2014 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 21, 2014).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K for the year ended December 31, 2011).
4.2	Stockholder Protection Rights Agreement, dated July 18, 2014 between TG Therapeutics, Inc. and American Stock Transfer & Trust Company, LLC, as Rights Agent (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 21, 2014).
4.3	Description of Securities of TG Therapeutics, Inc. (incorporated by reference to Exhibit 4.5 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020).

10.1	Employment Agreement, effective December 29, 2011, between the Registrant and Michael Weiss (incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
10.2	Restricted Stock Subscription Agreement, effective December 29, 2011, between the Registrant and Michael Weiss (incorporated by reference to Exhibit 10.31 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
10.3	Amendment to Restricted Stock Agreement, dated July 12, 2013, by and between TG Therapeutics, Inc. and Michael S. Weiss (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 16, 2013). †
10.4	Amendment to Restricted Stock Agreements, dated December 31, 2014, by and between TG Therapeutics, Inc. and Michael S. Weiss (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 7, 2015). †
10.5	Employment Agreement, effective December 29, 2011, between the Registrant and Sean Power (incorporated by reference to Exhibit 10.32 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
10.6	Restricted Stock Subscription Agreement, effective December 29, 2011 between the Registrant and Sean Power (incorporated by reference to Exhibit 10.33 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
10.7	Amendment to Restricted Stock Agreement, dated July 12, 2013, by and between TG Therapeutics, Inc. and Sean A. Power (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 16, 2013). †
10.8	Amendment to Restricted Stock Agreements, dated December 31, 2014, by and between TG Therapeutics, Inc. and Sean A. Power (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 7, 2015). †
10.9	License Agreement dated January 30, 2012, by and among the Registrant, GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S. and LFB/GTC LLC (incorporated by reference to Exhibit 10.35 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). *
10.10	Sublicense Agreement between TG Therapeutics, Inc. and Ildong Pharmaceutical Co. Ltd., dated November 13, 2012 (incorporated by reference to Exhibit 10.37 to the Registrant's Form 10-K for the fiscal year ended December 31, 2012). *
10.11	License Agreement between TG Therapeutics, Inc. and Ligand Pharmaceuticals Incorporated, dated June 23, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2014).*
10.12	License Agreement between TG Therapeutics, Inc. and Rhizen Pharmaceuticals SA, dated September 22, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 20, 2015). *
10.13	Collaboration Agreement between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated March 3, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended March 31, 2015). *
10.14	Sublicense Agreement between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated May 27, 2016, (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2016). *
10.15	Amendment to Employment Agreement, effective January 1, 2017, between TG Therapeutics, Inc. and Michael S. Weiss (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-K/A for the year ended December 31, 2016). †
10.16	License Agreement between TG Therapeutics, Inc. and Jiangsu Hengrui Medicine Co., dated January 8, 2018 (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K for the year ended December 31, 2017). *
10.17	Joint Venture and License Option Agreement by and between TG Therapeutics, Inc. and Novimmune S.A., dated June 18, 2018 (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-Q for the quarter ended June 30, 2018). *

10.18	Master Services Agreement between Samsung Biologics Co., Ltd. And TG Therapeutics, Inc., effective February 21, 2018 (incorporated by reference to the Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2019). *
10.19	Loan and Security Agreement, dated February 28, 2019, by and among TG Therapeutics, Inc., TG Biologics, Inc. and Hercules Capital, Inc. (incorporated by reference to the Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 5, 2019).
10.20	Warrant Agreement, dated February 28, 2019, by and between TG Therapeutics, Inc. and Hercules Capital, Inc. (incorporated by reference to the Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on March 5, 2019).
10.21	Warrant Agreement, dated February 28, 2019, by and between TG Therapeutics, Inc. and Hercules Technology III, L.P. (incorporated by reference to the Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on March 5, 2019).
10.22	Amended and Restated Collaboration Agreement by and between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated June 19, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2019). *
10.23	Amended and Restated Employment Agreement by and between TG Therapeutics, Inc. and Michael S. Weiss, dated June 18, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10 Q for the quarter ended June 30, 2021). †
10.24	Amended and Restated Loan and Security Agreement, dated December 30, 2021, by and among TG Therapeutics, Inc., TG Biologics, Inc. and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.28 to the Registrant's Form 10-K for the year ended December 31, 2021).
10.25	Warrant Agreement, dated December 30, 2021, by and between TG Therapeutics, Inc. and Hercules Capital Inc. (incorporated by reference to Exhibit 10.29 to the Registrant's Form 10-K for the year ended December 31, 2021).
10.26	Warrant Agreement, dated December 30, 2021, by and between TG Therapeutics, Inc. and Hercules Private Credit Fund I L.P. (incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-K for the year ended December 31, 2021).
10.27	Warrant Agreement, dated December 30, 2021, by and between TG Therapeutics, Inc. and Hercules Private Global Venture Growth Fund I L.P. (incorporated by reference to Exhibit 10.31 to the Registrant's Form 10-K for the year ended December 31, 2021).
10.28	TG Therapeutics, Inc. 2022 Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 23, 2022). †
10.29	First Amendment to Amended and Restated Loan and Security Agreement, dated March 31, 2023, by and among TG Therapeutics, Inc., TG Biologics, Inc. and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.30	Amended and Restated Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Capital Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.31	Amended and Restated Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Funding IV, LLC. (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.32	Amended and Restated Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Private Credit Fund 1 L.P. (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.33	Amended and Restated Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Private Global Venture Growth Fund I L.P. (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.34	Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Capital Inc. (incorporated by reference to Exhibit 10.6 to the Registrant's Form 10-Q for the quarter ended March 31, 2023).
10.35	Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Private Credit Fund 1 L.P. (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.36	Warrant Agreement, dated March 31, 2023, by and between TG Therapeutics, Inc. and Hercules Private Global Venture Growth Fund I L.P. (incorporated by reference to Exhibit 10.8 to the Registrant's Form 10-Q for the quarter ended March 31, 2023). *
10.37	Commercialization Agreement by and between TG Therapeutics, Inc. and Neuraxpharm Pharmaceuticals, S.L., dated as of July 28, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2023). *
10.38	License Agreement, dated January 7, 2024, by and between TG Therapeutics, Inc., TG Cell Therapy, Inc., and Precision BioSciences, Inc. # *
19.1	TG Therapeutics, Inc. Insider Trading Policy #
21.1	Subsidiaries of TG Therapeutics, Inc. #
23.1	Consent of Independent Registered Public Accounting Firm (KPMG, LLP). #
24.1	Power of Attorney (included in signature page).

31.1	Certification of Principal Executive Officer. #
31.2	Certification of Principal Financial Officer. #
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. #
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. #

97.1	TG Therapeutics, Inc. Clawback Policy #
101	The following financial information from TG Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023, formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, (v) the Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Filed Herewith.
† Indicates management contract or compensatory plan or arrangement.
* Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

TG Therapeutics, Inc.

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of TG Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, 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 December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 29, 2024 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

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 PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

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.

Commercialization agreement with Neuraxpharm

As discussed in Note 2 to the consolidated financial statements, the Company entered into a commercialization agreement (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm) that granted Neuraxpharm the exclusive right to commercialize BRIUMVI in certain territories. The arrangement also provides Neuraxpharm with the right to make optional purchases of BRIUMVI. The consideration for these optional purchases of BRIUMVI by Neuraxpharm approximates the price that a customer in the territories would be willing to pay for these goods. In 2023, the Company recognized a non-refundable upfront payment of $140.0 million as License Revenue related to the Commercialization Agreement.

We identified the evaluation of the accounting for the supply terms of the Commercialization Agreement with Neuraxpharm as a critical audit matter. Specifically, complex auditor judgment was required to evaluate the Company's assessment of whether the optional purchases of BRIUMVI granted a material right to Neuraxpharm, due to the complexity of evaluating whether the contractual pricing is commensurate with standalone selling price.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of an internal control in the Company's revenue process used to evaluate key terms of contracts with customers, including the evaluation of the standalone selling price of BRIUMVI. We obtained an understanding of the Commercialization Agreement by reading the contracts and conducting meetings with Company personnel responsible for negotiating the contracts. We evaluated management's accounting conclusions with respect to the supply terms within the Commercialization Agreement. We recalculated the contractual price of the optional purchases and inspected the Company's analysis of the standalone selling price of BRIUMVI using an expected cost plus a margin approach. We obtained and inspected both external and internal evidence used by the Company in its analysis of the standalone selling price and compared this evidence to available industry information for the relevant territories. We also performed a sensitivity analysis to evaluate the impact that a change in margin would have on the conclusion that the contractual pricing of optional purchases of BRIUMVI is commensurate with standalone selling price.

/s/ KPMG LLP

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

New York, New York
February 29, 2024

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited TG Therapeutics, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements), and our report dated February 29, 2024 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

/s/ KPMG LLP

New York, New York
February 29, 2024

TG Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets as of December 31
(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 92,933	$ 102,304
Short-term investment securities	124,575	59,374
Accounts receivable, net	51,093	—
Inventories	39,823	—
Prepaid research and development	4,183	4,237
Other current assets	5,336	2,359
Total current assets	317,943	168,274
Restricted cash	1,285	1,273
Long-term investment securities	—	12,404
Right of use assets	8,050	8,888
Leasehold interest, net	1,415	1,627
Equipment, net	95	307
Goodwill	799	799
Total assets	$ 329,587	$ 193,572
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 38,471	$ 42,019
Other current liabilities	1,631	1,169
Lease liability – current portion	1,446	1,581
Accrued compensation	12,172	8,432
Total current liabilities	53,720	53,201
Deferred revenue	6,016	305
Loan payable	100,118	71,135
Lease liability – non-current	9,231	10,344
Total liabilities	169,085	134,985
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value per share (175,000,000 shares authorized, 151,465,598 and 146,426,697 shares issued, 151,424,289 and 146,385,388 shares outstanding at December 31, 2023 and December 31, 2022, respectively	151	146
Additional paid-in capital	1,674,946	1,585,708
Treasury stock, at cost, 41,309 shares at December 31, 2023 and December 31, 2022	(234)	(234)
Accumulated deficit	(1,514,361)	(1,527,033)
Total stockholders' equity	160,502	58,587
Total liabilities and stockholders' equity	$ 329,587	$ 193,572

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

TG Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations for the Years Ended December 31
(in thousands, except share and per share amounts)

	2023	2022	2021
Revenue:			
Product revenue, net	92,005	2,633	6,537
License, milestone and other revenue	$ 141,657	$ 152	$ 152
Total revenue	233,662	2,785	6,689
Costs and expenses:			
Cost of revenue	14,131	265	790
Research and development:			
Noncash compensation	13,010	13,224	24,047
Other research and development	63,182	112,128	198,532
Total research and development	76,192	125,352	222,579
Selling, general and administrative:			
Noncash compensation	24,923	5,961	37,227
Other selling, general and administrative	97,783	64,046	90,863
Total selling, general and administrative	122,706	70,007	128,090
Total costs and expenses	213,029	195,624	351,459
Operating income (loss)	20,633	(192,839)	(344,770)
Other expense (income):			
Interest expense	12,615	10,191	5,638
Other income	(5,044)	(4,695)	(2,307)
Total other expense (income), net	7,571	5,496	3,331
Net income (loss) before taxes	$ 13,062	$ (198,335)	$ (348,101)
Income taxes	390	—	—
Net income (loss)	$ 12,672	$ (198,335)	$ (348,101)
Net income (loss) per common share:			
Basic	$ 0.09	$ (1.46)	$ (2.63)
Diluted	$ 0.09	$ (1.46)	$ (2.63)
Weighted-average shares outstanding:			
Basic	141,955,112	135,411,258	132,222,753
Diluted	148,508,465	135,411,258	132,222,753

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

TG Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity for the Years Ended December 31
(in thousands, except share amounts)

	Common Stock		Additional paid-in	Treasury Stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	Deficit	Total
Balance at January 1, 2021	140,617,606	141	1,500,040	41,309	(234)	(980,597)	519,350
Issuance of common stock in connection with exercise of options	52,694	*	216	—	—	—	216
Issuance of restricted stock	2,738,974	2	(2)	—	—	—	—
Warrants issued with debt financing	—	—	2,195	—	—	—	2,195
Forfeiture of restricted stock	(189,231)	*	—	—	—	—	—
Offering Costs Paid	—	—	(204)	—	—	—	(204)
Issuance of common stock in At-the-Market offerings (net of offering costs of $0.1 million)	72,000	*	2,423	—	—	—	2,423
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	61,274	—	—	—	61,274
Net income (loss)	—	—	—	—	—	(348,101)	(348,101)
Balance at December 31, 2021	143,292,043	143	1,565,942	41,309	(234)	(1,328,698)	237,153
Issuance of common stock in connection with exercise of options	142,409	*	584	—	—	—	584
Issuance of restricted stock	5,179,201	5	(5)	—	—	—	—
Forfeiture of restricted stock	(2,186,956)	(2)	2	—	—	—	—
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	19,185	—	—	—	19,185
Net income (loss)	—	—	—	—	—	(198,335)	(198,335)
Balance at December 31, 2022	146,426,697	146	1,585,708	41,309	(234)	(1,527,033)	58,587
Issuance of common stock in connection with exercise of options	246,156	—	1,534	—	—	—	1,534
Issuance of restricted stock	3,620,237	4	(4)	—	—	—	—
Warrants issued with debt financing	—	—	595	—	—	—	595
Forfeiture of restricted stock	(213,192)	—	—	—	—	—	—
Issuance of common stock in At-the-Market offerings (net of offering costs of $0.8 million)	1,385,700	1	46,295	—	—	—	46,296
Compensation in respect of restricted stock granted to employees, directors and consultants	—	—	40,818	—	—	—	40,818
Net income (loss)	—	—	—	—	—	12,672	12,672
Balance at December 31, 2023	151,465,598	$ 151	$ 1,674,946	41,309	$ (234)	$ (1,514,361)	160,502

* *Amount less than one thousand dollars.*

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

TG Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows for the Years Ended December 31
(in thousands)

	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES			
Net income (loss)	$ 12,672	$ (198,335)	$ (348,101)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Noncash stock compensation expense	37,933	19,185	61,274
Depreciation and amortization	211	303	282
Amortization of premium (discount) on investment securities	(2,236)	(331)	517
Amortization of debt issuance costs	2,378	1,844	1,080
Amortization of leasehold interest	212	212	212
Noncash change in lease liability and right of use asset	1,963	2,715	1,896
Change in fair value of notes payable	113	(116)	(578)
Changes in assets and liabilities:			
Increase in inventory	(36,938)	—	—
Decrease (increase) in other current assets	(2,831)	8,181	(8,508)
Decrease (increase) in accounts receivable	(51,093)	1,389	(1,389)
(Decrease) increase in accounts payable and accrued expenses	192	(11,010)	15,991
Decrease in lease liabilities	(2,375)	(2,332)	(2,012)
Increase (decrease) in other current liabilities	2,675	2,277	(16,146)
Increase (decrease) in deferred revenue	5,711	(152)	(152)
Net cash used in operating activities	(31,413)	(176,170)	(295,634)
CASH FLOWS FROM INVESTING ACTIVITIES			
Proceeds from maturity of short-term securities	96,229	87,275	55,600
Investment in held-to-maturity securities	(146,880)	(107,274)	(55,531)
Purchases of PPE	—	(14)	(401)
Net cash used in investing activities	(50,651)	(20,013)	(332)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payment of loan payable	—	(975)	(30,000)
Proceeds from sale of common stock, net	46,296	—	2,219
Proceeds from exercise of options	1,534	584	216
Proceeds from debt financings	25,000	—	70,000
Financing costs paid	(125)	—	(1,016)
Net cash provided by (used in) financing activities	72,705	(391)	41,419
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(9,359)	(196,574)	(254,547)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	103,577	300,151	554,698
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 94,218	$ 103,577	$ 300,151
Reconciliation to amounts on condensed consolidated balance sheets:			
Cash and cash equivalents	$ 92,933	$ 102,304	$ 298,887
Restricted cash	1,285	1,273	1,264
Total cash, cash equivalents and restricted cash	$ 94,218	$ 103,577	$ 300,151
Cash paid for:			
Interest	8,771	$ 5,445	$ 3,466
NONCASH TRANSACTIONS			
Deferred Financing Costs	$ 1,238	—	—
Warrants issued with debt financing	$ 595	—	—

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

Unless the context requires otherwise, references in this report to "TG," "Company," "we," "us" and "our" refer to TG Therapeutics, Inc. and our subsidiaries.

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF BUSINESS

TG Therapeutics is a fully-integrated, commercial stage, biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has received approval from the U.S. Food and Drug Administration (FDA) for BRIUMVI® (ublituximab-xiiy) for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults, as well as approval by the European Commission (EC) and the Medicines and Healthcare Products Regulatory Agency (MHRA) for BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features in Europe and the United Kingdom, respectively. We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities.

LIQUIDITY AND CAPITAL RESOURCES

Historically, we have incurred operating losses since our inception; however, the Company experienced a net profit during the twelve months ended December 31, 2023 due to a $140.0 million non-refundable upfront payment recognized as license revenue in the third quarter of 2023 as part of our ex-U.S. commercialization agreement (the Commercialization Agreement) with Neuraxpharm Pharmaceuticals, S.L. (Neuraxpharm) (see Note 2 for more information). We expect to continue to incur operating losses in the near term and may never become profitable. As of December 31, 2023, we have an accumulated deficit of $1.5 billion.

Our major sources of cash have been proceeds from private placements and public offerings of equity securities, from our loan and security agreements executed with Hercules Capital, Inc. (Hercules) (see Note 7 for more information), and the upfront payment from the Commercialization Agreement (see Note 2 for more information). Substantially all our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations, including our commercialization activities. As of December 31 2023, we had generated $92.0 million in product revenue from sales of BRIUMVI. BRIUMVI first became commercially available in the United States in January of 2023. We also began shipping BRIUMVI to our ex-U.S. licensing partner, Neuraxpharm, in November 2023. Even with the commercialization of BRIUMVI and the possible future commercialization of our other drug candidates, we may not become profitable. Our ability to achieve profitability depends on our ability to generate revenue and many other factors, including our ability to successfully commercialize our drug candidates alone or in partnership; successfully complete any post-approval regulatory obligations; and our ability to maintain or obtain regulatory approval for our drug candidates. We may continue to incur operating losses even now that we are generating revenues from BRIUMVI.

As of December 31, 2023, we had $217.5 million in cash and cash equivalents, and investment securities. We anticipate that our cash, cash equivalents, and investment securities as of December 31, 2023, combined with projected revenues associated with the sale of BRIUMVI in the U.S. and ex-U.S., will provide sufficient liquidity for more than a twelve-month period from the date of filing this Annual Report on Form 10-K. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, our commercialization efforts for BRIUMVI, preparations for the potential commercialization of our other drug candidates, and the timing, design and conduct of clinical trials for our drug candidates as well as the costs associated with licensing or otherwise acquiring new product candidates. We may be dependent upon significant future financing to provide the cash necessary to execute our ongoing and future operations, including the commercialization of any of our drug candidates.

Our common stock is quoted on the Nasdaq Capital Market and trades under the symbol "TGTX."

RECENTLY ISSUED ACCOUNTING STANDARDS

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

USE OF ESTIMATES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, accrued clinical trial expenses and stock-based compensation. Actual results could differ from those estimates. Such differences could be material to the financial statements.

CASH AND CASH EQUIVALENTS

We treat liquid investments with original maturities of less than three months when purchased as cash and cash equivalents.

RESTRICTED CASH

We record cash pledged or held in trust as restricted cash. As of December 31, 2023 and 2022, we have approximately $1.3 million of restricted cash pledged to secure a line of credit as a security deposit for an Office Agreement (see Note 7).

INVESTMENT SECURITIES

Investment securities at December 31, 2023 and 2022 consist of short-term and long-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

A decline in the market value of any investment security below cost that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is established. Other-than-temporary impairment charges are included in interest and other income (expense), net. Dividend and interest income are recognized when earned.

CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalents and short-term investments with high-credit quality financial institutions. At times, such amounts may exceed federally-insured limits.

REVENUE RECOGNITION

Pursuant to Topic 606, we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To achieve this core principle, Topic 606 includes provisions within a five-step model that includes i) identifying the contract with a customer, ii) identifying the performance obligations in the contract, iii) determining the transaction price, iv) allocating the transaction price to the performance obligations, and v) recognizing revenue when, or as, an entity satisfies a performance obligation.

At contract inception, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Product Revenue, Net – The Company recognizes product revenues, net of variable consideration related to certain allowances and accruals, when the customer takes control of the product, which is typically upon delivery to the customer. Product revenue is recorded at the net sales price, or transaction price. The Company records product revenue reserves, which are classified as a reduction in product revenues, to account for the components of variable consideration. Variable consideration includes the following components, which are described below: chargebacks, government rebates, trade discounts and allowances, commercial payer rebates, product returns, and co-payment assistance.

These reserves are based on estimates of the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is expected to be settled with a credit against the Company's customer account) or a liability (if the amount is expected to be settled with a cash payment). The Company's estimates of reserves established for variable consideration are calculated based upon a consistent application of the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. These estimates reflect the Company's current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be subject to constraint and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration received may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment.

Chargebacks: Chargebacks for discounts represent the Company’s estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers and government agencies at prices lower than the list prices charged to the customers who directly purchase the product from the Company. The customers charge the Company for the difference between what the customers pay the Company for the product and the customers’ ultimate contractually committed or government required lower selling price to the qualified healthcare providers.

Government Rebates: Government rebates consist of Medicare, Tricare, and Medicaid rebates. These reserves are recorded in the same period the related revenue is recognized. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom it will owe a rebate under the Medicare Part D program.

Trade Discounts and Allowances: The Company provides its customers with discounts that are explicitly stated in the contracts and are recorded in the period the related product revenue is recognized. In addition, the Company also receives sales order management, inventory management, and data services from its customers in exchange for certain fees.

Commercial Payer Rebates: The Company contracts with various private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of our product and contracted formulary status. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Product Returns: Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate in the period the related product revenue is recognized. The Company currently estimates product return liabilities based on data from similar products and other qualitative considerations, such as visibility into the inventory remaining in the distribution channel.

Subject to certain limitations, the Company’s return policy allows for eligible returns of commercial products sold for credit under the following circumstances:

- receipt of damaged product;
- shipment errors that were a result of an error by the Company;
- expired product that is returned during the period beginning three months prior to the product’s expiration and ending six months after the expiration date;
- product subject to a recall; and
- product that the Company, at its sole discretion, has specified can be returned for credit.

As of December 31, 2023, the Company has not received any returns related to sales of BRIUMVI.

Co-Payment Assistance Programs: Co-payment assistance is provided to qualified patients with commercial insurance, whereby the Company may provide financial assistance to patients with prescription drug co-payments required by the patient's insurance provider. Reserves for co-payment assistance are recorded in the same period the related revenue is recognized.

License Agreements –

The Company generates revenue from license or similar agreements with pharmaceutical companies for the development and commercialization of certain products. Such agreements *may* include the transfer of intellectual property rights in the form of licenses. Payments made by the customer *may* include non-refundable upfront fees, payments based upon the achievement of defined milestones, and royalties on sales of products. Licenses of intellectual property: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. All other promised goods or services in the agreement are evaluated to determine if they are distinct. If they are *not* distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct.

Milestone payments: Contingent milestones at contract inception are estimated at the amount which is *not* probable of a material reversal and included in the transaction price using the most likely amount method. Milestone payments that are *not* within the Company's control, such as regulatory approvals, are *not* considered probable of being achieved until those approvals are received and therefore the variable consideration is constrained. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development or sales-based milestone payments that *may not* be subject to a material reversal and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

Sales-based royalties: For arrangements that include sales-based royalties and a license of intellectual property that is deemed to be the predominant item to which the royalties relate, revenue is recognized at the later of when the related sales occur or when the performance obligation to which some or all of the royalties have been allocated has been satisfied (or partially satisfied).

Optional Purchases: The Company's arrangements may provide the licensee the right to make optional purchases of the licensed product. These optional purchases are accounted for as separate contracts when the licensee determines that it will make such a purchase, unless the option conveys a material right.

Other Revenue

Revenue is also generated from service-based fees recognized for providing regulatory support and development services to customers. Service fee revenue is recognized overtime as the services are transferred to the customer.

DEFERRED PRODUCT REVENUE

When consideration is received, or such consideration is unconditionally due, from a customer prior to the Company completing its performance obligation to the customer under the terms of a contract, a contract liability is recorded as deferred revenue. Deferred revenues expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current liabilities. Deferred revenues not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as long-term liabilities.

ACCOUNTS RECEIVABLE

In general, accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts, product returns and chargebacks. Our contracts with customers have standard payment terms. We analyze accounts that are past due for collectability, and regularly evaluate the creditworthiness of our customers so that we can properly assess and respond to changes in their credit profiles. As of December 31, 2023, we determined an allowance for expected credit losses related to outstanding accounts receivable was currently not required based upon our review of contractual payment terms and individual customer circumstances.

COST OF REVENUE

Cost of revenue consists primarily of third-party manufacturing costs, distribution, overhead and royalties owed to our licensing partner for BRIUMVI sales. Cost of revenue may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, a portion of the costs of producing BRIUMVI sold to date was expensed as research and development prior to FDA approval of BRIUMVI and therefore it is not reflected in the cost of revenue. Our cost of revenue also relates to providing regulatory support & development services to customers.

INVENTORY

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in-first-out method (FIFO). Prior to regulatory approval, we expense costs relating to the production of inventory as research and development expense in the period incurred. Following regulatory approval, costs to manufacture those approved products will be capitalized. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials.

Prior to the approval of BRIUMVI, all manufacturing and other potential costs related to the commercial launch of BRIUMVI were expensed to research and development expense in the period incurred.

RESEARCH AND DEVELOPMENT COSTS

Generally, research and development costs are expensed as incurred. Research and development expenses consist primarily of costs incurred to third-party service providers for the conduct of research, preclinical and clinical studies, contract manufacturing costs, license milestone fees, personnel costs for our research and development employees, consulting, and other related expenses. We recognize research, preclinical and clinical study expenses based on services performed, pursuant to contracts with third-party research and development organizations that conduct and manage research, preclinical and clinical activities on our behalf. We accrue these expenses based on the progress or stage of completion of services and the contracted fees to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the original accrual, we will adjust the accrual accordingly. With respect to clinical trial costs, the financial terms of these agreements are subject to an initial negotiation and vary from contract to contract. Payments under these contracts may be uneven and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. As such, certain expense accruals related to clinical site costs are recognized based on the degree of performance of the event or events specified in the specific clinical study or trial contract.

Prepaid research and development in our consolidated balance sheets includes, among other things, costs related to agreements with CROs, certain costs to third-party service providers related to development and manufacturing services as well as clinical development. These agreements often require payments in advance of services performed or goods received. Accordingly, as of December 31, 2023 and December 31, 2022, we recorded approximately $4.2 million in prepaid research and development related to such advance agreements.

INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than “more likely than not,” a valuation allowance is then created.

We, and our subsidiaries, file income tax returns in the U.S. federal jurisdiction and in various states. We have tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination. We recognize interest and penalties related to uncertain income tax positions in income tax expense. Refer to Note 9 for further information on impact of tax reform.

STOCK-BASED COMPENSATION

The Company measures employee and non-employee stock-based compensation based on the grant date fair value of the stock-based compensation award. The Company grants stock options at exercise prices equal to the fair value of the Company’s common stock on the date of grant, based on observable market prices. The Company uses the Black-Scholes option-pricing model to measure the fair value of stock option awards. We recognize all stock-based payments to employees and non-employee directors (as compensation for service) as noncash compensation expense in the consolidated financial statements. Stock-based compensation expense recognized each period is based on the value of the portion of stock-based payment awards that is ultimately expected to vest during the period. Forfeitures are recognized as they occur.

In addition, because some of the options, restricted stock and warrants issued to employees, consultants and other third parties vest upon achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestones becomes probable.

NET INCOME (LOSS) PER COMMON SHARE

Basic net income (loss) per share of our common stock is calculated by dividing net income (loss) applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, stock options, and restricted stock, which would result in the issuance of incremental shares of common stock. The impact of these items is anti-dilutive during periods of net loss. Therefore, basic and diluted net income (loss) per share were the same for all periods presented in the consolidated statement of operations, except for the year ended December 31, 2023, as the Company had net income for that period

The following table summarizes our potentially dilutive securities at December 31, 2023, 2022 and 2021:

	December 31,		
	2023	**2022**	**2021**
Unvested restricted stock	8,139,037	7,232,254	10,532,029
Options	4,697,029	5,135,685	2,467,537
Warrants	312,272	262,100	262,100
Shares issuable upon note conversion	20,902	20,619	18,942
Total	13,169,240	12,650,658	13,280,608

The computation of basic and diluted earnings per share (EPS) is as follows:

	Year ended December 31,		
(in thousands, except share and per share data)	**2023**	**2022**	**2021**
Net income (loss)	12,672	(198,335)	(348,101)
Weighted-average common shares outstanding	141,955,112	135,411,258	132,222,753
Dilutive effect of potential common shares	6,553,353	-	-
Weighted-average common shares outstanding assuming dilution	148,508,465	135,411,258	132,222,753
Net income (loss) per share - basic	0.09	(1.46)	(2.63)
Net income (loss) per share - diluted	0.09	(1.46)	(2.63)

LONG-LIVED ASSETS AND GOODWILL

Long-lived assets are reviewed for potential impairment when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized.

Goodwill results from excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized but is reviewed for impairment at least annually, or more frequently if impairment indicators are present, 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 the fair value is less than the carrying amount, a quantitative test that compares the fair value to its carrying value is performed to determine the amount of any impairment.

LEASES

All leases with a lease term greater than 12 months, regardless of lease type classification, are recorded as an obligation on the balance sheet with a corresponding right-of-use asset. Operating leases are reflected as lease liabilities on the commencement date of the lease based on the present value of the lease payments to be made over the lease term. Current operating lease liabilities are reflected in lease liabilities – current portion and noncurrent operating lease liabilities are reflected in lease liabilities – non-current on the consolidated balance sheet. Right-of-use assets are valued at the initial measurement of the lease liability, plus any initial direct costs or rent prepayments, minus lease incentives and any deferred lease payments. Operating lease right-of-use assets are recorded right of use assets on the consolidated balance sheet and lease cost is recognized on a straight-line basis. Leases with an initial term of 12 months or less are not recorded on the balance sheet and we recognize lease expense for these leases on a straight-line basis over the term of the lease. In determining whether a contract contains a lease, asset and service agreements are assessed at onset and upon modification for criteria of specifically identified assets, control and economic benefit.

NOTE 2 - REVENUE

As discussed in Note 1, revenues are recognized under guidance within ASC 606. The following table presents our disaggregated revenue for the periods presented (in thousands):

(in thousands)	Year ended December 31,		
	2023	**2022**	**2021**
Total product revenue, net	$ 92,005	2,633	6,537
License Revenue	140,153	152	152
Other Revenue	1,504	-	-
Total Revenue	$ 233,662	$ 2,785	$ 6,689

TG Therapeutics, Inc. and Subsidiaries
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Product revenue, net

The following table presents our disaggregated revenue by product and geography for the periods presented:

(in thousands)		Year ended December 31,		
		2023	2022	2021
BRIUMVI				
	U.S.	$ 88,786	$ -	$ -
	International	3,219	-	-
	Worldwide	$ 92,005	$ -	$ -
UKONIQ				
	U.S.	$ -	$ 2,633	$ 6,537
	International	-	-	-
	Worldwide	$ -	$ 2,633	$ 6,537
Total product revenue, net				
	U.S.	$ 88,786	$ 2,633	$ 6,537
	International	3,219	-	-
	Worldwide	$ 92,005	$ 2,633	$ 6,537

We began shipping BRIUMVI to our U.S. customers in January 2023. We also began shipping BRIUMVI to our ex-U.S. licensing partner, Neuraxpharm, in November 2023. UKONIQ was voluntarily withdrawn from the U.S. market effective May 31, 2022.

During 2023, approximately $9.2 million of gross-to-net accruals entirely related to U.S. sales of BRIUMVI have been recorded as a reduction of accounts receivable, net and within accounts payable and accrued expenses on the condensed consolidated balance sheets.

License Agreements

Neuraxpharm Commercialization Agreement

On July 28, 2023, the Company entered into the Commercialization Agreement with Neuraxpharm. The Company granted Neuraxpharm the exclusive right to commercialize BRIUMVI in certain territories outside the United States, Canada, and Mexico, the commercialization rights for which had been previously retained by the Company, thus excluding certain Asian countries subject to previously existing partnerships (the Territory). In addition, the Company will perform certain development and regulatory activities for Neuraxpharm to support its obligations under the Commercialization Agreement to secure and maintain the regulatory approvals required to sell BRIUMVI in the Territory. As part of the overall arrangement, the Company has agreed to supply BRIUMVI to Neuraxpharm throughout the term of the Commercialization Agreement.

In consideration for entering the Commercialization Agreement, the Company received a non-refundable upfront payment of $140.0 million. The Company will also receive tiered double-digit royalties up to 30% on net product sales in the Territory and is eligible to receive sales-based or other milestone payments totaling up to $505.0 million.

The Company evaluated the Commercialization Agreement under ASC 606 and concluded that Neuraxpharm represents a customer in the transaction. In accordance with this guidance, the Company identified the following commitments under the arrangement: (i) grant the exclusive right to develop, sell, offer to sell and import BRIUMVI in the Territory (the “License”); and (ii) perform certain development and regulatory activities (“Development and Regulatory Activities”).

The License to the Company’s intellectual property represents a distinct performance obligation, therefore, the $140 million non-refundable upfront payment related to this performance obligation was recognized as License Revenue in 2023.

The Development and Regulatory Activities also represent a distinct performance obligation and are satisfied over time because Neuraxpharm simultaneously receives and consumes the benefits provided by the Company’s performance of the services. Therefore, revenue is recognized as the activities are completed by the Company. During 2023 the Company recognized Other Revenue of $1.5 million related to the Development and Regulatory Activities.

The arrangement also provides Neuraxpharm with the right to make optional purchases of BRIUMVI (the “Supply of Licensed Product”). These optional purchases are accounted for as a separate contract when the right to purchase BRIUMVI is exercised. The consideration for optional purchases of BRIUMVI by Neuraxpharm approximates the price that a customer in the Territory would be willing to pay for these goods.

The performance obligation related to the Supply of Licensed Product is satisfied when control of the product passes to Neuraxpharm. The consideration received from Neuraxpharm for the supply of BRIUMVI is recognized by the Company as a component of product revenue, net. As of December 31, 2023, the Company has an unconditional right to receive $1.9 million in consideration from Neuraxpharm related to the performance obligation to supply BRIUMVI, which is recorded as accounts receivable, net. A portion of the performance obligation to supply BRIUMVI has not yet been satisfied, therefore, as of December 31, 2023, $5.9 million has been recorded as deferred revenue. During 2023 the Company recognized $3.2 million in BRIUMVI product sales, net related to performance obligations that were satisfied during the year ended December 31, 2023. The Company will reevaluate the consideration received, and performance obligations satisfied at the end of each reporting period. Such reevaluations may result in a change to the amount of product revenue, net, recognized and deferred revenue.

The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are highly dependent on factors outside of the Company’s control. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue in the period when the related sales threshold is met. All other milestones will be recognized as revenue immediately in the period the achievement of the underlying milestone is probable. Any consideration related to sales-based royalties will be recognized when the related sales occur. No royalty or milestone revenue was recognized during 2023.

NOTE 3 – INVESTMENT SECURITIES

Our investments as of December 31, 2023 and 2022 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at December 31, 2023 and 2022:

	December 31, 2023			
(in thousands)	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2024 and June 2024) (held-to-maturity)	$ 124,575	$ 30	$ 53	$ 124,552
Total short-term investment securities	$ 124,575	$ 30	$ 53	$ 124,552

	December 31, 2022			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2023 and December 2023) (held-to-maturity)	$ 59,374	$ —	$ 1,053	$ 58,321
Long-term investments:				
Obligations of domestic governmental agencies (maturing between January 2024 and February 2024) (held-to-maturity)	12,404	—	429	11,975
Total short-term and long-term investment securities	$ 71,778	$ —	$ 1,482	$ 70,296

NOTE 4 – INVENTORY

The following table presents our inventory as of December 31, 2023 (in thousands):

	December 31, 2023
Raw Materials	$ 6,582
Work in Process	31,243
Finished Goods	1,999
Total Inventory	$ 39,824

Inventory is stated at the lower of cost or net realizable value and consists of raw materials, work-in-process and finished goods. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. At December 31,2023, all our inventory was related to BRIUMVI, which was approved by the FDA on December 28, 2022, at which time we began to capitalize costs to manufacture BRIUMVI. Prior to FDA approval of BRIUMVI, all costs related to the manufacturing of BRIUMVI and related material were charged to research and development expense in the period incurred. No costs related to the manufacturing of BRIUMVI and the related material were incurred between the approval date and year end 2022, therefore, inventory is not included in the December 31, 2022 consolidated balance sheet. Inventory that is used for clinical development purposes is expensed to research and development expense when consumed. For December 30, 2023 we determined that a reserve related to BRIUMVI inventory is not required.

NOTE 5 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The fair value hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1 – quoted prices in active markets for identical assets and liabilities;
- Level 2 – inputs other than Level 1 quoted prices that are directly or indirectly observable; and
- Level 3 – unobservable inputs that are not corroborated by market data.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc. (Manhattan)) with Ariston Pharmaceuticals, Inc. (Ariston) in March 2010, Ariston issued $15.5 million of five-year 5% notes payable (the 5% Notes) in satisfaction of several note payable issuances. The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of $1,125 per share. We have no obligations under the 5% Notes aside from the conversion feature.

The following tables provide the fair value measurements of applicable financial liabilities as of December 31, 2023 and 2022:

	Financial liabilities at fair value as of December 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
5% Notes	$ —	$ —	$ 357	$ 357
Total	$ —	$ —	$ 357	$ 357

	Financial liabilities at fair value as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
5% Notes	$ —	$ —	$ 243	$ 243
Total	$ —	$ —	$ 243	$ 243

The Level 3 amounts above represent the fair value of the 5% Notes and related accrued interest.

The Company's financial instruments include cash, cash equivalents consisting of money market funds, accounts receivable, accounts payable and loan payable. As of December 31, 2023 and 2022, the fair values of cash and cash equivalents, restricted cash, accounts receivable, and loan and interest payable approximate their carrying value. The carrying value of loan payable on the Company's balance sheet is estimated to approximate its fair value as the interest rate approximates the market rate for loans with similar terms and risk characteristics.

We have no Level 1 or Level 2 instruments. Our Level 3 instrument amounts represent the fair value of the 5% Notes and related accrued interest. The following table summarizes the changes in Level 3 instruments for the years ended December 31, 2023 and 2022:

(in thousands)	
Balance at January 1, 2022	360
Interest accrued on face value of 5% Notes	1,073
Change in fair value of Level 3 liabilities	(1,190)
Balance at December 31, 2022	$ 243
Interest accrued on face value of 5% Notes	1,133
Change in fair value of Level 3 liabilities	(1,019)
Balance at December 31, 2023	$ 357

The change in the fair value of the Level 3 liabilities is reported in other (income) expense in the accompanying consolidated statements of operations.

NOTE 6 – STOCKHOLDERS' EQUITY

Preferred Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, $0.001 par value, with rights senior to those of our common stock, issuable in one or more series. Upon issuance, we can determine the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock.

Stockholder Rights Plan

On July 18, 2014, we adopted a stockholder rights plan. The stockholder rights plan is embodied in the Stockholder Protection Rights Agreement dated as of July 18, 2014 (the Rights Agreement), between us and American Stock Transfer & Trust Company, LLC, as rights agent (the Rights Agent).

Accordingly, the Board of Directors declared a distribution of one right (a "Right") for each outstanding share of common stock, to stockholders of record at the close of business on July 28, 2014, for each share of common stock issued (including shares distributed from Treasury) by us thereafter and prior to the Separation Time (as defined in the Rights Agreement), and for certain shares of common stock issued after the Separation Time. Following the Separation Time, each Right entitles the registered holder to purchase from us one one-thousandth (1/1,000) of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share (the Preferred Stock), at a purchase price of $100.00 (the Exercise Price), subject to adjustment. The description and terms of the Rights are set forth in the Rights Agreement. Each one one-thousandth of a share of Preferred Stock has substantially the same rights as one share of common stock. Subject to the terms and conditions of the Rights Agreement, Rights become exercisable ten days after the public announcement that a "Person" has become an "Acquiring Person" (as each such term is defined in the Rights Agreement). Any Rights held by an Acquiring Person are void and may not be exercised.

The Rights Agreement was approved by our Board of Directors on July 18, 2014. The Rights will expire at the close of business on its ten-year anniversary, unless earlier exchanged or terminated by us.

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 175,000,000 shares of $0.001 par value common stock.

On September 5, 2019, we filed an automatic "shelf registration" statement on Form S-3 (the 2019 WKSI Shelf) as a "well-known seasoned issuer" as defined in Rule 405 under the Securities Act, which registered an unlimited and indeterminate amount of debt or equity securities for future issuance and sale. The 2019 WKSI Shelf was declared effective in September 2019. In connection with the 2019 WKSI Shelf, we entered into an At-the-Market Issuance Sales Agreement (the 2020 ATM) with Jefferies LLC, Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (each a 2020 Agent and collectively, the 2020 Agents), relating to the sale of shares of our common stock. Under the 2020 ATM, we paid the 2020 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. In November 2020, we entered into an At-the-Market Issuance Sales Agreement (the 2021 ATM) with the same terms and agents (each a 2021 Agent and collectively, the 2021 Agents) as the 2020 ATM.

During the year ended December 31, 2021, we sold a total of 72,000 shares of common stock under the 2021 ATM for aggregate total gross proceeds of approximately $2.5 million at an average selling price of $34.25 per share, resulting in net proceeds of approximately $2.4 million after deducting commissions and other transactions costs.

On September 2, 2022, we filed an automatic "shelf registration" statement on Form S-3 (the 2022 WKSI Shelf) as a "well-known seasoned issuer" as defined in Rule 405 under the Securities Act, which registered an unlimited and indeterminate amount of debt or equity securities for future issuance and sale. The 2022 WKSI Shelf was declared effective in September 2022. In connection with the 2022 WKSI Shelf, we entered into an At-the-Market Issuance Sales Agreement (the 2022 ATM) with Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (each a 2022 Agent and collectively, the 2022 Agents), relating to the sale of shares of our common stock. Under the 2022 ATM, we will pay the 2022 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. The 2022 ATM has replaced the 2021 ATM as the only active ATM program.

During the year ended December 31, 2023, we sold a total of 1,385,700 shares of common stock under the 2022 ATM for aggregate total gross proceeds of approximately $47.1 million at an average selling price of $34.01 per share, resulting in net proceeds of approximately $46.3 million after deducting commissions and other transactions costs. The 2022 WKSI Shelf is currently our only active shelf-registration statement. We may offer any combination of the securities registered under the 2022 WKSI Shelf from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We may need to file additional shelf-registration statements in the future to provide us with the flexibility to raise additional capital to finance our operations as needed.

Treasury Stock

As of December 31, 2023 and 2022, 41,309 shares of common stock are being held in Treasury, at a cost of approximately $0.2 million, representing the fair market value on the date the shares were surrendered to the Company to satisfy employee tax obligations.

Equity Incentive Plans

The TG Therapeutics, Inc. 2022 Incentive Plan (the 2022 Incentive Plan) was approved by stockholders in June 2022 with 17 million shares available to be issued, of which not more than 10 million shares may be issued pursuant to "full-value awards." Full-value awards include any award other than an option or stock appreciation right and which is settled by the issuance of stock. As of December 31, 2023, 4,631,204 shares of restricted stock and 2,272,500 options were outstanding, and up to an additional 8,751,892 shares were available to be issued under the 2022 Incentive Plan.

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (the 2012 Incentive Plan) was approved by stockholders in June 2020. As of December 31, 2023, 5,007,864 shares of restricted stock and 2,424,529 options were outstanding, and no additional shares were available to be issued under the 2012 Incentive Plan as the 2022 Incentive Plan is now the only active incentive plan.

Total stock-based compensation expense included in the consolidated statements of operations was $37.9 million, $19.2 million and $61.3 million during the years ended December 31, 2023, 2022 and 2021, respectively. The $37.9 million is net of $2.9 million of stock-based compensation expense that was capitalized into inventory during the year ended December 31, 2023.

Stock Options

The estimated fair value of the options granted in the years ended December 31, 2023, 2022 and 2021 was determined utilizing the Black-Scholes option-pricing model at the date of grant. The following table summarizes stock option activity for the years ended December 31, 2023, 2022 and 2021:

	Number of shares	Weighted-average exercise price	Weighted-average contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2021	2,526,166	6.99	8.10	$ 115,472,832
Granted	—	$ —		
Exercised	(52,694)	4.10		
Forfeited	(5,935)	4.10		
Expired	—	—		
Outstanding at December 31, 2021	2,467,537	$ 7.06	6.99	$ 29,503,551
Granted	2,975,000	7.00		
Exercised	(142,409)	4.10		
Forfeited	(164,443)	7.84		
Expired	—	—		
Outstanding at December 31, 2022	5,135,685	$ 7.10	5.09	$ 25,064,799
Granted	—	—		
Exercised	(246,156)	6.08		
Forfeited	(192,500)	11.30		
Expired	—	—		
Outstanding at December 31, 2023	4,697,029	$ 6.98	4.10	$ 47,607,209
Exercisable at December 31, 2023	2,133,273	$ 6.60	4.72	$ 22,518,984

Total expense associated with stock options was approximately $3.9 million, $3.3 million and $2.9 million during the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, there was approximately $4.1 million of total unrecognized compensation cost related to unvested time-based stock options, which is expected to be recognized over a weighted-average period of 2.6 years. As of December 31, 2023, the stock options outstanding include options granted to both employees and non-employees which are both time-based and milestone-based. Stock-based compensation for milestone-based options will be recorded if and when a milestone becomes probable. We did not recognize stock-based compensation expense during the year ended December 31, 2023 for these stock options.

The fair value of the Company's option awards granted in each of the following years were estimated using the assumptions below:

	Year Ended		
	December 31, 2023	December 31, 2022	December 31, 2021
Volatility	N/A	88.37 - 89.67%	N/A
Expected term (in years)	N/A	3.13 - 4.0	N/A
Risk-free rate	N/A	2.99 - 3.35%	N/A
Expected dividend yield	N/A	—%	N/A

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the years ended December 31, 2023, 2022 and 2021:

	Number of shares	Weighted-average grant date fair value
Outstanding at January 1, 2021	10,785,034	13.38
Granted	2,738,974	39.49
Vested	(1,302,737)	18.14
Forfeited	(189,231)	21.80
Outstanding at December 31, 2021	12,032,040	18.67
Granted	5,179,201	12.75
Vested	(6,291,999)	11.28
Forfeited	(2,186,956)	22.44
Outstanding at December 31, 2022	8,732,286	16.12
Granted	3,620,237	13.77
Vested	(2,500,263)	11.98
Forfeited	(213,192)	12.14
Outstanding at December 31, 2023	9,639,068	$ 17.05

Total compensation expense associated with restricted stock grants was $34.1 million, $15.8 million and $58.4 million during the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, there was approximately $27.8 million of total unrecognized compensation expense related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 2.7 years. This amount does not include, as of December 31, 2023, 2,470,770 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones. Milestone-based noncash compensation expense will be measured and recorded if and when a milestone becomes probable.

Warrants

The Company's only outstanding warrants are the warrants issued to Hercules as part of the Loan Agreement, the Amended Loan Agreement and the First Amendment (please refer to Note 7– Loan Payable) to purchase 147,058, 115,042 and 50,172 shares of our common stock with exercise prices of $4.08, $17.95 and $14.70, respectively. See Note 7 for further details. As the warrants could not require cash settlement, the warrants were classified as equity. There will not be any ongoing stock compensation expense volatility associated with these warrants.

NOTE 7– LOAN PAYABLE

On February 28, 2019 (the Closing Date), we entered into a term loan facility with Hercules Capital, Inc. (Hercules or Lender), which provided us with the capacity to borrow up to an aggregate principal amount of $60.0 million (Term Loan). The Term Loan is governed by a loan and security agreement, dated February 28, 2019 (the Loan Agreement), which provides for up to four separate advances. The first advance of $30.0 million was drawn on the Closing Date. An additional $30.0 million under the Term Loan was previously available upon the completion of different milestones and time points that have now lapsed.

On December 30, 2021 (the Amended Loan Agreement Closing Date), the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules Capital, Inc. The Amended Loan Agreement amended the terms of the Loan Agreement to, among other things, (i) increase the aggregate principal amount of the loan, available at the Company's option, from $60.0 million to $200.0 million (the Amended Term Loan), (ii) issue a first advance of $70.0 million drawn at the Amended Loan Agreement Closing Date, a portion of which was used to refinance the current outstanding loan balance of approximately $7.8 million and pay for expenses incurred by the Lender in executing the agreements, (iii) change the draw amounts and dates available in subsequent tranches, (iv) extend the maturity date of the facility from the original March 1, 2022 to January 1, 2026, (v) reset and extend the interest only period from April 1, 2021 to February 1, 2025 and extendable to August 1, 2025 subject to the achievement of certain performance milestones, and (vi) modify the cash interest rate to be the greater of either (a) the "prime rate" as reported in The Wall Street Journal plus 2.15%, and (b) 5.40%. In addition to the cash interest rate, the principal balance accrues paid-in-kind interest at a rate of 3.45%, which amount will be capitalized and added to the outstanding principal balance of the Amended Term Loan and payable at the maturity date of the Amended Loan Agreement.

On March 31, 2023 (the First Amendment Effective Date), the Company entered into a First Amendment to the Amended and Restated Loan and Security Agreement (the First Amendment) with Hercules. The First Amendment amended the terms of the Amended Loan Agreement to, among other things: (i) issue an advance of $25.0 million drawn at the First Amendment Effective Date (the Tranche 3A Advance), (ii) provide for the formal expiration of Tranche 2, (iii) change the draw amounts and dates available under subsequent tranches, including splitting the remaining balance of Tranche 3 into two additional advances in an aggregate principal amount of up to $20.0 million, in increments of $10.0 million (a Tranche 3B Advance and a Tranche 3C Advance), decreasing the amount available under Tranche 4 from $65.0 million to $60.0 million, and adding a Tranche 5 of $25.0 million, subject to the achievement of revenue related performance milestones, (iv) extend the interest only period from February 1, 2025 to August 1, 2025 and (v) modify the cash interest rate to be the greater of either (a) the "prime rate" as reported in The Wall Street Journal plus 1.20%, and (b) 8.95%. In addition to the cash interest rate, the principal balance will accrue paid-in-kind interest at a rate of 2.25%, which amount will be capitalized and added to the outstanding principal balance of the Amended Term Loan and payable at the maturity date of the Amended Loan Agreement, as amended. The Amended Loan agreement, as amended, contains financial covenants that require the Company to maintain certain levels of unrestricted cash and additional financial covenants related to market capitalization. As of December 31, 2023, we are in compliance with all financial covenants.

The First Amendment also contains warrant coverage of 2.95% of each advance amount funded. A warrant (the Warrant) was issued by the Company to Hercules to purchase 115,042 shares of common stock with an exercise price of $17.95 for the initial amount funded at the Closing Date. The Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. Additionally, a warrant was issued by the Company to Hercules to purchase 50,172 shares of common stock with an exercise price of $14.70 for the amount funded pertaining to the Tranche 3A Advance (the First Amendment Warrant). The First Amendment Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the First Amendment Warrant either by (a) cash or check or (b) through a net issuance conversion

In addition, the Company is required to pay a final payment fee equal to 5.95% of the aggregate principal amount of the Term Loan Advances (as defined in the Amended Loan Agreement, as amended) plus 4.95% of the aggregate principal amount of all other advances.

The Company may, at its option, prepay the Amended Term Loan in full or in part, subject to a prepayment penalty equal to (i) 1.5% of the principal amount prepaid if the prepayment occurs prior to the first anniversary of the First Amendment Effective Date, and (ii) 1.0% of the principal amount prepaid if the prepayment occurs on or after the first anniversary of the First Amendment Effective Date.

The Company evaluated whether the First Amendment represented a debt modification or extinguishment of the Amended Term Loan in accordance with ASC 470-50, Debt – Modifications and Extinguishments. As a result of the modification of terms and no repayment or retirement of the Amended Term Loan, the Amended Term Loan was accounted for by the Company under the modification accounting model. The Company capitalized the facility charge from the First Amendment advance to debt issuance costs and expensed third party fees in the Company's statement of operations for the year ended December 31, 2023.

The Company estimated the fair value of the Warrant using the Black-Scholes model based on the following key assumptions:

	The First Amendment	The Amended Loan Agreement	The Loan Agreement
Exercise price	$ 14.70	$ 17.95	$ 4.08
Common share price on date of issuance	$ 15.04	$ 19.35	$ 6.80
Volatility	0.88%	184.40%	195.90%
Risk-free interest rate	3.6%	1.4%	2.6%
Expected dividend yield	—%	—%	—%
Contractual term (in years)	7.00	7.00	7.00

The Company incurred financing expenses of $2.0 million (including the fair value of the First Amendment Warrant) related to the First Amendment which are recorded as debt issuance costs and as an offset to loan payable on the Company's consolidated balance sheet The debt issuance costs are being amortized over the term of the debt using the straight-line method, which approximates the effective interest method, and will be included in interest expense in the Company's consolidated statements of operations. Amortization of debt issuance costs was $2.4 million, $1.8 million and $1.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. At December 31, 2023, the remaining unamortized balance of debt issuance costs was $5.1 million.

The loan payable as of December 31, 2023 and 2022, is as follows:

(in thousands)	**December 31, 2023**	**December 31, 2022**
Loan payable	$ 95,000	$ 70,000
Add: Accreted Liability of final payment fee	10,230	6,667
	105,230	76,667
Less: unamortized debt issuance costs	(5,112)	(5,532)
	100,118	71,135
Less: principal payments	—	—
Total loan payable	100,118	71,135
Less: current portion	—	—
Loan payable non-current	$ 100,118	$ 71,135

NOTE 8– LEASES

In October 2014, we entered into an agreement (the Office Agreement) with Fortress Biotech, Inc. (FBIO) to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of $1.8 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. At January 1, 2019, we recognized a lease liability and corresponding right-of-use (ROU) asset of $9.5 million and $8.1 million, respectively, based on the present value of the remaining lease payments for all of our leased office spaces, the majority of which is comprised of our New York City office space. The present values of our lease liability and corresponding ROU asset are $10.7 million and $8.1 million, respectively, as of December 31, 2023. Our leases have remaining lease terms of approximately 2 years to 8 years. One lease has a renewal option to extend the lease for an additional term of five years.

Also, in connection with this lease, in October 2014 we pledged $0.6 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying consolidated balance sheets. Additional collateral of $0.6 million was pledged in April 2018 to increase the letter of credit for the office space.

In October 2019, we finalized a five-year lease for office space in New Jersey (the NJ Lease). We approximate an average annual rental obligation of $0.3 million under the NJ Lease.

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In October 2021, we finalized a five-year lease for office space in North Carolina (the NC Lease). We approximate an average annual rental obligation of $0.2 million under the NC Lease. We took possession of this space in February 2022, with rental payments beginning in April 2022.

Operating lease cost was $2.2 million, $2.7 million and $2.2 million for the years ended December 31, 2023, 2022 and 2021, respectively.

As of December 31, 2023, the weighted-average remaining operating lease term was 5.8 years and the weighted-average discount rate for operating leases was 10.00%. Cash paid for amounts included in the measurement of operating lease liabilities during the year ended December 31, 2023 was $2.4 million.

The balance sheet classification of lease liabilities was as follows:

(in thousands)	December 31, 2023	December 31, 2022
Liabilities		
Lease liability current portion	$ 1,446	$ 1,581
Lease liability non-current	9,231	10,344
Total lease liability	$ 10,677	$ 11,925

As of December 31, 2023, the maturities of lease liabilities were as follows:

	Operating leases
2024	$ 2,388
2025	2,100
2026	2,080
2027	1,913
2028	1,827
After 2028	4,715
Total lease payments	15,023
Less: interest	(4,346)
Present value of lease liabilities(*)	$ 10,677

(*) As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date and considering the term of the lease to determine the present value of lease payments. We used the incremental borrowing rate of 10.25% on February 28, 2019, for leases that commenced prior to that date through December 31, 2021. We used an incremental borrowing rate of 5.65% for the NC lease.

NOTE 9 – INCOME TAXES

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management's assessment of all available evidence, we believe that it is more-likely-than-not that the deferred tax assets will not be realizable, and therefore, a valuation allowance has been established. The valuation allowance for deferred tax assets was approximately $418.3 million and $400.4 million as of December 31, 2023 and 2022, respectively.

The Tax Cuts and Jobs Act of 2017 (TCJA) included changes to the treatment of research and development expenses under IRC Section 174. Formerly, a company could deduct research and development expenses under IRC Section 174 as incurred. Effective for tax years beginning after December 31, 2021, research and development expenses under IRC Section 174 are required to be capitalized, with an amortization period of 5 years for costs incurred in the U.S. and 15 years for costs incurred in a non-U.S. jurisdiction. The Company incurred approximately $61.8 million of U.S. research and development costs and approximately $13.9 million of non-U.S. research and development costs that were capitalized during the year ended December 31, 2023.

The Inflation Reduction Act of 2022 (IRA) was enacted on August 16, 2022. The IRA provided for a Corporate Alternative Minimum Tax (Corp AMT), applicable to tax years beginning after December 31, 2022. The Corp AMT will impose a 15% tax on companies with adjusted financial statement income of over $1 billion for US-based organizations. At this time, it is not anticipated that the Corp AMT will be applicable for the Company.

As of December 31, 2023, we have U.S. net operating loss carryforwards of approximately $1.4 billion , research and development credit carryforwards (R&D credits) of approximately $45.8 million and business interest expense carryforward of $14.5 million. For income tax purposes, these NOLs and R&D credits will expire in various amounts through 2040. NOLs generated after 2017 and the business interest expense carryforwards do not expire. The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss carryforwards and R&D credit carryforwards in the case of certain events including significant changes in ownership interests. The Exchange Transaction with TG Bio may have resulted in a “change in ownership” as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended. Additionally, stock issuance activities may have resulted in a “change in ownership” as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended. Accordingly, a substantial portion of the Company’s NOLs above may be subject to annual limitations in reducing any future year’s taxable income, and a substantial portion of the R&D Credit carryforwards may be subject to annual limitations in reducing any future year’s tax.

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The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2023 and 2022 are presented below.

(in thousands)	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 316,962	$ 303,729
Research and development credit	45,806	42,031
Noncash compensation	12,275	10,325
Disallowed interest	3,328	3,882
Capitalized R&D Expenses	36,613	39,411
Other	3,333	985
Deferred tax asset, excluding valuation allowance	418,317	400,363
Less valuation allowance	(418,317)	(400,363)
Net deferred tax assets	$ —	$ —

There was approximately $0.4 million of current income tax expense for the year ended December 31, 2023. Income tax expense differed from amounts computed by applying the US federal income tax rate of 21% for the years ending December 31, 2023, 2022 and 2021, to pretax income (loss) as follows:

	For the year ended December 31,		
(in thousands)	2023	2022	2021
Loss before income taxes, as reported in the consolidated statements of operations	$ 13,062	$ (198,335)	$ (348,101)
Computed “expected” tax benefit	$ 2,743	$ (41,650)	$ (73,101)
Increase (decrease) in income taxes resulting from:			
Expected benefit from state and local taxes	111	(7,242)	(3,445)
Research and development credits	(3,430)	(6,389)	(8,337)
Officer Compensation Limitation	1,167	4,391	439
Other	(179)	374	428
Stock options	(12,445)	17,599	(6,726)
Change in state tax rates	(5,531)	-	-
Change in the balance of the valuation allowance for deferred tax assets	17,954	32,917	90,742
	$ 390	$ —	$ —

We file income tax returns in the U.S federal and various state and local jurisdictions. With certain exceptions, the Company is no longer subject to U.S. federal and state income tax examinations by tax authorities for years prior to 2020. However, NOLs and tax credits generated from those prior years could still be adjusted upon audit.

The Company would recognize interest and penalties, if any, to uncertain tax position in income tax expense in the statement of operations. There was no accrual for interest and penalties related to uncertain tax positions for 2023. We do not believe that there will be a material change in our unrecognized tax positions over the next twelve months. All of the unrecognized tax benefits, if recognized, would be offset by the valuation allowance.

NOTE 10 – LICENSE AGREEMENTS

BRIUMVI (Ublituximab)

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the LFB License Agreement). Under the terms of the LFB License Agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. For the period ended December 31, 2023, we have incurred expenses of approximately $31.0 million related to the achievement of certain milestones of the LFB License Agreement. These expenses are included in other research and development expenses in the accompanying consolidated statements of operations. As of December 31, 2023, we had approximately zero recorded in accounts payable related to the LFB License Agreement.

LFB Group is eligible to receive future payments of approximately $6.0 million, upon our successful achievement of certain regulatory milestones, in addition to royalty payments on net sales of ublituximab at a royalty rate in the high-single digits. The license will terminate on a country-by-country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by LFB if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party. During the year ended December 31, 2023, the Company recorded $8.7 million related to the worldwide royalty due under the LFB License Agreement in cost of revenue based on U.S. sales of BRIUMVI and as of December 31, 2023, approximately $3.9 million in royalties were payable under the LFB License Agreement.

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong Pharmaceutical Co. Ltd. (Ildong) relating to the development and commercialization of ublituximab in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize ublituximab in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar.

An upfront payment of $2.0 million, which was received in December 2012, net of $0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately $0.2 million for each of the years ended December 31, 2023, 2022 and 2021, and at December 31, 2023 and 2022, have deferred revenue of approximately $0.3 million and $0.5 million, respectively, associated with this $2 million payment.

We may receive up to an additional $5.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, Ildong will make royalty payments to us on net sales of ublituximab in the sublicense territory.

In July 2023, the Company entered into the Commercialization Agreement with Neuraxpharm. The Company granted Neuraxpharm the exclusive right to commercialize BRIUMVI in certain territories outside the United States, Canada, and Mexico, the commercialization rights for which had been previously retained by the Company, thus, and excluding certain Asian countries subject to previously existing partnerships. Under the terms of the Commercialization Agreement, the Company received a one-time, non-refundable payment of $140.0 million upon contract execution (please refer to Note 2 – Revenue). The Company is eligible to receive an additional $12.5 million upon first key market commercial launch in the EU and up to an additional $492.5 million in milestone-based payments on achievement of certain launch and commercial milestones. In addition, TG will receive tiered double-digit royalties on net product sales up to 30%. In the event of a change of control of the Company (as defined in the Commercialization Agreement), the Company retains an option to buy back all rights under the Commercialization Agreement for a period of two years thereafter.

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui, to acquire worldwide intellectual property rights, excluding Asia but including Japan, and for the research, development, manufacturing, and commercialization of products containing or comprising of any of Hengrui's Bruton's Tyrosine Kinase inhibitors containing the compounds of either TG-1701 (SHR1459 or EBI1459) or TG1702 (SHR1266 or EBI1266). Hengrui is eligible to receive milestone payments totaling approximately $350 million upon and subject to the achievement of certain milestones. Various provisions allow for payments in conjunction with the agreement to be made in cash or our common stock, while others limit the form of payment. In July 2020, we paid Hengrui $2.0 million as part of a milestone in accordance with the license agreement. Royalty payments in the low double digits are due on net sales of licensed products and revenue from sublicenses.

TG-1801: anti-CD47/anti-CD19

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune to collaborate on the development and commercialization of Novimmune's novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies. We serve as the primary responsible party for the development, manufacturing and commercialization of the product. Milestone payments will be paid based on early clinical development, and the Company will be responsible for the costs of clinical development of the product through the end of the Phase 2 clinical trials, after which the Company and Novimmune will be jointly responsible for all development and commercialization costs. The Company and Novimmune will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TG-1801, in which case Novimmune is eligible to receive additional milestone payments totaling approximately $185 million as well as tiered royalties on net sales in the high single to low double digits upon and subject to the achievement of certain milestones.

UKONIQ (umbralisib)

On September 22, 2014, we exercised our option to license the global rights to umbralisib, thereby entering into an exclusive licensing agreement (the TGR-1202 License) with Rhizen Pharmaceuticals, SA (Rhizen) for the development and commercialization of umbralisib. As of December 31, 2023, we have incurred approximately $24.0 million related to the achievement of certain milestones of the Umbralisib License.

Under the terms of the TGR 1202 License, Rhizen is eligible to receive approval and sales-based milestone payments in the aggregate of approximately $175 million payable. For the year ended December 31, 2021, we paid Rhizen $12.0 million as part of a primary indication approval milestone for launch of product in the US in accordance with the terms of the Umbralisib License. Additionally, Rhizen receives tiered royalties that escalate from high single digits to low double digits on any net sales of umbralisib. UKONIQ was officialy withdrawn from the market in May 2022 and all commercialization activities were discontinued. As a result of the withdrawal, during the year ended December 31, 2023, the Company recorded zero related to the worldwide royalty due under the Umbralisib License in cost of revenue based on U.S. sales of UKONIQ, and as of December 31, 2023, no royalties were payable under the Umbralisib License. Due to the withdrawal of UKONIQ from the U.S. market and discontinuation of all commercialization activities, we do not expect to incur any additional costs related to this license agreement.

TG-1501: Cosibelimab

In March 2015, we entered into a Global Collaboration Agreement (Collaboration Agreement) with Checkpoint for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. The Collaboration Agreement was amended in June 2019 and in March of 2020. We incurred expenses of approximately $0.1 million for each of the years ended December 31, 2023, 2022 and 2021, the majority of which relates to manufacturing expenses, clinical study expenses and milestone payments of PD-L1. The relevant expenses are recorded in other research and development in the accompanying consolidated statements of operations.

NOTE 11 – RELATED PARTY TRANSACTIONS

In July 2015, we entered into a Shared Services Agreement (the Shared Services Agreement) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. This Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately $0.9 million, $1.3 million and $0.9 million for shared services for the years ended December 31, 2023, 2022 and 2021, respectively, primarily related to shared personnel. Mr. Weiss, our Chairman and Chief Executive Officer, also serves as a director and Executive Vice Chairman, Strategic Development of FBIO.

In March 2015, we entered into the Collaboration Agreement with Checkpoint, a subsidiary of FBIO, for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. In May 2016, as part of a broader agreement with Jubilant, we entered into a sublicense agreement (JBET Agreement) with Checkpoint for the development and commercialization of Jubilant's novel BET inhibitor program in the field of hematological malignancies. Mr. Weiss also serves as Chairman of the Board of Directors of Checkpoint.

Please refer to Note 8 - Leases for details regarding the Office Agreement with FBIO, as well as Note 10 - License Agreements for details regarding the Collaboration Agreement with Checkpoint.

NOTE 12 – COMMITMENTS AND CONTINGENCIES

As of December 31, 2023, we have known contractual obligations; commitments and contingencies of $115.4 million related to our short- and long-term liabilities and operating lease obligations.

Payment due by period (in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual obligations					
Operating leases	$ 15,023	$ 2,388	$ 4,180	$ 3,740	$ 4,715
Long-term debt	100,403	—	100,403	—	—
Total	$ 115,426	$ 2,388	$ 104,583	$ 3,740	$ 4,715

Leases

See Note 8 - leases for a detailed description of our lease arrangements in New York, New Jersey and North Carolina. Total rental expense was approximately $2.2 million, $2.7 million and $2.2 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Future minimum lease commitments as of December 31, 2023, in the aggregate total approximately $15.0 million through July 31, 2031. The preceding table shows future minimum lease commitments, which include our office leases in New York, New Jersey, and North Carolina by year as of December 31, 2023.

Loan Payable

See Note 7 – Loan payable for a detail description of our loan agreement.

NOTE 13 – SUBSEQUENT EVENTS

Precision Bio

On January 7, 2024, TG and its wholly-owned subsidiary, TG Cell Therapy, Inc., entered into a License Agreement (the Precision License Agreement) with Precision BioSciences, Inc. (Precision), pursuant to which Precision granted the Company certain exclusive and non-exclusive license rights to develop, manufacture, and commercialize Precision's allogeneic CAR T therapy azercabtagene zapreleucel (azer-cel) for the treatment of autoimmune and other non-oncology diseases and conditions (collectively, the Field).

Pursuant to the Precision License Agreement, the Company will make an upfront payment to Precision of $7.5 million, consisting of (i) $5.25 million in cash and (ii) $2.25 million, as an equity investment, for the purchase of 2,920,816 shares of Precision's common stock at a price of $0.77 per share. Within 12 months of the Precision License Agreement, the Company will make a deferred payment of $2.5 million to Precision, consisting of an equity investment in Precision's common stock at a 100% premium to the 30-day volume-weighted average price (the 30-day VWAP) prior to purchase. Upon achievement of certain near-term clinical or time-based milestones, the Company will make a $7.5 million payment to Precision, a portion of which will also be an equity investment in Precision's common stock at a 100% premium to the 30-day VWAP prior to purchase. Precision will be eligible to receive up to $288 million in additional milestone payments based on the achievement of certain clinical, regulatory, and commercial milestones. In addition, the Company is obligated to pay Precision high-single-digit to low-double-digit royalties on net sales of the licensed product on a country-by-country basis until the latest to occur of patent expiration, loss of regulatory exclusivity, and a period of ten years following the first commercial sale of the licensed product in such country. The Company has also agreed to make certain payments to Precision's licensors during the term of the Precision License Agreement.

Ex-U.S. BRIUMVI Launch

On February 26, 2024, TG announced that its ex-US partner, Neuraxpharm launched BRIUMVI in Europe, for the treatment of adults patients with relapsing forms of multiple sclerosis (RMS), who have active disease defined by clinical or imaging features. The launch commenced in Germany, with additional launches throughout Europe to follow. In accordance with the ex-US commercialization agreement, TG will receive a milestone payment of $12.5 million for the first launch of BRIUMVI in a European country.

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.

TG THERAPEUTICS, INC.

Date: February 29, 2024

By: /s/ Michael S. Weiss
Michael S. Weiss
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael S. Weiss and Sean A. Power, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on February 29, 2024, and in the capacities indicated:

Signatures	Title
/s/ Michael S. Weiss Michael S. Weiss	Chairman, Chief Executive Officer and President
/s/ Sean A. Power Sean A. Power	Chief Financial Officer, Treasurer and Corporate Secretary
/s/ Laurence N. Charney Laurence N. Charney	Director
/s/ Yann Echelard Yann Echelard	Director
/s/ Kenneth Hoberman Kenneth Hoberman	Director
/s/ Daniel Hume Daniel Hume	Director
/s/ Sagar Lonial Sagar Lonial	Director

Exhibit 10.38

Certain information marked as [***] has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

LICENSE AGREEMENT

by and among

TG THERAPEUTICS, INC.,

TG CELL THERAPY, INC.

and

PRECISION BIOSCIENCES, INC.

LICENSE AGREEMENT

This **License Agreement** ("***Agreement***") is entered into as of January 7, 2024 (the "***Effective Date***"), by and among **Precision BioSciences, Inc.**, a corporation organized and existing under the laws of Delaware, having an address at 302 East Pettigrew St., Suite A-100, Durham, North Carolina 27701 ("***Precision***"), **TG Cell Therapy, Inc.**, a corporation organized and existing under the laws of Delaware, with its principal business office located at 3020 Carrington Mill Blvd, Suite 475, Morrisville, North Carolina 27560 ("***TGTX***"), and, with respect to Sections 8.14 and 15.18 (including the other sections or subsections referred to therein or applicable thereto), **TG Therapeutics, Inc.**, a corporation organized and existing under the laws of Delaware, with its principal business office located at 3020 Carrington Mill Blvd, Suite 475, Morrisville, North Carolina 27560 ("***TGTX Parent***"). TGTX and Precision are each hereafter referred to individually as a "***Party***" and together as the "***Parties***."

WHEREAS, Precision is a Nasdaq-listed, genome-editing and cell therapy company, which leverages its proprietary ARCUS Technology (as defined below) that is based on I-CREI derived engineered meganucleases and cell therapy platform to develop, manufacture, and commercialize allogeneic CAR-T (as defined below) products and for in vivo gene editing for the treatment of genetic disease;

WHEREAS, TGTX and its Affiliates, including its parent, TGTX Parent, are engaged in the research, development, and commercialization of pharmaceutical products targeting B-cell diseases and conditions; and

WHEREAS, TGTX desires to obtain from Precision, and Precision desires to grant to TGTX, certain exclusive and non-exclusive license rights to develop, manufacture, and commercialize Precision's current investigational cell therapy product, known as "azer-cel," for treatment of autoimmune and other non-oncology diseases and conditions, all subject to the terms and conditions of this Agreement.

NOW, **THEREFORE**, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Capitalized terms used in this Agreement and the Schedules and Exhibits hereto shall have the following meanings (or as defined elsewhere in this Agreement):

1.1 "***Acquirer***" has the meaning set forth in the definition of Change of Control.

1.2 "***Active Ingredient***" means, with respect to a Combination Product, an active therapeutic ingredient having a different therapeutic target or mode of action, or which is otherwise treated or designated by the applicable Regulatory Authority as a separate active ingredient, than the applicable Licensed Product.

1.3 "***Affiliate***" means, with respect to any Person, any entity that, at the relevant time (whether as of the Effective Date or thereafter), directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person, for so long as such control exists. As used in this Section 1.3, "control" means: (a) to possess, directly or indirectly, the power to direct or cause the direction of the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect ownership of fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction) or more of the voting share capital or other equity interest in such entity. Notwithstanding anything to the contrary in this Agreement, Precision, on the one hand, and TGTX, on the other hand, shall not be considered Affiliates of each other.

1.4 "***Agreement***" has the meaning set forth in the Preamble.

1.5 "***Applicable Laws***" means the applicable provisions of any and all federal, national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, guidelines or requirements, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, or permits of or from any court, arbitrator, Regulatory Authority, Governmental Authority, taxing authority, national securities exchange or exchange listing organization having jurisdiction over or related to the relevant subject item that may be in effect from time to time during the Term.

1.6 "***ARCUS Nuclease***" means any fully synthetic nuclease derived from a homing endonuclease and made using the ARCUS Technology.

1.7 "***ARCUS Regulatory Matters***" has the meaning set forth in Section 4.1.3.

1.8 "***ARCUS Technology***" means Precision's proprietary genome editing platform known as ARCUS™, relating to the design, creation, selection, development, optimization and delivery of fully synthetic enzymes derived from homing endonucleases, including any modifications or improvements to the foregoing.

1.9 "***Background IP***" means TGTX Background IP or Precision Background IP, as applicable.

1.10 "***Bayh-Dole Act***" has the meaning set forth in Section 10.2.6.

1.11 "***Biosimilar Product***" means a product that is developed and commercialized by a Third Party, without any involvement (contractual or otherwise) of TGTX or its Affiliates, that the applicable Regulatory Authority has determined is a biosimilar to the Licensed Product, meaning it is highly similar to and has no clinically meaningful differences from the Licensed Product, that is approved by an abbreviated marketing authorization process that relies on the Marketing Authorization of the Licensed Product as the original or reference biological product as to which the determination of biosimilarity is made, and that is approved for use in the Licensed Field.

1.12 "***BLA***" means a Biologic License Application (as more fully described in U.S. 21 C.F.R. Part 601.20 or its successor regulation), as may be amended from time to time, or any analogous application or submission with any Regulatory Authority outside of the United States.

1.13 "***Business Day***" means any day, other than any Saturday, Sunday, or any day that banks are authorized or required to be closed in Durham, North Carolina, or New York, New York.

1.14 "***Calendar Quarter***" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31 of any Calendar Year.

1.15 "***Calendar Year***" means each respective period of twelve (12) consecutive months commencing on January 1 and ending on December 31.

1.16 "***CAR-T***" means human T cells genetically engineered *ex vivo* with Chimeric Antigen Receptor(s).

1.17 "***CD19***" means B-lymphocyte antigen CD19.

1.18 "***Cellectis Agreement***" has the meaning set forth in Section 7.5.2.

1.19 "***Cellectis Patents***" has the meaning set forth in Section 7.5.2.

1.20 "***Cellectis S.A.***" has the meaning set forth in Section 7.5.2.

1.21 "***Change of Control***" means, with respect to a Person: (a) the acquisition by a person or group (each as used in this definition uncapitalized, such terms have the meanings specified in Section 13(d) of the Exchange Act and Rule 13d-3 thereunder), in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of such Person (excluding, for clarity, an acquisition by a person or group where the equity holders of such acquired Person or its parent immediately prior to such transaction hold a majority of the outstanding voting equity securities of the surviving entity or the parent of the surviving entity immediately following such transaction); (b) a merger, reorganization or consolidation involving such Person as a result of which (1) a person or group acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the surviving entity immediately after such merger, reorganization or consolidation and (2) the voting securities of such Person outstanding immediately prior to such merger, reorganization or consolidation, or any securities into which such voting securities have been converted or exchanged, cease to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately following such merger, reorganization or consolidation; or (c) a sale, exclusive license or other transfer of all or a material part of the assets of such Person related to the transactions contemplated by this Agreement in one transaction or a series of related transactions to a person or group. The acquiring or combining person or group in any of (a), (b) or (c), and any of such person's or group's Affiliates (whether in existence as of or any time following the applicable transaction, but other than such acquired Person and its Affiliates as in existence prior to the applicable transaction or Affiliates it controls after the applicable transaction) are referred to collectively herein as the "***Acquirer***."

1.22 "***Chimeric Antigen Receptor***" means a genetically engineered molecule that (a) when present on the surface of human T cells, enables the T cells to recognize and bind to specific antigens that are present on the surface of cells, and (b) comprises a single-chain antibody fragment (scFv), a transmembrane domain, and at least one intracellular signaling domain.

1.23 "***Claim***" has the meaning set forth in Section 11.1.1.

1.24 "***Clinical Trial***" means a clinical study conducted on certain numbers of human subjects (depending on the phase of the trial) that is designed to (a) establish that a product for the treatment of human diseases and conditions is reasonably safe for continued testing, (b) investigate the safety and efficacy of the product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the product in the dosage range to be prescribed, or (c) support Marketing Authorization or Pricing and Reimbursement Approval of such product or label expansion of such product.

1.25 "***CMO***" means contract manufacturing organization.

1.26 "***Code***" has the meaning set forth in Section 13.7.

1.27 "***Combination Product***" has the meaning set forth in the definition of Net Sales.

1.28 "***Commercial Milestone Payment***" has the meaning set forth in Section 8.4.

1.29 "***Commercialization***" means any and all activities directed to the commercial exploitation of a Licensed Product, including: (a) activities directed to storing, marketing, promoting, detailing, distributing, importing, exporting, selling and offering to sell that Licensed Product; (b) conducting Clinical Trials after Marketing Authorization of a Licensed Product with respect to such Licensed Product; (c) interacting with Regulatory Authorities regarding the foregoing; and (d) seeking Regulatory Approvals (as applicable) for and registration of that Licensed Product; *provided* that seeking Marketing Authorization constitutes Development and not Commercialization. When used as a verb, "to ***Commercialize***" and "***Commercializing***" means to engage in Commercialization and "***Commercialized***" has a corresponding meaning.

1.30 "***Commercially Reasonable Efforts***" means:

1.30.1 with respect to the obligations of a Party under this Agreement relating to Development activities, the level of efforts and expenditure of resources required to carry out such obligation in a sustained manner consistent with the efforts and resources such Party or its Affiliates typically devotes to a product of similar market potential, resulting from its own research efforts or development and commercialization collaborations for which it is responsible, at a similar stage in its development or product life, taking into account Relevant Factors;

1.30.2 with respect to the level of obligations of a Party under this Agreement relating to Commercialization activities, the level of efforts and expenditure of resources required to carry out such obligation in a sustained manner consistent with the efforts and resources of a typical Third Party biopharmaceutical company of similar size and with similar resources as such Party or its Affiliates typically devotes to a product of similar market potential, at a similar stage in its development or product life, taking into account Relevant Factors; or

1.30.3 with respect to the obligations of a Party under this Agreement relating to any other objective, reasonable, good-faith efforts, taking into account industry practices.

Provided that, if in consideration of the Relevant Factors (or, as it relates to Section 1.30.3, industry practices), Commercially Reasonable Efforts requires any act to be performed, with respect to such performance and for the period of time during which Commercially Reasonable Efforts dictates such performance, Commercially Reasonable Efforts requires that the applicable Party (a) promptly assign responsibility for obligations to specific employee(s) who are held accountable for progress and monitor such act on an on-going basis, (b) set and consistently seek to achieve specific, meaningful and measurable objectives for carrying out such act, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such act.

1.31 [***].

1.32 "***Confidential Proprietary Information***" has the meaning set forth in Section 12.1.1.

1.33 "***Confidentiality Agreement***" means that certain Confidentiality Agreement entered into between the Parties as of September 11, 2023.

1.34 "***Control***" or "***Controlled***" means, with respect to any Know-How, Patents, other intellectual property rights, Clinical Data and Documentation, or Regulatory Filings, that a Party has the legal authority or right (whether by ownership, license, or otherwise, but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) to grant to the other Party a license, covenant not to sue, sublicense, access, or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without violating any obligations of the granting Party owed to a Third Party or breaching the terms of any agreement with a Third Party.

1.35 "***Cover***" means, with respect to a claim of a Patent and given product or other subject matter, that such claim would be infringed, in the absence of a license, or ownership, by the Exploitation of such product or other subject matter (considering claims of patent applications to be issued as then pending).

1.36 "***Currently Outstanding Precision Common Stock***" refers to the number of shares of Precision Common Stock that are issued and outstanding as of the applicable date.

1.37 "***Development***" means all activities related to the development of products, including Licensed Products, for the treatment of human diseases and conditions. When used as a verb, "***Develop***" or "***Developing***" means to engage in Development and "***Developed***" has a corresponding meaning.

1.38 "***Development Records***" has the meaning set forth in Section 3.2.1.

1.39 "***Disclosing Party***" has the meaning set forth in Section 12.1.2.

1.40 "***Dispute***" has the meaning set forth in Section 14.2.

1.41 "***Distributor***" means, as applicable, with respect to a given Licensed Product, any Person appointed by (a) TGTX, (b) any of TGTX's Affiliates or (c) any of their respective Sublicensees that is not an Affiliate of (a) or (b), to distribute, market and sell the Licensed Product in one or more countries in the Territory, in circumstances where the Person (x) purchases its requirements of the Licensed Product from TGTX for their respective Affiliates or its or their Sublicensees but (y) has no right to conduct any Development or Manufacturing (other than packaging) activities with respect to such Licensed Product.

1.42 "***Dollar***" means a U.S. dollar, and "***$***" is to be interpreted accordingly.

1.43 "***Duke***" has the meaning set forth in the definition of Duke Agreement.

1.44 "***Duke Agreement***" means the License Agreement entered into by Precision and Duke University ("***Duke***") on April 17, 2006, as amended by the Amendment, dated May 31, 2007, and as further amended by the Letter Agreements, dated December 10, 2007, February 13, 2009, January 17, 2012, December 6, 2013, December 13, 2013, and February 4, 2014, and as further amended from time to time.

1.45 "***Duke IP***" means all Patents and Know-How licensed to Precision under the Duke Agreement that constitute Precision Background IP. The patent numbers and patent application numbers of the Patents that are included within the Duke IP as of the Effective Date are set forth in Schedule 1.45.

1.46 "***Effective Date***" has the meaning set forth in the Preamble.

1.47 "***Equity Termination Event***" has the meaning set forth in Section 8.2.5.

1.48 "***E.U.***" means, except as set forth in Section 8.5, the European Union as constituted on the Effective Date.

1.49 "***Exchange Act***" has the meaning set forth in Section 8.2.2(e).

1.50 "***Exchange Cap***" refers to the maximum number of Precision Shares that may be issued pursuant to this Agreement, it being acknowledged and agreed that in no event shall the Precision Shares that may be issued pursuant to the terms of this Agreement exceed either of the following: (a) 19.99% of the Currently Outstanding Precision Common Stock as of the Effective Date of this Agreement; or (b) with respect to a "change of control" (as defined by Nasdaq Listing Rule 5635), the number of shares of Precision Common Stock that would result in beneficial ownership of more than 19.99% of the Currently Outstanding Precision Common Stock following such issuance, in each case (i) subject to appropriate adjustments being made in respect of any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split, reconstruction, consolidation, division, reclassification of such shares into a lesser or greater number of securities or other similar transaction that occurs after the Effective Date and (ii) in accordance with the rules and regulations of Nasdaq.

1.51 "***Executive Officers***" means (a) with respect to Precision, [***], and (b) with respect to TGTX, [***]; or the successor of such person in the foregoing (a) or (b) or any other person that such person in the foregoing (a) or (b) designates from time to time.

1.52 "***Existing In-License Agreements***" means the Duke Agreement and the Cellectis Agreement.

1.53 "***Existing Patents***" has the meaning set forth in Section 10.2.2.

1.54 "***Existing Third Party Agreements***" has the meaning set forth in Section 10.2.3.

1.55 "***Exploit***" means to Research, Develop, Manufacture, Commercialize and otherwise exploit. "***Exploitation***" has correlating meaning.

1.56 "***Extraordinary Matter***" has the meaning set forth in Section 8.2.7.

1.57 "***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

1.58 "***Final Precision Stock Issuance***" has the meaning set forth in Section 8.2.1(d).

1.59 "***Final Precision Stock Payment***" has the meaning set forth in Section 8.2.1(d).

1.60 "***First Commercial Sale***" means, with respect to a Licensed Product, the first sale of such Licensed Product by the applicable Selling Party to a Third Party for end use or consumption of such Licensed Product in a given country in the Territory after Marketing Authorization required to market and sell the Licensed Product has been granted with respect to such Licensed Product by the applicable Regulatory Authority in such country in which such Licensed Product is sold.

1.61 [***].

1.62 "***Good Clinical Practices***" or "***cGCP***" means all applicable current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of Clinical Trials, including, as applicable: (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("***ICH***") E6 and any other guidelines for good clinical practice for trials on medicinal products in the Territory; (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto; (c) U.S. Code of Federal Regulations Title 21, Parts 50, 54, 56, 312 and 314, as may be amended from time to time; and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time, and in each case ((a)-(d)), that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.63 "***Good Laboratory Practices***" or "***GLPs***" means all applicable Good Laboratory Practice standards, including, as applicable: (a) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58; and (b) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.64 "***Good Manufacturing Practices***" or "***cGMP***" means all applicable current Good Manufacturing Practices including, as applicable: (a) the principles detailed in the US Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820; (b) European Directive 2003/94/EC and Eudralex 4; (c) the principles detailed in the WHO TRS 986 Annex 2, TRS 961 Annex 6, TRS 957 Annex 2, and TRS 999 Annex 2; (d) ICH Q7 guidelines; and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.65 "***Government Official***" has the meaning set forth in Section 10.6.4.

1.66 "***Governmental Authority***" means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, and any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.67 "***Holding Period***" has the meaning set forth in Section 8.2.6.

1.68 "***ICD-11***" means the 11th revision of the International Classification of Diseases of the World Health Organization or a successor thereto.

1.69 "***ICH***" has the meaning set forth in the definition of Good Clinical Practices.

1.70 "***Imugene***" means Imugene (USA) Inc.

1.71 "***IND***" means an investigational new drug application filed with the FDA or any similar application filed with a Regulatory Authority in a country outside the U.S. required to commence Clinical Trials of a pharmaceutical product.

1.72 "***Indemnitee***" has the meaning set forth in Section 11.1.3.

1.73 "***Indemnitor***" has the meaning set forth in Section 11.1.3.

1.74 "***Infringement***" has the meaning set forth in Section 9.3.1.

1.75 "***Initiation***" means with respect to any Clinical Trial, the enrollment of the first human subject in such Clinical Trial.

1.76 "***Initiation Deadline***" has the meaning set forth in Section 3.1.2.

1.77 "***Insolvency Event***" means any of the events set out in Section 13.2.3.

1.78 "***Internal Compliance Codes***" has the meaning set forth in Section 10.6.2.

1.79 "***Inventions***" means all Know-How and inventions, whether or not patentable, and all rights, title and interest in and to the intellectual property rights (including Patent rights) therein.

1.80 "***Joint IP***" has the meaning set forth in Section 9.1.2.

1.81 "***Joint Patents***" means any Patent constituting or claiming any Joint IP.

1.82 "***JSC***" has the meaning set forth in Section 2.3.1.

1.83 "***Know-How***" means any proprietary scientific, clinical or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form, including databases, safety and efficacy information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know-how, trade secrets, materials, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their Exploitation or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, physical and analytical, safety, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process and development information, results and data.

1.84 "***Knowledge***" means the actual knowledge of each of Precision's Chief Executive Officer, Chief Research Officer, Chief Financial Officer, Chief Business Officer and Vice President of Intellectual Property after due inquiry.

1.85 "***Licensed ARCUS Nuclease***" means [***].

1.86 "***Licensed Field***" means the treatment, prevention, cure, mitigation or palliation of any and all human diseases, conditions or disorders, excluding the treatment, prevention, cure, mitigation and palliation of any and all cancers (i.e., diseases, conditions or disorders identified in chapter 2 ("Neoplasms") of the ICD-11).

1.87 "***Licensed Product***" means the investigational allogeneic CAR-T product directed to CD19 known as "azercabtagene zapreleucel" or "azer-cel" and having the Precision internal designation PBCAR0191, including any preparation, formulation, dosage, packaging or method of administration thereof.

1.88 "***Licensed Product Trademarks***" has the meaning set forth in Section 9.8.

1.89 "***Lock-Up Securities***" has the meaning set forth in Section 8.2.6.

1.90 "***Losses***" has the meaning set forth in Section 11.1.1.

1.91 [***]

1.92 "***Manufacture***" and "***Manufacturing***" means any and all activities related to the production, manufacture, formulation, finishing, packaging, labeling, shipping and holding of a Licensed Product, or other product or therapy, or any component, intermediary or precursor thereof (including, for clarity, [***]), and including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture, characterization, quality assurance and quality control (including testing).

1.93 "***Marketing Authorization***" means, with respect to a particular Licensed Product in a particular country or regulatory jurisdiction, collectively, all Regulatory Approvals (including any Pricing and Reimbursement Approval or access approvals, if applicable) required by the relevant Regulatory Authority in order to initiate marketing, selling or Commercializing a Licensed Product in such country or jurisdiction.

1.94 "***MaxCyte***" has the meaning set forth in Section 8.5.

1.95 "***MaxCyte Agreement***" means the License Agreement entered into by Precision and MaxCyte on November 12, 2018, as amended by the Amendment, dated as of April 1, 2020, and as further amended from time to time.

1.96 "***Medical Affairs***" means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs related to the Licensed Product and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Product and are not conducted by a Party's medical affairs (or equivalent) departments. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

1.97 "***Medical Affairs Plan***" means, with respect to the Licensed Product, the written high-level strategic and tactical plans for the Medical Affairs activities for such Licensed Product to be conducted in the Licensed Field in the Territory that will be prepared and updated by TGTX as provided in Section 4.6.

1.98 "***Milestone 1 Precision Stock Issuance***" has the meaning set forth in Section 8.2.1(c).

1.99 "***Milestone 1 Precision Stock Payment***" has the meaning set forth in Section 8.2.1(c).

1.100 "***Milestone Event***" means any milestone event set forth in Section 8.3 or Section 8.4.

1.101 "***Minimum Price***" means the price that is the lower of the following: (a) the Nasdaq official closing price (as reflected on Nasdaq.com) immediately preceding the signing of this Agreement; or (b) the average Nasdaq official closing price of the Precision Common Stock (as reflected on Nasdaq.com) for the five Trading Days immediately preceding the signing of this Agreement. For purposes of this Agreement, the Minimum Price is $0.3722 per share, subject to appropriate adjustments being made in respect of any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split, reconstruction, consolidation, division, reclassification of such shares into a lesser or greater number of securities or other similar transaction that occurs after the Effective Date.

1.102 "***Nasdaq***" means the Nasdaq Stock Market LLC.

1.103 "***Net Sales***" means [***].

The foregoing amounts shall be determined from the books and records of the Selling Party, maintained in accordance with U.S. GAAP, consistently applied. [***]. In the case of sale or disposal of the applicable Licensed Product for consideration other than exclusively monetary consideration, Net Sales for such Licensed Product shall be the value of the non-cash consideration received, as determined in accordance with U.S. GAAP. In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of the applicable Licensed Product between the individual Selling Parties for such Licensed Product for resale shall be excluded from the computation of Net Sales (unless such Licensed Product is consumed by such Selling Party), but the subsequent resale of such Licensed Product by such Selling Party to a Third Party shall be included within the computation of Net Sales. Licensed Products transferred as part of an expanded access program, compassionate sales or use program, an indigent program, as *bona fide* samples, as donations, or for the performance of Clinical Trials, shall not be included in Net Sales for such Licensed Product.

For purposes of determining Net Sales of the Licensed Product sold in combination with or as part of a bundle with other products, or in packaged arrangements to customers that include the Licensed Product, in each case other than Combination Products (which are addressed below), [***].

In the event that the Licensed Product is sold as part of a Combination Product (where "***Combination Product***" means any pharmaceutical product which comprises the Licensed Product and one or more other Active Ingredients that do not constitute the Licensed Product, whether co-formulated, co-packaged or otherwise sold together for one price), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by [***].

[***].

1.104 "***Parent Obligations***" has the meaning set forth in Section 15.18.1.

1.105 "***Party***" and "***Parties***" has the meaning set forth in the Preamble.

1.106 "***Patent Defense Matters***" means the conduct of interferences, derivation proceedings, *inter partes* review and post-grant review, the defense of oppositions and other similar proceedings with respect to a Patent, excluding any activities associated with claims, including as a counterclaim or declaratory judgment action, of unpatentability, invalidity or unenforceability of such Patent that are brought by a Third Party in connection with an alleged or threatened infringement by a Third Party of a Patent.

1.107 "***Patents***" mean: (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

1.108 "***Permitted Transferee***" means TGTX Parent or any entity controlled by TGTX Parent that is an Affiliate of TGTX and to whom the Shares are being transferred without consideration; *provided*, however, that no such Person shall be deemed a Permitted Transferee for any purpose under this Agreement unless (a) the Permitted Transferee, prior to or simultaneously with any transfer of Shares to such Affiliate, shall have agreed in writing to be subject to and bound by, and makes the representations and warranties set forth in, Sections 8.2.3, 8.2.4, 8.2.6, 8.2.7 and 8.2.8 (and all other provisions of this Agreement referred to therein or applicable thereto) as though it were "TGTX" or "TGTX Parent" hereunder, as applicable (including specifically executing an irrevocable proxy to vote the Shares as required by Section 8.2.7), (b) each of TGTX and TGTX Parent acknowledges and agrees that it continues to be bound by the terms of this Agreement, and (c) TGTX provides written documentation, reasonably acceptable to Precision, that such permitted transfer complies with all applicable securities laws.

1.109 "***Person***" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.110 "***Phase I Clinical Trial***" means a Clinical Trial that would satisfy the requirements of 21 C.F.R. § 312.21(a) (or equivalent regulation in countries other than the United States).

1.111 "***Phase II Clinical Trial***" means a Clinical Trial that would satisfy the requirements of 21 C.F.R. § 312.21(b) (or equivalent regulation in countries other than the United States). [***].

1.112 "***Phase III Clinical Trial***" means a controlled or uncontrolled human Clinical Trial of a product that would satisfy the requirements of 21 C.F.R. § 312.21(c) (or equivalent regulation in countries other than the United States). [***].

1.113 "***Pivotal Clinical Trial***" means [***].

1.114 "***Precision***" has the meaning set forth in the Preamble.

1.115 "***Precision Arising IP***" means, individually or collectively, Precision Sole IP and Precision's share in Joint IP.

1.116 "***Precision Arising Platform IP***" means any and all Precision Arising IP that is not Precision Arising Product IP.

1.117 "***Precision Arising Product IP***" means Precision Arising IP that is necessary or reasonably useful for the Exploitation of the Licensed Product.

1.118 "***Precision Background IP***" means any and all (a) Patents Controlled by Precision or its Affiliates at any time during the Term that Cover a Licensed Product, or use of the Licensed ARCUS Nuclease to make a Licensed Product, or any Know-How in the following clause (b); (b) Know-How Controlled by Precision or its Affiliates (i) as of the Effective Date or (ii) during the Term, in each case (i) and (ii) that is necessary or reasonably useful for the Exploitation of a Licensed Product in the Licensed Field; and (c) [***].

1.119 "***Precision Background Platform IP***" means any and all Precision Background IP that is not Precision Background Product IP, including ARCUS Technology.

1.120 "***Precision Background Product IP***" means any and all Precision Background IP that is directly and particularly related to the Exploitation of the Licensed Product in the Licensed Field.

1.121 "***Precision Common Stock***" means Precision's common stock, par value $0.000005 per share.

1.122 "***Precision-Imugene JSC***" means the joint steering committee existing under Section 2.2 of the Precision-Imugene License Agreement.

1.123 "***Precision-Imugene License Agreement***" means the License Agreement between Imugene and Precision, dated August 15, 2023, as amended from time to time.

1.124 "***Precision Indemnitee***" has the meaning set forth in Section 11.1.2.

1.125 "***Precision Patent***" means any Patent included in the Precision Technology.

1.126 "***Precision Platform IP***" means, individually or collectively, the Precision Background Platform IP and the Precision Arising Platform IP.

1.127 "***Precision Product IP***" means, individually or collectively, the Precision Background Product IP and the Precision Arising Product IP.

1.128 "***Precision Product Patent***" means [***].

1.129 "***Precision Product-Specific Claim***" means [***].

1.130 "***Precision Share Price***" means the greater of (a) two hundred percent (200%) of the VWAP of the Precision Common Stock calculated during the applicable period specified in this Agreement and (b) the Minimum Price (for clarity, the Precision Share Price applicable to any Precision Stock Issuance shall not be less than the Minimum Price); provided, however, that if the Precision Common Stock is no longer listed on Nasdaq or another securities exchange, the Precision Share Price shall be equal to two hundred percent (200%) of the fair market value of a share of Precision Common Stock, as reasonably determined in good faith by the Precision Board of Directors or any successor thereof.

1.131 "***Precision Shares***" refers to the shares of Precision Common Stock issued by Precision to TGTX in accordance with, and subject to the terms and conditions specified in, this Agreement.

1.132 "***Precision Sole IP***" has the meaning set forth in Section 9.1.2(b).

1.133 "***Precision Stock Issuances***" has the meaning set forth in Section 8.2.1(d).

1.134 "***Precision Stock Payments***" has the meaning set forth in Section 8.2.1(d).

1.135 "***Precision Technology***" means, individually or collectively, the Precision Background IP and the Precision Arising IP.

1.136 "***Pricing and Reimbursement Approval***" means, with respect to a particular Licensed Product and a particular country or regulatory jurisdiction, any approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Licensed Product, as required in a given country or jurisdiction prior to sale of such Licensed Product in such country or jurisdiction at the relevant time.

1.137 "***Prosecute and Maintain***" or "***Prosecution and Maintenance***" with respect to a particular Patent, means (a) all activities associated with the preparation, filing, prosecution and maintenance of such Patent, and (b) all Patent Defense Matters with respect to such Patent.

1.138 "***Prosecuting Party***" has the meaning set forth in Section 9.2.2.

1.139 "***Proxyholder***" has the meaning set forth in Section 8.2.7.

1.140 "***Publication***" has the meaning set forth in Section 12.3.

1.141 "***Receiving Party***" has the meaning set forth in Section 12.1.2.

1.142 "***Regulatory Approvals***" means, collectively, any and all approvals (including supplements, amendments, pre- and post-approvals, Pricing and Reimbursement Approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations) or waivers of any Regulatory Authority that are necessary for the testing or Exploitation of a pharmaceutical product (including the Licensed Product) in any country or jurisdiction, including Pricing and Reimbursement Approval, as applicable.

1.143 "***Regulatory Authority***" means any Governmental Authority that has responsibility in its applicable jurisdiction over the Exploitation of pharmaceutical products (including the Licensed Product) in any country or jurisdiction. For countries or jurisdictions where governmental approval is required for pricing or reimbursement for a pharmaceutical product (including the Licensed Product) to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority includes any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.144 "***Regulatory Filings***" means, collectively, any and all applications, filings, submissions, approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations), non-clinical and clinical study authorization applications or notifications (including all supporting files, writings, data, studies and reports) or waivers with respect to the Commercialization of a pharmaceutical product (including Licensed Products) made to or received from any Regulatory Authority or research ethics committee in a given country or jurisdiction, including INDs and BLAs.

1.145 "***Relevant Factors***" means all factors that are relevant to the Development, Manufacture or Commercialization of a product, including its safety and efficacy, product profile, cost to develop, cost and availability of supply, the time required to complete Development, the competitiveness of the marketplace (including the proprietary position and anticipated market share of the product), the patent position with respect to such product (including the ability to obtain or enforce, or have obtained or enforced, such patent rights), the third-party patent landscape relevant to the product, the regulatory structure involved, the likelihood of regulatory approval, the anticipated or actual profitability of the applicable product and other technical, commercial, legal, scientific, regulatory and medical considerations, in all cases, on a country-by-country basis, including, without limitation, decisions and actions relating to the sequence and advisability of initiating Development in [***], and including, with respect to TGTX's efforts [***].

1.146 "***Representatives***" has the meaning set forth in Section 9.1.6.

1.147 "***Research***" means, with respect to a Licensed Product, or other product or therapy, any and all activities directed to the discovery, identification, screening, testing, assessment and optimization of such Licensed Product, or other product or therapy.

1.148 "***Restricted Period***" has the meaning set forth in Section 8.2.7.

1.149 "***Review Period***" has the meaning set forth in Section 12.3.

1.150 "***Right of Reference***" means the right and authority to rely upon, and otherwise use, a study or an investigation for the purpose of filing, and conducting a Clinical Trial under, an IND, or obtaining approval of a Marketing Authorization or other Regulatory Approval, including the ability to make available the underlying raw data from the study or investigation for audit by the applicable Regulatory Authority in such country or other jurisdiction, if necessary.

1.151 "***Royalty***" has the meaning set forth in Section 8.6.2.

1.152 "***Royalty Term***" has the meaning set forth in Section 8.6.1.

1.153 "***Rule 144***" has the meaning set forth in Section 8.2.4.

1.154 [***].

1.155 "***Securities Act***" has the meaning set forth in Section 8.2.2(a).

1.156 "***Selling Party***" means TGTX, its Affiliates or its or their Sublicensees.

1.157 "***Servier***" has the meaning set forth in the definition of Servier Agreement.

1.158 "***Servier Agreement***" means the Program Purchase Agreement entered into by Precision and Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, "***Servier***") on April 9, 2021, as amended from time to time.

1.159 "***Standstill Provisions***" has the meaning set forth in Section 8.2.8.

1.160 "***Stockholder Approval***" means such approval as may be required by the applicable rules and regulations of Nasdaq (or any successor entity) or any other applicable exchange from the stockholders of Precision with respect to issuance of Precision Shares.

1.161 "***Stockholder Matter***" has the meaning set forth in Section 8.2.7.

1.162 "***Sublicensee***" means a Third Party that is granted a license or sublicense to Develop, Manufacture or Commercialize a Licensed Product in the Licensed Field in the Territory, beyond the mere right to purchase such Licensed Product from TGTX and its Affiliates, and excludes TGTX's and its Affiliates' Distributors.

1.163 "***Term***" has the meaning set forth in Section 13.1.

1.164 "***Terminated Product***" has the meaning set forth in Section 13.3.

1.165 "***Territory***" means worldwide.

1.166 "***TGTX***" has the meaning set forth in the Preamble.

1.167 "***TGTX Arising IP***" means, individually or collectively, TGTX Sole IP and TGTX's share in Joint IP.

1.168 "***TGTX Background IP***" means any and all Patents and Know-How that TGTX or any of its Affiliates Controls as of the Effective Date, or discovers, creates or acquires outside the scope of its performance of activities under this Agreement; in each case, that is necessary or reasonably useful for the Exploitation of a Licensed Product.

1.169 "***TGTX Indemnitee***" has the meaning set forth in Section 11.1.1.

1.170 "***TGTX Parent***" has the meaning set forth in the Preamble.

1.171 "***TGTX Parent Common Stock***" means TGTX Parent's common stock, par value $0.001 per share.

1.172 "***TGTX Parent Consideration Shares***" refers to the shares of TGTX Parent Common Stock issued by TGTX Parent to Precision in accordance with, and subject to the terms and conditions specified in, this Agreement.

1.173 "***TGTX Patent***" means any Patent constituting or claiming any TGTX Background IP or TGTX Sole IP.

1.174 "***TGTX Promotional Materials***" has the meaning set forth in Section 5.1.3(a).

1.175 "***TGTX Sole IP***" has the meaning set forth in Section 9.1.2.

1.176 "***TGTX Technology***" means TGTX Background IP and TGTX Sole IP.

1.177 [***].

1.178 "***Third Party***" means any Person other than TGTX or Precision (or their respective Affiliates).

1.179 "***Trading Day***" means a day on which the Nasdaq is open for trading, *provided* that if no closing price or daily trading volume is reported in respect of the relevant shares on the Nasdaq for one (1) or more consecutive trading days, such day or days will be disregarded in any relevant calculation and shall be deemed not to have existed when ascertaining any period of trading days.

1.180 "***Transfer***" has the meaning set forth in Section 8.2.6.

1.181 [***].

1.182 "***Upfront Precision Stock Issuance***" has the meaning set forth in Section 8.2.1(a).

1.183 "***Upfront Precision Stock Payment***" has the meaning set forth in Section 8.2.1(a).

1.184 "***U.S.***" means the United States of America and its territories and possessions.

1.185 "***U.S. GAAP***" has the meaning set forth in the definition of Net Sales.

1.186 "***Valid Claim***" means, with respect to a given Licensed Product, a claim that Covers (a) [***], (b) [***] or (c) [***], in each case (a) - (c) contained in (y) an issued and unexpired Patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal; or (z) a pending patent application that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken and that has been pending for no longer than [***].

1.187 "***VWAP***" means the arithmetic average of the daily volume-weighted average per share price of the relevant shares of common stock on Nasdaq (or, if such shares are no longer listed on Nasdaq, the applicable securities exchange, if any, on which they are then listed) during the Trading Day (subject to appropriate adjustments being made in respect of any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split, reconstruction, consolidation, division, reclassification of such shares into a lesser or greater number of securities or other similar transaction, other than a buyback or capital reduction, during the relevant period or subsequent thereto and prior to the issuance of the relevant shares of common stock, and in respect of certain other market circumstances to adjust for market anomalies, such as suspensions of trading).

1.188 "***Withholding Tax Action***" has the meaning set forth in Section 8.11.4.

ARTICLE 2

GOVERNANCE AND JOINT STEERING COMMITTEE

2.1 **Relationship Managers**. No later than [***] after the Effective Date, each Party will appoint an individual to act as its relationship manager under this Agreement as soon as practicable after the Effective Date (each a "***Relationship Manager***"). The Relationship Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, and; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC meetings, in each case, as a non-voting member. A Relationship Manager may also bring any matter to the attention of the JSC if such Relationship Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Relationship Manager at any time upon written notice to the other Party. [***].

2.2 **Coordination with Imugene**. Precision will use Commercially Reasonable Efforts to facilitate TGTX's entry into a cooperation agreement with Imugene, in form reasonably acceptable to TGTX, as promptly as possible following the Effective Date (but in any event no later than [***] following the Effective Date) to enable TGTX to Develop, Manufacture and Commercialize the Licensed Product in accordance with the terms of this Agreement, and providing for, among other things, information sharing (including, without limitation, with respect to all chemistry, manufacturing, and controls (CMC) data), regulatory coordination, promotional materials, compliance policies, complaints or inquiries, and coordination of prosecution and maintenance of Patents, in each case, between TGTX and Imugene relating to the Licensed Product. [***].

2.3 **Joint Steering Committee**.

2.3.1 **Establishment; Purpose of JSC**. No later than [***] after the Effective Date, the Parties will establish a joint steering committee (the "***JSC***") to monitor the Exploitation of the Licensed Product in the Licensed Field in the Territory. The JSC will be composed of an equal number of representatives from each Party, and a minimum of three (3) representatives of each Party, and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least [***] prior to the next scheduled meeting of the JSC. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at any meeting by another person designated by the absent representative. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth hereunder.

2.3.2 **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

2.3.3 **Meetings**. The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. The JSC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method; *provided* that the Parties will use reasonable efforts for at least one meeting each Calendar Year to be conducted in person at a location selected alternatively by Precision and TGTX or such other location as the Parties may agree. Each Party will be responsible for all of its own costs and expenses of participating in any JSC meeting. The Relationship Managers will jointly prepare and circulate minutes for each JSC meeting within [***] after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [***] thereafter.

2.3.4 **JSC Responsibilities**. The responsibilities of the JSC will be to:

(a) provide a forum for the discussion of the Parties' activities and the flow of information contemplated under this Agreement;

(b) review and discuss the Development of each Licensed Product, including clinical trial protocols, monitoring plans, and data disclosure plans included with each such protocol;

(c) [***], review and discuss any clinical trial protocols, monitoring plans, and data disclosure plans included with each such protocol with respect to each Licensed Product;

(d) review and discuss matters that may have a material adverse impact upon the regulatory status of the Licensed Product, as described in Section 4.1.2(f);

(e) review and discuss Medical Affairs Plans and any updates thereto for any Licensed Product, as described in Section 4.6;

(f) review and discuss the Commercialization of the Licensed Product;

(g) oversee the implementation of activities to be performed under any other written agreement between the Parties with respect to the subject matter hereof; and

(h) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

2.4 **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives (which may include legal counsel), to attend a meeting of the JSC (in a non-voting capacity), if such participants have expertise that is relevant to the planned agenda for such JSC meeting; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 12 [***].

2.5 **Decision-Making**.

2.5.1 **General Process**. The JSC will only have the advisory powers expressly assigned to it in this Article 2 and elsewhere in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with the terms of this Agreement. [***]. No action taken at any meeting of the JSC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if two voting representatives of each Party are present or participating in such meeting. Except as otherwise expressly set forth in this Agreement, the phrases "determine," "designate," "confirm," "approve," or "determine whether to approve" by the JSC and similar phrases used in this Agreement will mean approval in accordance with this Section 2.5, including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 2.3.4 to be reviewed and discussed (as opposed to approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 2.5.

2.5.2 **Decisions of the JSC**. The JSC will use good faith efforts, in compliance with this Section 2.5.2, to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter that is within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of [***], then a Party may refer such matter for resolution in accordance with Section 2.6.1.

2.6 **Resolution of JSC Disputes**.

2.6.1 **Referral to Executive Officers**. If a Party makes an election under Section 2.5.2 to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

2.6.2 **No Change; Status Quo**. If the Executive Officers are unable to reach agreement on any such matter referred to them within [***] after such matter is so referred (or such longer period as the Executive Officers may agree upon), then neither Party will have final decision-making authority over approval of such matter and all such matters must be decided by unanimous agreement of the Parties in order to take any action or adopt any change from the then-current *status quo*, as applicable, *provided* that TGTX will have final decision-making authority with respect to [***].

2.6.3 **Limitations on Decision-Making**. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Party (in the exercise of a Party's final decision-making authority), the JSC, nor a Party's Executive Officer, in each case, may make a decision that could reasonably be expected to [***].

2.7 **Discontinuation of JSC**. The JSC will continue to exist until the first to occur of (a) [***] or (b) [***]. Once the JSC is disbanded, the JSC will have no further obligations under this Agreement and, thereafter, the Relationship Managers will be the points of contact for the exchange of information between the Parties under this Agreement.

ARTICLE 3

DEVELOPMENT MATTERS

3.1 **Licensed Product.**

3.1.1 **Conduct of the Parties**. The Parties' mutual objective is to permit TGTX, pursuant to and in accordance with the terms of this Agreement, to Develop the Licensed Product(s) in the Licensed Field while not taking any action that would be reasonably likely to materially adversely affect Development of the Licensed Product outside the Licensed Field. Each Party shall conduct itself and its activities hereunder consistent with that understanding, consistent with sound and ethical business and scientific practices. In all matters related to such activities (including, with respect to Precision, its actions under the Precision-Imugene License Agreement), the Parties shall strive to balance, as best as reasonably possible, their respective legitimate interests and concerns and to realize the economic potential of the Licensed Product(s) in the Licensed Field and outside the Licensed Field.

3.1.2 **Development Responsibility; Diligence Obligations**. Subject to the terms of this Agreement, TGTX shall be responsible for, at its sole cost and expense, all Development of the Licensed Product in the Licensed Field in the Territory, including all Clinical Trials and activities that are necessary for or otherwise support obtaining and maintaining Regulatory Approvals in the Licensed Field in the Territory. TGTX shall use Commercially Reasonable Efforts to Develop and seek and obtain Regulatory Approval for the Licensed Product in the Licensed Field in the Territory [***], all in accordance with all Applicable Laws. [***] (such date, as may be extend by clause (a) or (b), the "***Initiation Deadline***").

3.1.3 **Standard of Conduct**. TGTX will perform, and will cause its Affiliates, Sublicensees, and subcontractors to perform, all Development activities for the Licensed Product in a timely, good scientific manner, in accordance with GLP, cGMP, and cGCP, as applicable, and in compliance with Applicable Laws and Commercially Reasonable Efforts. In addition, TGTX will conduct its obligations with respect to any Clinical Trial with the study design set forth in the applicable protocol, each as may be amended from time to time.

3.2 **Development Records**.

3.2.1 **Generally**. TGTX will, and will cause its Affiliates, Sublicensees, and subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of TGTX, and its Affiliates, Sublicensees, and subcontractors, respectively, pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are materially in compliance with 21 C.F.R. §11 and in accordance with Applicable Laws ("***Development Records***"). Such Development Records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Products in good scientific manner appropriate for regulatory and patent purposes.

3.2.2 **Additional Requirements**. TGTX will maintain all Development Records related to the Licensed Product for a period of [***] after the end of the Term. TGTX will document all non-clinical and preclinical studies and Clinical Trials of the Licensed Product in formal written study reports in accordance with GLP, cGMP, and cGCP, as applicable, and in compliance with Applicable Law.

(a) Upon Precision's reasonable request, not more frequently than [***] during which TGTX or its Affiliates, Sublicensees, or subcontractors are performing or having performed Development activities for any Licensed Product, TGTX will, and will cause its Affiliates, Sublicensees, and subcontractors to, allow Precision to access, review, and copy such records (including access to relevant databases). Precision will have the right to use the data and results generated by or on behalf of TGTX and its Affiliates, Sublicensees, and subcontractors hereunder to Exploit any Licensed Product outside of the Licensed Field in the Territory. TGTX will ensure that all records or other documents that it transmits to Precision electronically under this Agreement are transmitted over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

(b) Upon TGTX's reasonable request during the Term, not more frequently than [***] during which Precision or its Affiliates, Sublicensees, or subcontractors are performing or having performed development activities for any Licensed Product, Precision will allow TGTX to access, review, and copy all data and other information resulting from such activities (including access to relevant databases) that are Controlled by Precision. TGTX will have the right to use such data and information hereunder to Exploit any Licensed Product in the Licensed Field in the Territory. Precision will ensure that all data and other information that it transmits to TGTX electronically under this Agreement are transmitted over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

3.3 **Data Exchange and Use**. In addition to its adverse event and safety data reporting obligations set forth in Section 4.4, each Party will promptly provide the other Party, through the JSC (or, based on the time sensitivity or urgency of such data and results, directly between representatives of the Parties outside of the JSC), with copies of all data and results and all supporting documentation (*e.g.*, protocols, Investigator's Brochures, case report forms, analysis plans, and all in English language) (collectively, "***Clinical Data and Documentation***") (a) Controlled by such Party or its Affiliates (or Sublicensees, in the case of TGTX) (b) owned by, or licensed to, Precision's licensees, to the extent Controlled by Precision, in each case, (a) or (b), that are generated by or on behalf of such Party or its Affiliates (or its licensees or Sublicensees, as applicable) in the Development of each Licensed Product, including in the Development of the existing Licensed Product under the Precision-Imugene License Agreement. TGTX will have the right to use and reference such data and results provided by Precision for the purpose of performing Development activities under this Agreement, obtaining, supporting, and maintaining Regulatory Approvals and any Reimbursement Approval, as applicable, of Licensed Products in the Licensed Field in the Territory, without additional consideration. Precision and its Affiliates and licensees will have the right to use and reference such data and results provided by TGTX for the purpose of Developing the Licensed Product (but, during the Term, only outside the Licensed Field) or any other products based on ARCUS Technology, and obtaining, supporting, and maintaining Regulatory Approvals or any Reimbursement Approvals, as applicable, of any such product, without additional consideration. For clarity, Precision shall not clinically Develop the Licensed Product in the Licensed Field in the Territory during the Term. [***].

3.4 **Development Reports**. On an annual basis, during any period in which TGTX is performing, or having performed, Development activities for the Licensed Product, TGTX will provide Precision, at TGTX's sole cost and expense, with reasonably detailed written reports summarizing the Development activities performed during the period since the preceding report, the Development activities in process, and the future activities that TGTX or its Sublicensees or subcontractors expect to initiate. Without limiting the foregoing, such reports will contain sufficient detail to enable Precision to assess TGTX's compliance with its Development diligence obligations set forth in this Article 3. TGTX will promptly respond to Precision's reasonable requests from time to time for additional information regarding significant Development activities for the Licensed Product performed by or on behalf of TGTX or its Affiliates, Sublicensees, or subcontractors.

ARTICLE 4

REGULATORY MATTERS; MEDICAL AFFAIRS

4.1 **Regulatory Responsibilities**.

4.1.1 **Licensed Product Outside the Licensed Field**. As between Precision and TGTX, Precision (or its licensees) shall be solely responsible for any and all regulatory activities with respect to the Licensed Product outside the Licensed Field, including filing of all Regulatory Filings for the Licensed Product, maintenance of all Regulatory Approvals, any reports or submissions required to be made to any non-governmental Third Party payors, and any and all regulatory matters arising after obtaining Regulatory Approval, including post-marketing inquiries and safety surveillance activities. Precision shall keep TGTX reasonably and promptly apprised of such activities.

4.1.2 **Licensed Product in the Licensed Field**.

(a) As between Precision and TGTX, subject to the terms of this Agreement, TGTX shall be responsible for regulatory activities with respect to the Licensed Product in the Licensed Field in the Territory, and shall use Commercially Reasonable Efforts to prepare any and all Regulatory Filings for all indications in the Licensed Field. TGTX shall provide the JSC with drafts of all chemistry, manufacturing, and controls (CMC) and quality-related filings for Licensed Products in the Licensed Field in the Territory at least [***] prior to submission to a Regulatory Authority to allow the JSC a reasonable opportunity to review and comment on such filings. TGTX shall consider the JSC's comments on such filings in good faith but has no obligation to accept any comments of the JSC. TGTX shall submit all Regulatory Filings for Licensed Products in the Licensed Field in the Territory in the name of TGTX or its Affiliate or designee, and all resulting Regulatory Approvals will be owned by, and held in the name of, TGTX or its Affiliate or designee.

(b) To the extent possible, and as soon as reasonably possible, each Party shall provide to the JSC reasonable written notice of all meetings and conference telephone calls with any Regulatory Authority in which matters that would be expected to relate to the Licensed Product will be discussed.

(c) Each Party shall notify the JSC within [***] after it receives information about the initiation of any investigation or inquiry by any Regulatory Authority concerning the Development, Manufacture or Commercialization of the Licensed Product to the extent such investigation or inquiry would be reasonably likely to adversely affect the other Party. Precision shall keep TGTX reasonably and promptly informed of any such information it receives from Imugene.

(d) If a Regulatory Authority desires to conduct an inspection or audit with regard to the Licensed Product or TGTX's facility or a facility under contract with TGTX or its Affiliate with respect to the activities relevant to this Agreement, TGTX shall permit and cooperate with such inspection or audit, and shall cause the contract facility to permit and cooperate with such Regulatory Authority during such inspection or audit. TGTX shall conform its activities under this Agreement to any commitments made in such a response, except to the extent that TGTX believes in good faith that such commitments violate Applicable Laws.

(e) If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of either Party, its Affiliate, or licensee (or Sublicensee, in the case of TGTX) relating to the Licensed Product, then such Party will notify the JSC of such contact, inspection, or notice or action within [***] after receipt of such notice (or, if later, within [***] of such Party becoming aware of such action). Such Party will have the final decision-making authority with respect to [***]. The costs and expenses of any such regulatory action will be borne by such Party. Precision shall keep TGTX reasonably and promptly informed of any such notice received by the Precision-Imugene JSC.

(f) If either Party believes that the other Party, its Affiliate, or licensee (or Sublicensee, in the case of TGTX) is taking or intends to take any action with respect to the Licensed Product that could have a material adverse impact upon the regulatory status of the Licensed Product, [***]. Precision shall keep TGTX reasonably and promptly informed of any such matter brought to the attention of the Precision-Imugene JSC.

4.1.3 **ARCUS Nuclease Matters**. Notwithstanding anything to the contrary and without limiting any other right of Precision in this Article 4, Precision shall have the right, prior to BLA approval for the Licensed Product, to have its employees attend each INTERACT meeting or pre-IND submission meeting, the end of the Phase II Clinical Trial meeting for the Licensed Product, and any other meeting with the FDA or EMA if such other meeting has any item on the agenda specifically directed to the manufacturing, quality, safety (including non-clinical safety related to production of ARCUS Nucleases) or delivery of ARCUS Nucleases or ARCUS Technology for the portion of the meeting specifically directed to such topics (collectively, "***ARCUS Regulatory Matters***"). Prior to BLA approval for the Licensed Product, TGTX will provide drafts of its communications with the FDA and EMA (including with respect to CMC-related matters) to the extent they relate to ARCUS Regulatory Matters to Precision for review and comment, and will consider Precision's comments in good faith and not unreasonably reject any such comments, before submitting such communications to the FDA or EMA. Following BLA approval for the Licensed Product, TGTX shall provide Precision notice regarding any communications from Regulatory Authorities regarding ARCUS Regulatory Matters.

4.2 **Regulatory Costs**. TGTX shall bear all costs and expenses it incurs to conduct all regulatory activities under this Agreement.

4.3 **Right of Reference**. Each Party hereby grants, and shall cause its Affiliates and require its licensees (and Sublicensees, in the case of TGTX) to grant, at no cost, to the other Party, its Affiliates and any of their respective licensees (in the case of Precision) or Sublicensees (in the case of TGTX) a Right of Reference and right to use and reference (which, for the purposes of Section 13.7, the Parties agree is a license) any data and Regulatory Filings Controlled by the granting Party, its Affiliates, or its licensees (or Sublicensees, in the case of TGTX) that relates to the Licensed Product that the other Party reasonably believes may be necessary or useful to the Development, Manufacture or Commercialization of the Licensed Product in such other Party's respective field (i.e., in the Licensed Field, in the case of TGTX, or outside the Licensed Field, in the case of Precision), and the granting Party will provide, and shall cause its Affiliates and require its licensees (in the case of Precision) and Sublicensees (in the case of TGTX) to provide, a signed statement to the foregoing effect, as reasonably requested by the other Party. [***].

4.4 **Adverse Event Reporting; PV Agreement.**

4.4.1 **Generally**. As between the Parties, TGTX shall be responsible for the timely reporting of all relevant adverse drug reactions/experiences, product quality, product complaints and safety data relating to Licensed Products in the Licensed Field to the appropriate Regulatory Authorities in the Territory, in each case in accordance with Applicable Laws of the relevant countries and Regulatory Authorities. [***]. The PV Agreement shall include terms that comply with ICH guidelines, taking into account the roles of Imugene as data holder and TGTX as data generator, including timely reporting of all relevant adverse drug reactions/experiences, product quality, product complaints and safety data relating to Licensed Products to the appropriate Regulatory Authorities in the Territory in accordance with Applicable Laws of the relevant countries and Regulatory Authorities. In addition, the PV Agreement shall include provisions (a) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety data relating to the Licensed Product or the Licensed ARCUS Nuclease worldwide within appropriate timeframes and in an appropriate format to enable each Party to meet both expedited and periodic regulatory reporting requirements; and (b) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities on a worldwide basis for the reporting of safety data in accordance with standards stipulated in the ICH guidelines, and all applicable regulatory and legal requirements regarding the management of safety data. Pursuant to the PV Agreement, each party thereof shall be solely responsible for all costs and expenses it incurs to conduct its pharmacovigilance responsibilities. [***].

4.4.2 **Right to Audit for Licensed Product**. Each Party shall have the right to perform audits of the other Party's pharmacovigilance activities relating to the Parties' activities in relation to the Licensed Product under the terms of this Agreement including compliance by the other Party with Applicable Laws. The frequency of such audits will be no more than [***] during the Term; *provided* that such audits may be more frequent if, in the auditing Party's sole discretion, more frequent audits are necessary by a risk-based approach, and except in 'for cause' situations where, in the event of a serious or potentially serious issue, additional audits may be conducted. The notification of one Party's intent to conduct such an audit will be provided in writing to the other Party within a reasonable time period in advance, based upon the particular circumstances of the situation.

4.5 **Product Withdrawals and Recalls**. In the event that (a) an event, incident, or circumstance has occurred which may result in the need for a recall or other removal of the Licensed Product or any lot or lots thereof from the market in the Licensed Field in the Territory; (b) any Regulatory Authority in the Territory threatens or initiates any action to remove the Licensed Product from the market in the Licensed Field in the Territory; or (c) any Regulatory Authority in the Territory requires distribution of a "Dear Doctor" letter or its equivalent, regarding use of the Licensed Product in the Licensed Field in the Territory, TGTX shall promptly advise Precision in writing with respect thereto, and shall provide to Precision copies of all relevant correspondence, notices, and any other related documents. In the event that (x) an event, incident, or circumstance has occurred which may result in the need for a recall or other removal of any Licensed Product or any lot or lots thereof from the market outside the Licensed Field in the Territory; (y) any Regulatory Authority in the Territory threatens or initiates any action to remove any Licensed Product from the market outside the Licensed Field in the Territory; or (z) any Regulatory Authority in the Territory requires distribution of a "Dear Doctor" letter or its equivalent, regarding use of the Licensed Product outside the Licensed Field in the Territory, Precision shall promptly (after it becomes aware of any of the events in (x) – (z)) advise TGTX, and shall require its licensees to promptly advise Precision, in writing with respect thereto, and shall provide to TGTX, and shall require its licensees to provide to Precision, copies of all relevant correspondence, notices, and any other related documents in its, or its licensee's, as applicable, possession. Unless otherwise agreed by the Parties, TGTX shall be responsible for conducting a recall of the Licensed Product in the Licensed Field. TGTX will have the right to make the final determination whether to voluntarily implement any such recall, market suspension, or market withdrawal of the Licensed Product in the Licensed Field in the Territory. Each Party will cooperate with the other Party in the performance of any recall or withdrawal.

4.6 **Medical Affairs** No later than [***] prior to the anticipated date of performance of Medical Affairs activities for the Licensed Product in the Territory, TGTX will prepare an initial draft of each Medical Affairs Plan for the Licensed Product and provide such initial draft to the JSC to review and discuss. The Medical Affairs Plan will contain a high-level summary of the major Medical Affairs activities to be undertaken by TGTX for the Licensed Product in the Licensed Field in the Territory and the estimated timelines for performing such activities. Thereafter, from time to time, but at least annually, TGTX will propose updates to the Medical Affairs Plan for the Licensed Product in the Licensed Field in the Territory to reflect changes in such plan, including to account for relevant facts and circumstances that may influence such plan and the Medical Affairs activities set forth therein and provide each such update to the JSC to review and discuss. For each Calendar Quarter in which any Medical Affairs are conducted by or on behalf of TGTX or its Affiliates or Sublicensees for the Licensed Product in the Licensed Field in the Territory, TGTX will provide updates on Medical Affairs activities at each meeting of the JSC. The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the Licensed Product(s) inside and outside of the Licensed Field. Accordingly, the Parties will coordinate such activities through the JSC where appropriate.

ARTICLE 5

COMMERCIALIZATION

5.1 **Licensed Product**.

5.1.1 **Principles of Commercialization**. The Parties intend for TGTX to use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Licensed Field in the Territory, following Regulatory Approval thereof, as set forth in this Section 5.1. Each Party shall appoint a representative to be such Party's single point of contact to facilitate information flow between the Parties relating to each Party's experience and relationships in the Licensed Field (in the case of TGTX) and outside the Licensed Field (in the case of Precision). Each Party shall first address any communications relating to Commercialization by the other Party to such representatives unless otherwise agreed to by the Parties on a case-by-case basis. Such representatives shall, without limitation, coordinate direct involvement or meetings with subject matter experts within each Party's internal organization and/or its field account management organization. Notwithstanding the foregoing, neither TGTX's nor Precision's representative shall be required to provide details relating to any customer specific transaction or agreement.

5.1.2 **Commercialization Activities**. TGTX shall (a) use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Licensed Field following Regulatory Approval thereof in the Licensed Field in the Territory [***]; and (b) use Commercially Reasonable Efforts to perform other activities not otherwise identified herein but which are required by Regulatory Authorities to Commercialize the Licensed Product in any indication in the Licensed Field for which Regulatory Approval has been obtained in the Territory.

5.1.3 **Advertising and Promotional Materials**.

(a) **TGTX Promotional Materials**. TGTX will be responsible for development of all advertising and promotional materials, programs and initiatives related to the use of the Licensed Product in the Licensed Field in the Territory, including medical education, symposia, opinion leader development, peer-to-peer development, publications, journal ads, and all other written communications that describe the features or benefits of the Licensed Product, in each case in the Licensed Field in the Territory (the "***TGTX Promotional Materials***"). All TGTX Promotional Materials shall be prepared in accordance with Applicable Law, TGTX's policies for compliance with Applicable Laws, industry guidelines relating to promotional and advertising materials, any requirements of the FDA imposed as a condition of any Regulatory Approval, industry marketing codes such as the PhRMA code, and implementation guidelines to be mutually agreed upon by the Parties. TGTX shall implement appropriate policies and procedures relating to safety reporting, approval of TGTX Promotional Materials, sales force training and similar matters.

(b) **TGTX's Compliance Policies**. TGTX, on Precision's request, shall provide Precision copies of and access to TGTX's policies for compliance with Applicable Law relating to promotional and advertising materials, and TGTX's procedures relating to the approval of promotional materials, sales force compliance training, and related matters. Precision shall have the right to audit TGTX's compliance policies and procedures, no more than [***].

5.1.4 **Complaints and Inquiries**. The Parties shall mutually develop a protocol for responding to any and all complaints, medical questions, or other inquiries relating to the Licensed Product in the Licensed Field in the Territory, which are directed to such Parties' respective sales representatives. TGTX shall be responsible for responding to complaints, medical questions, or other inquiries relating to the TGTX Commercialization Activities and Precision or its designee shall be responsible for responding to all other complaints, medical questions, or other inquiries. TGTX shall notify Precision of, and provide to Precision, all pertinent information in TGTX's possession relating to any and all suspected or actual tampering, counterfeiting, or contamination or other similar problems with respect to the Licensed Product in the Licensed Field in the Territory. Precision shall notify TGTX of, and provide to TGTX, all pertinent information in Precision's possession relating to any and all suspected or actual tampering, counterfeiting, or contamination or other similar problems with respect to any Licensed Product outside the Licensed Field.

5.2 **Reports**. On an annual basis commencing on the first anniversary of the First Commercial Sale, TGTX will be obligated to deliver to Precision a report describing the status of TGTX's and its Affiliates and Sublicensees' Commercialization efforts with respect to Licensed Products in the Licensed Field in the Territory. In addition, Precision may from time to time provide TGTX with written requests describing specific types of information Precision requires in order to comply with Precision's reporting and disclosure obligations under any Applicable Laws, and TGTX shall include such information in such reports.

5.3 **Compensation for Sales Outside the Licensed Field**. If Precision reasonably believes that there are material sales recorded or conducted by or on behalf of TGTX, its Affiliates, or its Sublicensees of the Licensed Product outside the Licensed Field in the Territory, Precision shall be permitted to implement and conduct reasonable procedures under which material sales and purchases of the Licensed Product in the Territory and other related market research data shall be audited and monitored, using for example IQVIA data and information, and TGTX agrees to reasonably cooperate with Precision in the implementation and conduct of such procedures.

ARTICLE 6

MANUFACTURING

6.1 **Licensed Products**. Except as provided in Section 6.2, and subject to the terms of this Agreement, TGTX shall be solely responsible, at its sole cost and expense, for all Manufacturing (or having Manufactured through a CMO), including development of any Chemistry, Manufacturing and Controls sections of any Regulatory Filings or Regulatory Approval, for all Licensed Products for TGTX's, its Affiliates' and Sublicensees' pre-clinical and clinical Development and Commercialization in the Licensed Field in the Territory under this Agreement.

6.2 **Clinical Supply**.

6.2.1 Within [***] after the Effective Date, Precision shall deliver to TGTX [***] a single batch (batch number PBCAR0191-2023-0006) of released Clinical Trial material for the Licensed Product (in its form in existence as of the Effective Date). [***], together with access to all relevant quality, facility and equipment-related documentation in respect of such batch. Precision shall use Commercially Reasonable Efforts to promptly respond to any questions or inquiries from TGTX with respect to such batch. TGTX and Precision will also, within [***] after the Effective Date, enter into a quality agreement, in standard and customary form, with respect to such batch. In addition, Precision shall facilitate TGTX's entering into agreements with Precision's Third Party vendors for the storage, handling and shipping of such batch and, until such time, shall reasonably continue to provide such services directly or with its vendors with respect to such batch at Precision's reasonable cost, which TGTX shall promptly reimburse.

6.2.2 Precision acknowledges and agrees that, pursuant to Section 7.3 of the Precision-Imugene License Agreement, Precision has the right to designate, and hereby designates TGTX, and will communicate such designation to Imugene promptly after entering into this Agreement, as the party with which Imugene must enter into an agreement to provide for the supply to TGTX of [***], together with a quality agreement setting forth Imugene's (or its Affiliate's) quality and compliance obligations with respect to the manufacture and supply of the applicable product, in each case, in accordance with Section 7.3 of the Precision-Imugene License Agreement, [***] (such agreement, including the documentation of the technology transfer right and obligation described in this Section 6.2.2, the "***Clinical Supply Agreement***"). [***]. In addition, Precision acknowledges and agrees that, pursuant to Section 7.2 of the Precision-Imugene License Agreement, Precision has the right to designate, and hereby designates, TGTX, and will communicate such designation to Imugene promptly after entering into this Agreement, as the party with which Imugene shall conduct a manufacturing technology transfer in accordance with Section 7.2 of the Precision-Imugene License Agreement, including entering into a technology transfer plan, with such technology transfer right and obligation to be set forth in the Clinical Supply Agreement or a related agreement, in form reasonably acceptable to TGTX. [***].

ARTICLE 7

LICENSE RIGHTS

7.1 **License Grants to TGTX**.

7.1.1 **Exclusive License**. Subject to the terms and conditions of this Agreement, Precision (on behalf of itself and its Affiliates) hereby grants to TGTX an exclusive (even as to Precision and its Affiliates), royalty-bearing (as set forth in Section 8.6), license, with the right to grant sublicenses (through multiple tiers, as provided in Section 7.3), under the Precision Product IP, to Exploit, or to have Exploited, the Licensed Product in the Licensed Field in the Territory; *provided*, however that the foregoing license shall be non-exclusive with respect to Manufacture of the Licensed Product. Notwithstanding the foregoing, Precision or its designee may conduct Research and other Development activities with the Licensed Product; *provided* that such activities are directed to the Research and Development of the ARCUS Technology and not the Licensed Product itself, and further *provided* that Precision shall not have the right to conduct, or authorize any Affiliate or Third Party to conduct: (a) Research or other Development activities with the Licensed Product that are specifically directed to (i) any disease, condition or disorder in the Licensed Field or (ii) [***]; or (b) any clinical study of the Licensed Product in the Licensed Field in the Territory. For the avoidance of doubt, TGTX may utilize TGTX Arising IP in connection with the foregoing license.

7.1.2 **Non-Exclusive Licenses**. Subject to the terms and conditions of this Agreement, Precision (on behalf of itself and its Affiliates) hereby grants to TGTX a non-exclusive, royalty-bearing (as set forth in Section 8.6) license, with the right to grant sublicenses (through multiple tiers, as provided in Section 7.3), under the Precision Platform IP, to Exploit, or to have Exploited, the Licensed Product in the Licensed Field in the Territory. The license set forth in this Section 7.1.2 under Precision Platform IP is intended to provide TGTX a "freedom to operate" license with respect to the Precision Platform IP solely for the Exploitation of Licensed Products in the Licensed Field, and not for TGTX's independent use of the Precision Platform IP. TGTX acknowledges and agrees that TGTX will not have any right to (a) access or receive any ARCUS Technology, (b) design, create, select, or optimize any ARCUS Nucleases using the ARCUS Technology, or (c) otherwise use the ARCUS Technology as a genome engineering tool; in the case of (a) and (c), except to the extent that the ARCUS Technology is embodied in the Licensed ARCUS Nuclease or the Licensed Product and utilized solely in TGTX's practice of the licenses granted in Section 7.1.1. The Parties agree that ARCUS Technology will not be transferred to TGTX or its designee under this Agreement. For the avoidance of doubt, TGTX may utilize TGTX Arising IP in connection with the foregoing license.

7.1.3 **Restrictions on Licensed ARCUS Nuclease**. TGTX acknowledges and agrees that the foregoing license does not include any right to, and TGTX shall not, and shall not permit any of its Affiliates or its or their Sublicensees to (a) modify the Licensed ARCUS Nuclease, or (b) [***], in each case (a) and (b), without Precision's prior written consent.

7.2 **License Grant to Precision**. Subject to the terms and conditions of this Agreement, TGTX agrees to grant and hereby grants (on behalf of itself and its Affiliates) to Precision a perpetual, fully-paid, royalty-free, non-exclusive license, with right to grant sublicenses through multiple tiers, under all TGTX Arising IP and any TGTX Background IP that is necessary or reasonably useful for the applicable Licensed Product, or its use or manufacture, to Exploit, or to have Exploited, any Licensed Product in all fields in the Territory. Notwithstanding the non-exclusive nature of the foregoing license, TGTX shall not Research, Develop (including conduct of any Clinical Trial) or otherwise Exploit the Licensed Products outside the Licensed Field. Precision shall not practice the foregoing license in the Licensed Field unless and until the Licensed Product has become a Terminated Product in accordance with Article 13.

7.3 **Third Party Sublicenses**.

7.3.1 **Generally**. TGTX and Precision may grant one or more sublicenses under the rights and licenses granted to it under Section 7.1 (in the case of TGTX) or Section 7.2 (in the case of Precision), in full or in part, to Third Parties (with the right to sublicense through multiple tiers); *provided*, that: (a) any such permitted sublicense is consistent with and subject to the terms and conditions of this Agreement, including the confidentiality provisions of Article 12 and the intellectual property provisions of Article 9 (in the case of TGTX); and (b) the Party granting such sublicense shall remain responsible for performance of such Party's obligations under this Agreement and shall be responsible for all actions of each such sublicensee as if such sublicensee were the Party hereunder.

7.3.2 **By TGTX**. TGTX will not grant any sublicense or other right that permits any Research, Development or Commercialization of the Licensed Product by any Third Party without Precision's prior written consent, *provided* that TGTX may grant any sublicense or other right, without Precision's prior written consent, to (a) a contract Distributor, Third Party contractor or service provider, including a CMO or contract research organization, in order to provide services for a fee for the benefit of TGTX or (b) a sublicensee that is a pharmaceutical or biotechnology company that [***]. Without limiting the foregoing, any sublicense or other right must include in the written agreement pursuant to which such sublicense or other right is granted provisions ensuring that (x) the Licensed Product is Exploited in a manner consistent with the requirements set forth in this Agreement, (y) Precision is an intended third party beneficiary to such agreement and (z) all rights attaching therefrom in relation to any activities contemplated by this Agreement and the right to enforce the provisions of such agreement against the applicable Third Party are vested in Precision. To the extent required by the Cellectis Agreement, each sublicense granted by TGTX under any Patents within Precision Product IP must grant the same scope of rights for all Patents within Precision Product IP and each sublicense granted by TGTX under any Patents within Precision Platform IP must grant the same scope of rights for all Patents within Precision Platform IP. Any purported sublicense or other right granted by TGTX that is not in compliance with the requirements of this Section 7.3.2 shall be null and void. TGTX shall deliver a copy of each sublicense, or amendment thereto, to Precision promptly following the execution thereof.

7.4 **Retention of Rights; No Implied Rights**. Except as expressly set forth in this Agreement, neither Party shall be granted, by implication, estoppel or otherwise, any license or right to or under any other intellectual property interest, including any trademarks, Know-How, or Patents, of the other Party. The licenses granted by Precision to TGTX hereunder do not include any rights with respect to other products or therapies with which a Licensed Product may be combined or any other products or therapies other than the Licensed Products under this Agreement. Each Party covenants that it will not use or practice any of the other Party's intellectual property rights licensed to it under this Agreement except for the purposes expressly permitted in the applicable license grant. TGTX agrees to impose the foregoing covenant in this Section 7.4 on all of its Affiliates and sublicensees.

7.5 **Existing In-License Agreements**.

7.5.1 For clarity, the license granted to TGTX in Section 7.1 includes a sublicense under certain Duke IP and Cellectis Patents.

7.5.2 **Cellectis Patents.** TGTX acknowledges and agrees that rights under certain Precision Patents are licensed to Precision by Cellectis S.A. (the "***Cellectis Patents***") under that certain Patent Cross-License Agreement between Cellectis S.A. ("***Cellectis S.A.***") and Precision dated January 23, 2014 (the "***Cellectis Agreement***"), and, notwithstanding any exclusive license granted to TGTX under this Agreement, (a) Cellectis S.A. retains rights under the Cellectis Patents and is not restricted from granting rights to Third Parties under the Cellectis Patents, (b) any licenses and rights granted by Precision to TGTX under the Cellectis Patents are granted only within the permissible scope of sublicenses granted under the Cellectis Agreement, and (c) pursuant to the Cellectis Agreement, Cellectis S.A. retains non-exclusive rights under certain Precision Patents identified in the Cellectis Agreement, which may be further sublicensed by Cellectis S.A. without Precision control or consent. TGTX acknowledges and agrees that any exercise of any right by Cellectis S.A., or by any Third Party through Cellectis S.A., under the Cellectis Agreement shall not constitute a breach of this Agreement by Precision.

7.5.3 **Duke IP.** TGTX acknowledges and agrees that any licenses and rights granted by Precision to TGTX under the Duke IP are granted subject to the terms and conditions of the Duke Agreement, including Duke's right to practice under the Duke IP for its own internal, non-commercial, educational, research and clinical purposes, and subject to the rights of the United States Government and applicable limitations under 37 C.F.R. § 401, Public Law 96-517 and Public Law 98-620 resulting from the United States Government's funding of research leading to creation of the Duke IP. Without limiting the foregoing, TGTX agrees to comply with any obligations resulting from such government rights with respect to its practice of the Duke IP (if any) under this Agreement.

7.5.4 **Other Third Party IP**. In the event that, after the Effective Date, any Know-How or Patent licensed to Precision by a Third Party (other than the Duke IP or Cellectis Patents) becomes necessary or reasonably useful for the Exploitation of a Licensed Product, then the Parties would discuss in good faith the terms pursuant to which Precision would grant a sublicense to TGTX under such Know-How or Patent, and subject to and effective upon the Parties' mutual written agreement to such terms, such Know-How or Patent would be sublicensed by Precision to TGTX; *provided*, however, that nothing in this Agreement shall require Precision to grant any rights to TGTX under Precision's agreement with MaxCyte. For the avoidance of doubt, this Section 7.5.4 does not (a) apply to the Duke IP, Cellectis Patents or Existing In-License Agreements or (b) limit any of Precision's representations and warranties under Section 10.1 and Section 10.2.

7.6 **Consideration**. The Parties acknowledge that each of the licenses and rights granted by Precision in this Agreement and each of the provisions of this Agreement for efforts or assistance by Precision and access to Precision Technology, individually and collectively, constitute good, valuable and sufficient consideration for each and all of the fees and payments called for hereunder and for each and all of the other obligations of TGTX, its Affiliates and its and their Sublicensees; and the Parties further acknowledge that the individual and collective rights under and access to Precision Technology renders the way in which those fees and payments hereunder are determined, their amount (and potential reduction) and their duration, appropriate and desirable as a matter of convenience.

7.7 **Notice**. Precision shall provide notice to TGTX in the event that Precision begins a process or enters into negotiations with any Third Party regarding a grant of license or other rights in [***].

ARTICLE 8

FEES, EQUITY ISSUANCES, ROYALTIES, & PAYMENTS

8.1 **Upfront Payment**. As partial consideration for the rights granted by Precision to TGTX pursuant to the terms of this Agreement, within thirty (30) days following the Effective Date, TGTX shall make a one-time payment to Precision equal to Five Million Two Hundred Fifty Thousand Dollars ($5,250,000).

8.2 **Matters Related to Precision Equity Issuances**.

8.2.1 **Equity Issuances by Precision**. As partial consideration for the rights granted by Precision to TGTX pursuant to the terms of this Agreement, Precision agrees to issue to TGTX, and TGTX agrees to pay for and accept, the Precision Shares, subject to the terms and conditions specified herein:

(a) Within thirty (30) days following the Effective Date, together with payment of the upfront payment pursuant to Section 8.1, TGTX shall make a one-time payment to Precision equal to Two Million Two Hundred Fifty Thousand Dollars ($2,250,000) (the "***Upfront Precision Stock Payment***"). TGTX shall, at least [***] prior to the date on which TGTX shall make the Upfront Precision Stock Payment, deliver a notice to Precision specifying the date on which such payment shall be made. Upon receipt of such payment and satisfaction of TGTX's obligations under Section 8.1, Precision shall issue to TGTX the number of Precision Shares (rounded down to the nearest whole share) obtained by dividing the Upfront Precision Stock Payment by the Precision Share Price for the thirty (30) Trading Days preceding the Effective Date (the "***Upfront Precision Stock Issuance***");

(b) Within twelve (12) months following the Effective Date, TGTX shall make a one-time payment to Precision equal to Two Million Five Hundred Thousand Dollars ($2,500,000) (the "***Deferred Precision Stock Payment***"). TGTX shall, at least [***] prior to the date on which TGTX shall make the Deferred Precision Stock Payment, deliver a notice to Precision specifying the date on which such payment shall be made. Upon receipt of such payment, Precision shall issue to TGTX the number of Precision Shares (rounded down to the nearest whole share) obtained by dividing the Deferred Precision Stock Payment by the Precision Share Price for the thirty (30) Trading Days preceding the date on which Precision receives the payment required by this Section 8.2.1(b) (such issuance, the "***Deferred Precision Stock Issuance***");

(c) Upon the achievement of Milestone Event 1 (as set forth in Section 8.3), together with payment of the corresponding milestone payment pursuant to Section 8.3, TGTX shall make a one-time payment to Precision equal to Two Million Two Hundred Fifty Thousand Dollars ($2,250,000) (the "***Milestone 1 Precision Stock Payment***") no later than thirty (30) days following the achievement of Milestone Event 1. TGTX shall, at least [***] prior to the date on which TGTX shall make the Milestone 1 Precision Stock Payment, deliver a notice to Precision specifying the date on which such payment shall be made. Upon receipt of such payment and satisfaction of TGTX's payment obligations under Section 8.3 with respect to Milestone Event 1, Precision shall issue to TGTX the number of Precision Shares (rounded down to the nearest whole share) obtained by dividing the Milestone 1 Precision Stock Payment by the Precision Share Price for the thirty (30) Trading Days preceding the achievement date of Milestone Event 1 (such issuance, the "***Milestone 1 Precision Stock Issuance***"); and

(d) Upon the achievement of Milestone Event 2 (as set forth in Section 8.3), together with payment of the corresponding milestone payment pursuant to Section 8.3, TGTX shall make a one-time payment to Precision equal to Three Million Dollars ($3,000,000) (the "***Final Precision Stock Payment***" and together with the Upfront Precision Stock Payment, the Deferred Precision Stock Payment and the Milestone 1 Precision Stock Payment, the "***Precision Stock Payments***") no later than thirty (30) days following the achievement of Milestone Event 2. TGTX shall, at least [***] prior to the date on which TGTX shall make the Final Precision Stock Payment, deliver a notice to Precision specifying the date on which such payment shall be made. Upon receipt of such payment and satisfaction of TGTX's payment obligations under Section 8.3 with respect to Milestone Event 2, Precision shall issue to TGTX the number of Precision Shares (rounded down to the nearest whole share) obtained by dividing the Final Precision Stock Payment by the Precision Share Price for the thirty (30) Trading Days preceding the achievement date of Milestone Event 2 (such issuance, the "***Final Precision Stock Issuance***", and, together with the Upfront Precision Stock Issuance, the Deferred Precision Stock Issuance and the Milestone 1 Precision Stock Issuance, the "***Precision Stock Issuances***").

8.2.2 **Representations and Warranties**. Precision represents and warrants, as of the Effective Date, that:

(a) Subject to the accuracy of the representations made by TGTX in Section 8.2.3 of this Agreement, the offer, issuance and sale of the Precision Shares to TGTX as contemplated hereby will be exempt from the registration requirements of the Securities Act of 1933, as amended (the "***Securities Act***") and the registration and qualification requirements of all applicable securities laws of the states of the United States;

(b) Precision has all requisite corporate power and authority to enter into and to perform its obligations under this Agreement and to consummate the transactions contemplated hereby;

(c) Precision has all requisite corporate power and authority to issue the Precision Shares in accordance with the terms hereof;

(d) The Precision Shares have been duly authorized and, upon issuance in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable and will not be subject to liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal, purchase options, call options, subscription rights or other similar rights of stockholders of Precision, other than as arising pursuant to this Agreement, as a result of any action by TGTX, or any of its Affiliates, or under federal or state securities laws. No stop order or suspension of trading of the Precision Common Stock has been imposed by Nasdaq or the Securities and Exchange Commission and remains in effect;

(e) The Precision Common Stock is listed on Nasdaq and registered pursuant to Section 12(b) of the Exchange Act of 1934, as amended (the "***Exchange Act***"), and Precision has taken no action designed to or reasonably likely to have the effect of terminating the registration of the Precision Common Stock under the Exchange Act or delisting the Precision Common Stock from Nasdaq or any other applicable exchange; and

(f) The issuance and sale of the Precision Shares will not, on the date of the issuance and sale of the Precision Shares, (i) conflict with or result in a violation of any provision of Precision's amended and restated certificate of incorporation, amended and restated bylaws and similar organizational documents, (ii) result in any encumbrance upon any of the Precision Shares, other than restrictions on resale pursuant to securities laws or as set forth in this Agreement, (iii) materially violate or conflict with, or result in a material breach, default, modification, acceleration of payment or termination under any provision of, or constitute a material default under, any contract entered into by Precision that is required to be filed as an exhibit by Precision in its public filings with the Securities and Exchange Commission pursuant to Items 601(b)(2), 601(b)(4), 601(b)(9) and 601(b)(10) of Regulation S-K promulgated by the Securities and Exchange Commission.

8.2.3 **Representations and Warranties of TGTX**. TGTX represents and warrants that (a) it is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act; (b) it is acquiring the Precision Shares for investment for TGTX's own account and not as a nominee or agent, and not with a view to the resale or distribution of any part thereof; (c) it does not have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to such Person or to any Third Party, with respect to any of such Precision Common Stock; and (d) it acknowledges that Precision is under no obligation to register the Precision Shares or to furnish any information or take any other action to assist TGTX in complying with the terms and conditions of any exemption which might be available under the Securities Act or any state securities laws with respect to sales of the Precision Shares in the future.

8.2.4 **Restrictions on the Precision Shares**. TGTX understands and agrees that the Precision Shares may not be sold, transferred, or otherwise disposed of without registration under the Securities Act or an exemption therefrom, and that in the absence of an effective registration statement covering the Precision Shares or any available exemption from registration under the Securities Act, the Precision Shares must be held indefinitely. TGTX understands the Precision Shares will bear restrictive legends in substantially the following form (and a stop-transfer order may be placed against transfer of the Precision Shares):

> THESE SHARES HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY APPLICABLE STATE SECURITIES LAWS AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR APPLICABLE STATE SECURITIES LAWS OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO PRECISION BIOSCIENCES, INC.) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT.
>
> THE SALE, PLEDGE, HYPOTHECATION AND TRANSFER OF THESE SHARES IS SUBJECT TO THE TERMS AND CONDITIONS OF THE LICENSE AGREEMENT DATED JANUARY 7, 2024 BY AND AMONG PRECISION BIOSCIENCES, INC., TG CELL THERAPY, INC. AND TG THERAPEUTICS, INC., AS SUCH AGREEMENT MAY BE AMENDED FROM TIME TO TIME.
>
> THESE SHARES ARE SUBJECT TO AN AGREEMENT TO VOTE THESE SHARES IN THE MANNER SET FORTH IN THE LICENSE AGREEMENT DATED JANUARY 7, 2024 BY AND AMONG PRECISION BIOSCIENCES, INC., TG CELL THERAPY, INC., AND TG THERAPEUTICS, INC, AS SUCH AGREEMENT MAY BE AMENDED FROM TIME TO TIME.

If such Precision Shares are transferred (other than to a Permitted Transferee) pursuant to Section 8.2.6 of this Agreement, TGTX may request that Precision remove, and if so requested, Precision shall agree to authorize and instruct (including by causing any required legal opinion to be provided) the removal of any legend from the Precision Shares, if permitted by applicable securities law, within [***] of any such request; *provided*, however, that each Party will be responsible for any fees it incurs in connection with such request and removal.

Upon request from TGTX, subject to and following the expiration of the applicable Holding Period (as defined below), in connection with a sale or otherwise pursuant to Rule 144 of the Securities Act ("***Rule 144***"), Precision shall remove the legend on such Precision Shares set forth above, to be re-issued in certificate form or book-entry evidence of ownership, in each case without such legend; provided, that, (a) such Precision Shares are eligible to be sold pursuant to Rule 144 at a time the transferor is not, and has not been for ninety (90) days prior to such time, an affiliate of Precision as defined under Rule 144, or (b) if an affiliate, then sold or transferred in compliance with Rule 144, including without limitation in compliance with the current public information requirements of Rule 144 if applicable to Precision at the time of such sale or transfer, and, in the cases of clauses (a) and (b), the holder and its broker have delivered customary documents requested by counsel to Precision in connection with such sale or transfer; and, provided, further, that if an opinion of counsel is required, then, subject to receipt of customary documents requested by counsel to Precision, Precision shall instruct Precision's counsel to deliver such legal opinion.

8.2.5 **Limitations on the Number of Precision Shares Issued and Issuance Price**. Notwithstanding anything to the contrary in this Agreement, in no event shall the aggregate number of Precision Shares issuable pursuant to the Precision Stock Issuances exceed the Exchange Cap or otherwise cause Precision to be required to obtain Stockholder Approval. If, at any time following the Upfront Precision Stock Issuance but prior to any issuance of Precision Shares contemplated by Sections 8.2.1(b), 8.2.1(c), or 8.2.1(d), Precision (y) is no longer registered pursuant to Section 12(b) of the Exchange Act, or (z) has undergone a merger or consolidation with a Third Party in which Precision is not the surviving entity (each, an "***Equity Termination Event***"), then Precision (or its successor) shall not be obligated to issue any Precision Shares (or shares of any successor's equity) following such Equity Termination Event; *provided*, however, that nothing in this Section 8.2.5 shall limit the aggregate cash payments (including the Precision Stock Payments) payable to Precision in connection with any Milestone Event.

8.2.6 **Lock Up**. TGTX agrees that it will hold and will not, directly or indirectly, without Precision's prior approval, sell, transfer or otherwise dispose of any shares of Precision Common Stock or any securities convertible into or exercisable or exchangeable for Precision Common Stock (the "***Lock-Up Securities***"), or otherwise make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale of the Lock-Up Securities (any such transaction, a "***Transfer***"), until the expiration of the following holding periods (each, a "***Holding Period***"): (a) the three (3) year anniversary of the Effective Date with respect to the Precision Shares issued in connection with the Upfront Precision Stock Issuance; (b) the two (2) year anniversary of the Deferred Precision Stock Issuance with respect to the Precision Shares issued in connection with the Deferred Precision Stock Issuance; (c) the two (2) year anniversary of the Milestone 1 Precision Stock Issuance with respect to the Precision Shares issued in connection with the Milestone 1 Precision Stock Issuance; and (d) the two (2) year anniversary of the Final Precision Stock Issuance with respect to the Precision Shares issued in connection with the Final Precision Stock Issuance. Notwithstanding the foregoing, TGTX shall not be prohibited from (y) transferring any Lock-Up Securities to (i) a Permitted Transferee or (ii) Precision; or (z) disposing any Lock-Up Securities pursuant to (i) any merger, consolidation or similar transaction to which Precision is a constituent corporation or (ii) a bona fide tender offer or exchange offer made to all of the holders of Precision Common Stock by a Person other than TGTX (or any of its Affiliates or any Person acting on behalf of or as part of a group or in concert with TGTX or any of its Affiliates). Notwithstanding the foregoing, the restrictions on the Lock-Up Securities automatically shall terminate and be of no further force or effect (aa) in the event Precision enters into any definitive agreement with a Third Party during a Holding Period contemplating a (i) Change of Control pursuant to a merger, consolidation or similar transaction to which Precision is a constituent corporation or (ii) tender offer or exchange offer to be made to all of the holders of Precision Common Stock by a Third Party (other than a Third Party acting on behalf of or as part of a group or in concert with TGTX), (bb) if at any time during a Holding Period the Precision Shares represent greater than 19.99% ownership of Precision's then-outstanding voting securities solely as a result of an action taken by Precision (*provided* that the restrictions shall only terminate and be of no further force and effect to the extent necessary to permit TGTX to reduce its ownership of shares to 19.99%), or (cc) upon the termination of this Agreement in accordance with its terms, whichever first occurs.

8.2.7 **Voting Agreement**. During the three (3) year period following the Effective Date (the "***Restricted Period***"), if Precision, its Chief Executive Officer and/or its Chief Financial Officer (each, a "***Proxyholder***") instructs TGTX in writing to vote in favor of, or against, any matter, action, ratification or other event for which approval of the holders of Precision Common Stock is sought or upon which such holders are otherwise entitled to vote, including the election of directors, but excluding any Extraordinary Matter (collectively, a "***Stockholder Matter***"), then TGTX will (a) after receiving proper notice of any meeting of stockholders of Precision related to such Stockholder Matter (or, if no notice is required or such notice is properly waived, after notice from the Proxyholder is given), be present, in person or by proxy, as a holder of shares of Precision Common Stock at all such meetings and be counted for the purposes of determining the presence of a quorum at such meetings and (b) vote (in person or by proxy, as applicable) all voting securities of Precision as to which TGTX has beneficial ownership or as to which TGTX otherwise exercises voting or dispositive authority in the manner directed by the Proxyholder. Notwithstanding the foregoing, TGTX may vote any or all of the securities of Precision as to which it is entitled to vote, as it may determine in its sole discretion, with respect to (y) any transaction which would result in a Change of Control of Precision and (z) any liquidation or dissolution of Precision (each, an "***Extraordinary Matter***"), if such Extraordinary Matter is presented to Precision's stockholders for approval. To secure TGTX's obligations to vote in accordance with this Agreement and to comply with the other terms hereof, TGTX hereby appoints the Proxyholder, or his or her designees, as TGTX's true and lawful proxy and attorney, with the power to act alone and with full power of substitution, to vote all voting securities of Precision as to which TGTX has beneficial ownership or as to which TGTX otherwise exercises voting or dispositive authority in accordance with the provisions set forth in this Agreement and to execute all appropriate instruments consistent with this Agreement. The proxy and power of attorney granted by TGTX pursuant to this Section 8.2.7 are coupled with an interest, are given to secure the performance of TGTX's duties under this Agreement and will be irrevocable until the third (3rd) anniversary following the Effective Date. The proxy and power of attorney will survive any merger, consolidation, conversion or reorganization of TGTX or any other entity holding any voting securities of Precision (other than any securities sold by TGTX to a Third Party in compliance with Section 8.2.6). For the avoidance of doubt, the proxy granted by this Section 8.2.7 shall not apply to any Extraordinary Matter. Notwithstanding the foregoing, the provisions of this Section 8.2.7 shall automatically terminate and be of no further force or effect upon the termination of this Agreement in accordance with its terms.

8.2.8 **Standstill**. During the Restricted Period, TGTX and its Affiliates will not, directly or indirectly, except as expressly approved or invited by Precision in writing:

(a) effect or seek, offer or propose (whether publicly or otherwise) to effect, or cause or participate in or in any way advise, assist or encourage any other Person to effect or seek, offer or propose (whether publicly or otherwise) to effect or participate in, directly or indirectly, (i) any acquisition of any securities of Precision or any of its subsidiaries or any securities convertible into or exercisable or exchangeable for any securities of Precision or any of its subsidiaries (or beneficial ownership thereof); (ii) any acquisition of any material assets of Precision or any of its subsidiaries, (iii) any tender or exchange offer, merger or other business combination or Change of Control involving Precision or any of its subsidiaries, (iv) any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to Precision or any of its subsidiaries, or (v) any "solicitation" of "proxies" (as such terms are used in the proxy rules of the Securities and Exchange Commission) or consents to vote any securities of Precision;

(b) form, join or in any way participate in a "group" (as defined under the Exchange Act) with respect to any securities of Precision or any of its subsidiaries;

(c) otherwise act, alone or in concert with others, to seek to control or influence the board of directors or the management or policies of Precision or any of its subsidiaries;

(d) take any action that would reasonably be expected to require Precision to make a public announcement regarding any of the matters set forth in this Section 8.2.8;

(e) enter into any discussions or arrangements with any Third Party with respect to any of the foregoing; or

(f) publicly disclose any intention, plan or arrangement regarding any of the matters set forth in this Section 8.2.8.

Notwithstanding the provisions set forth in this Section 8.2.8 (the "***Standstill Provisions***"), (x) if at any time (i) a Third Party enters into an agreement with Precision contemplating a Change of Control of Precision, including a merger, consolidation or other business combination transaction or tender offer related thereto, or the purchase of all or substantially all of the assets of Precision and its subsidiaries, or publicly announces its intention to do so, then the Standstill Provisions shall be suspended and of no further force or effect until the termination of such agreement or the public announcement of a withdrawal or abandonment of such intention, at which time the Standstill Provisions will be reinstated and apply in full force and effect or (ii) a Third Party commences, or publicly announces an intention to commence, a tender, exchange or offer that, if consummated, would result in a Change of Control of Precision, then the Standstill Provisions shall be suspended and of no force or effect until the expiration or termination of a tender, exchange or offer that has been commenced or the public announcement of a withdrawal or abandonment of an intention to commence a tender, exchange or offer at which time such restrictions will be reinstated and apply in full force and effect; (y) TGTX will not be precluded from making any confidential offers or proposals to the Precision Board of Directors in a manner reasonably believed not to require Precision to make a public announcement of such offer or proposal; *provided* that TGTX shall not publicly disclose any such offers or proposals; and (z) TGTX shall not be precluded from owning or acquiring interests in mutual funds or similar entities that own shares of Precision Common Stock, and nothing herein shall prohibit passive investments by pension or employee benefit plans of TGTX. Notwithstanding the foregoing, the Standstill Provisions shall automatically terminate and be of no further force or effect upon the termination of this Agreement in accordance with its terms.

8.3 **Clinical and Regulatory Milestones**. As partial consideration for the rights granted by Precision to TGTX hereunder with respect to the Licensed Product, TGTX shall pay to Precision or its designee the following milestone payments in the corresponding amount set forth in the right-hand column of the table immediately below upon the first achievement of each of the following milestone events in the left-hand column of the table immediately below by TGTX, its Affiliates or Sublicensees. The Milestone Events set forth below are intended to be sequential; achievement of a particular Milestone Event shall result in deemed achievement of all earlier Milestone Events; for example, achievement of Milestone Event 4 or Milestone Event 7 shall result in deemed achievement of Milestone Events 1 – 3.

	Clinical and Regulatory Milestone Event	**Milestone Payment (USD)**
1	[***]	$5,250,000
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]
5	[***]	[***]
6	[***]	[***]
7	[***]	[***]
8	[***]	[***]
9	[***]	[***]

8.3.1 For the avoidance of doubt, each of Milestone Events 1 – 9 is achievable only once.

8.3.2 TGTX shall notify Precision in writing no later than [***] after the achievement of each Milestone Event set forth in the table above and shall make the corresponding milestone payment within [***] after receipt by TGTX of an invoice from Precision delivered after such achievement; *provided*, however, that, subject to Section 8.14, TGTX may elect, in its discretion, to pay any such milestone payment (other than the payments with respect to Milestone Events 1 and 2) in (a) cash or (b) a combination of at least fifty percent (50%) cash and at most fifty percent (50%) TGTX Parent Consideration Shares that equal, in aggregate, the amount of such milestone payment.

8.4 **Commercial Milestones**. As partial consideration for the rights granted by Precision to TGTX hereunder with respect to the Licensed Product, TGTX shall pay to Precision the following milestone payments in the corresponding amount set forth in the right-hand column of the table immediately below (each, a "***Commercial Milestone Payment***") upon the first achievement of each of the following milestone events in the left-hand column of the table immediately below by TGTX, its Affiliates or Sublicensees. For purposes of determining whether the Net Sales thresholds in the table below have been achieved, all Net Sales of all Licensed Products shall be aggregated globally for all sales made by TGTX or any of its Affiliates or its or their Sublicensees of all Licensed Product (regardless of indication), in any and all preparations, formulations, dosages, packaging or methods of administration thereof.

Commercial Milestone Event	Milestone Payment (USD)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

TGTX shall promptly notify Precision in writing of the achievement of each Milestone Event set forth in the table above within [***] after the end of the Calendar Year in which such milestone has been achieved and shall make the corresponding milestone payment within [***] after receipt by TGTX of an invoice from Precision delivered after such achievement; *provided*, however, that, subject to Section 8.14, TGTX may elect, in its discretion, to pay any such milestone payment in (a) cash or (b) a combination of at least fifty percent (50%) cash and at most fifty percent (50%) TGTX Parent Consideration Shares that equal, in aggregate, the amount of such milestone payment. Achievement of each Milestone Event measured by Net Sales shall result in achievement of all Milestone Events measured by a lower amount of Net Sales. To clarify, each Milestone Payment shall be a one-time payment, and once paid by TGTX to Precision, TGTX shall have no further obligation to make additional payments for the same Milestone Event.

8.5 **[***].**

8.6 **Royalties**.

8.6.1 **Royalty Term**. TGTX shall pay Precision royalties as set forth in this Section 8.6 on a Licensed Product-by-Licensed Product and country-by-country basis in the Territory during the period of time beginning on the date of the First Commercial Sale of such Licensed Product in such country and continuing until the latest to occur of: (a) the expiration of the last-to-expire Valid Claim in such country Covering such Licensed Product; (b) the expiration of any period of data, regulatory, or market exclusivity, or supplemental protection certificates (other than Patents) covering the Licensed Product in such country; and (c) ten (10) years after the First Commercial Sale of such Licensed Product in such country (the "***Royalty Term***").

8.6.2 **Royalty Rates**. On a Licensed Product-by-Licensed Product and country-by-country basis, during the Royalty Term, TGTX shall pay to Precision a royalty equal to the percentages of aggregate annual Net Sales of such Licensed Product, as set forth below (the "***Royalty***"), calculated by multiplying the applicable royalty rate percentage for the region in which the applicable Net Sales occurred by the portion of aggregate, global Net Sales of the Licensed Products that occurred in the applicable region (i.e., inside or outside of the U.S.) in such Calendar Year. For purposes of determining whether the Net Sales thresholds in the table below have been achieved, all Net Sales of all Licensed Products shall be aggregated globally for all sales made by TGTX or any of its Affiliates or its or their Sublicensees of all Licensed Product (regardless of indication), in any and all preparations, formulations, dosages, packaging or methods of administration thereof, in all applicable countries during the Royalty Term (i.e., regardless of whether such Net Sales occur inside or outside of the U.S.).

Location of Net Sales	Annual Net Sales of the Licensed Products	Royalty Rate
Net Sales occurring inside the U.S.	Aggregate annual global Net Sales of Licensed Products less than [***]	[***]
Net Sales occurring inside the U.S.	Aggregate annual global Net Sales of Licensed Products equal to or greater than [***] but less than [***]	[***]
Net Sales occurring inside the U.S.	Aggregate annual global Net Sales of Licensed Products equal to or greater than [***] but less than [***]	[***]
Net Sales occurring inside the U.S.	Aggregate annual global Net Sales of Licensed Products equal to or greater than [***]	[***]
Net Sales occurring outside the U.S.	Aggregate annual global Net Sales of Licensed Products less than [***]	[***]
Net Sales occurring outside the U.S.	Aggregate annual global Net Sales of Licensed Products equal to or greater than [***] but less than [***]	[***]
Net Sales occurring outside the U.S.	Aggregate annual global Net Sales of Licensed Products equal to or greater than [***] but less than [***]	[***]
Net Sales occurring outside the U.S.	Aggregate annual global Net Sales of Licensed Products equal to or greater than [***]	[***]

8.6.3 **Royalty Reduction**.

(a) **Valid Claim**. If, at the time a Licensed Product is sold in a country during the Royalty Term for such Licensed Product, there is no longer a Valid Claim that Covers such Licensed Product in such country, the Royalty rates provided in Section 8.6.2 above for the sale of such Licensed Product in such country will be reduced in such country by [***].

(b) **Biosimilar Competition**. If, on a country-by-country basis, one or more Third Parties commercializes one or more Biosimilar Products with respect to a Licensed Product in a country and the aggregate units of such Licensed Product sold in that country during any Calendar Quarter following introduction of such Biosimilar Products have fallen by at least:

(i) [***] in that country as compared to the average quarterly total aggregate units of such Licensed Products sold in such country during the [***] immediately prior to the Calendar Quarter in which such Biosimilar Products were first introduced, where unit volume sales will be identified and calculated based on relevant information published by IQVIA, any successor to IQVIA, or any other similar Third Party source reasonably agreed upon by the Parties, or, if unavailable, data obtained by TGTX from its Distributors and presented to Precision with sufficient detail to reasonably demonstrate its validity, then the Net Sales in such country used to calculate the Royalty payments due to Precision pursuant to Section 8.6.2 for such Licensed Product will be reduced by [***]; or

(ii) [***] in that country as compared to the average quarterly total aggregate units of such Licensed Products sold in such country during the last [***] immediately prior to the Calendar Quarter in which such Biosimilar Products were first introduced, where unit volume sales will be identified and calculated based on relevant information published by IQVIA, any successor to IQVIA, or any other similar Third Party source reasonably agreed upon by the Parties, or, if unavailable, data obtained by TGTX from its Distributors and presented to Precision with sufficient detail to reasonably demonstrate its validity, then the Net Sales in such country used to calculate the Royalty Payments due to Precision pursuant to Section 8.6.2 for such Licensed Product will be reduced by [***].

(c) **Third Party Licenses**. If TGTX obtains a license under Patents owned or controlled by a Third Party in a country that [***] any Licensed Product in the Licensed Field, then TGTX may offset against the Royalty payments due to Precision with respect to sales of such Licensed Product in such country an amount equal to [***] paid to such Third Party under such agreement in such country with respect to such sales.

(d) **Cumulative Effect of Royalty Reductions**. On a Licensed Product-by-Licensed Product and country-by-country basis, in no event will the royalty reductions for such Licensed Product permitted under subsections (a) to (c) of this Section 8.6.3, alone or together, reduce the Royalty payments due to Precision with respect to such Licensed Product pursuant to Section 8.6.2 in a country in a given Calendar Quarter by more than [***] of the applicable Royalty payments that would otherwise be owed on the Net Sales of such Licensed Product in such country.

8.7 **Payment; Reports**. Royalty payments due by TGTX to Precision under Section 8.6 shall be: (a) calculated and reported for each Calendar Quarter; (b) paid within [***] after the end of each Calendar Quarter; and (c) accompanied by a report setting forth, with respect to each Calendar Quarter, on a Licensed Product-by-Licensed Product and country-by-country basis: (i) Net Sales of the Licensed Product by the applicable Selling Party(ies) in the Territory, and (ii) a calculation of the Royalty due by TGTX to Precision on such Net Sales.

8.8 **Method of Payment; Currency Conversion**. Unless otherwise agreed by the Parties, all payments due under this Agreement shall be paid in Dollars by wire transfer or electronic funds transfer of immediately available funds to an account designated by the payee; *provided* however, that a Party shall only be required to disburse funds to the payee's jurisdiction of incorporation or to a jurisdiction in which the payee has a significant business presence. When conversion of payments from any currency other than Dollars is required, such Party's then-current standard exchange rate methodology will be employed for the translation of foreign currency sales into Dollars; *provided*, that this methodology is used by such Party in the translation of its foreign currency operating results, is consistent with U.S. GAAP or IFRS, as applicable, is audited by such Party's independent certified public accountants in connection with the audit of the consolidated financial statements of such Party, and is used for external reporting of foreign currency operating results.

8.9 **Records and Audits**. TGTX shall maintain complete and accurate records in sufficient detail to permit Precision to confirm the accuracy of Commercial Milestone Payments and Royalty payments payable under this Agreement. Upon reasonable prior notice, such records shall be open during regular business hours for a period of [***] from the creation of individual records, for examination at Precision's expense, and not more often than [***], by an independent certified public accountant selected by Precision and reasonably acceptable to TGTX for the sole purpose of verifying for Precision the accuracy of the financial statements or reports furnished by TGTX pursuant to this Agreement or of any payments made, or required to be made, by TGTX to Precision pursuant to this Agreement. No Calendar Quarter shall be subject to audit more than one time. Any such auditor shall not disclose TGTX's Confidential Proprietary Information to Precision, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by TGTX or the amount of payments due by TGTX under this Agreement. Any amounts shown to be owed but unpaid, or overpaid and in need of reimbursement, shall be paid or refunded (as the case may be) within [***] after the accountant's report, plus interest (as set forth in Section 8.10) from the original due date (unless challenged in good faith by TGTX, in which case any undisputed portion shall be paid in accordance with the foregoing timetable, any dispute with respect to such challenge shall be resolved in accordance with Section 14.2, and any remaining disputed portion shall be paid within [***] after resolution of the dispute). Precision shall bear the full cost of such audit unless such audit reveals an underpayment by TGTX during the applicable audit period, which underpayment was more than [***] of the amount set forth in such report, in which case TGTX shall bear the full cost of such audit.

8.10 **Late Payments**. If any payment properly due under this Agreement and not subject to a good faith dispute is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at [***]. The payment of such interest shall not limit Precision from exercising any other rights it may have as a consequence of the lateness of any payment.

8.11 **Taxes**.

8.11.1 **Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

8.11.2 **Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of any payments made by TGTX to Precision under this Agreement. Without limiting the generality of the foregoing, Precision shall provide TGTX any tax forms and other information that may be reasonably necessary in order for TGTX to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

8.11.3 **Payment of Taxes.** To the extent TGTX is required by Applicable Law to deduct and withhold taxes on any payment to Precision, such amount shall be withheld or deducted from the payment to be made by TGTX and TGTX shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Precision an official tax certificate or other evidence of such withholding sufficient to enable Precision to claim such payment of taxes. For the avoidance of doubt, to the extent that any such amount is withheld or deducted by TGTX, such withheld or deducted amount shall be treated for all purposes of this Agreement as having been paid to Precision, and TGTX shall not increase any payment due to Precision under this Agreement for any such withholding or deduction.

8.11.4 **Treatment of Certain Withholding Taxes**. Notwithstanding anything to the contrary in Section 8.11.3, if TGTX is required to deduct and withhold taxes on any payment to Precision and such withholding obligation arises as a result of any action by TGTX that has the effect of modifying the tax treatment of the Parties (including any assignment or sublicense, any change of domicile, or any failure on the part of the paying Party to comply with Applicable Law or filing or record retention requirements) (a "***Withholding Tax Action***"), then the sum payable by TGTX (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Precision actually receives, as appropriate, a sum equal to the sum that it would have received had no such Withholding Tax Action occurred. For clarity, this Section 8.11.4 does not apply with respect to taxes that TGTX includes in its calculation of Net Sales in accordance with U.S. GAAP. For the avoidance of doubt, TGTX shall not be required to increase any sum payable for any deduction or withholding obligation arising as a result of any action by Precision that has the effect of modifying the tax treatment of the Parties (including any assignment, any change of domicile, or any failure on the part of Precision to comply with Applicable Law or filing or record retention requirements), which action(s) shall not constitute a Withholding Tax Action.

8.12 **Blocked Currency.** In each country where the local currency is blocked and cannot be removed from the country, royalties accrued on Net Sales in that country shall be paid in the equivalent amount in Dollars.

8.13 **Manner and Place of Payment.** All payments (other than payments made by TGTX in TGTX Parent Consideration Shares) owed under this Agreement to Precision shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Precision, unless otherwise specified in writing by Precision.

8.14 **TGTX Equity Issuances.** For purposes of determining the number of TGTX Parent Consideration Shares to be issued pursuant to Section 8.3 or 8.4, the value of such shares shall be based on the thirty (30) Trading Day VWAP of the TGTX Parent Common Stock immediately prior to the date on which the corresponding Milestone Event is achieved. In the event that TGTX elects to make any portion of an applicable milestone payment with a combination of cash and TGTX Parent Consideration Shares, TGTX and TGTX Parent shall satisfy and comply with each of the following obligations, and if any of the following obligations are and have not been satisfied as of each applicable payment date, TGTX shall be required to pay the applicable milestone payment entirely in cash:

8.14.1 The representations and warranties made by Precision in Section 8.2.2 shall be made by each of TGTX and TGTX Parent, and the representations and warranties made by TGTX in Sections 8.2.3(a), (b) and (c) shall be made by Precision as of the Effective Date, in each case as if such representations and warranties were restated in this Section 8.14.1, *mutatis mutandis*, with the applicable references to "Precision" being replaced with references to "each of TGTX and TGTX Parent" (except with, for purposes of Section 8.2.2(c), the applicable references to "Precision" being replaced with reference to "TGTX Parent") and the applicable references to "TGTX" being replaced with references to "Precision"; *provided*, however, that references to "Precision" in "Precision Shares" and "Precision Common Stock" shall be replaced with "TGTX Parent"; and *provided*, further, for the avoidance of doubt, Precision shall be entitled to (and does not make any representations or warranties that it will not) immediately sell any TGTX Parent Consideration Shares upon issuance;

8.14.2 the representations and warranties described in Section 8.14.1 that are made by TGTX and TGTX Parent shall be deemed to be made as of, and accurate on, each date that TGTX Parent issues TGTX Parent Consideration Shares to Precision in accordance with this Agreement;

8.14.3 the TGTX Parent Consideration Shares issued with respect to the applicable Milestone Event shall be freely and immediately tradable by Precision on Nasdaq;

8.14.4 TGTX Parent shall have taken, and shall take, all appropriate actions to comply with applicable securities laws and regulations and Nasdaq listing requirements to enable the immediate and continuous sale of the TGTX Parent Consideration Shares by Precision without restriction, including, at TGTX Parent's election, (a) obtaining an opinion from counsel to TGTX Parent or a no-action letter confirming that such shares, when issued, are not subject to any holding period or other restriction under Rule 144 or (b) filing and continuously maintaining the effectiveness of a registration statement registering the offer and sale of such shares under the Securities Act until all such shares may be sold by Precision under Rule 144 free of any restrictions; and

8.14.5 the covenants made by TGTX and Precision in Sections 8.2.7 and 8.2.8 shall be covenanted and agreed to by Precision and TGTX, respectively, as if such covenants were restated in this Section 8.14.5, *mutatis mutandis*, with the applicable references to "Precision" being replaced with references to "TGTX" or "TGTX Parent," as appropriate, the applicable references to "TGTX" being replaced with references to "Precision," and the applicable cross-references updated accordingly in the context of the restatement of such covenants in this Section 8.14.5.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 **Ownership of Intellectual Property**.

9.1.1 **Background IP**. As between the Parties, and subject to the licenses granted under this Agreement (a) TGTX shall solely own (or retain ownership of) all rights, title and interests in and to the TGTX Background IP, and (b) Precision shall solely own (or retain ownership of) all rights, title and interests in and to the Precision Background IP. If any Third Party becomes an Acquirer of a Party after the Effective Date pursuant to a Change of Control of such Party, any Patents and Know-How Controlled by the Acquirer before the relevant Change of Control transaction or thereafter during the Term will not be considered part of the Precision Background IP (where Precision is the acquired Party) or TGTX Background IP (where TGTX is the acquired Party); *provided*, however, that any Patents or Know-How that would otherwise constitute Precision Background IP or TGTX Background IP, as applicable, and are discovered or created by or on behalf of the Acquirer after the relevant Change of Control transaction in connection with activities under this Agreement, will be considered part of the Precision Background IP or TGTX Background IP, accordingly.

9.1.2 **Inventions**. Ownership of Inventions arising under this Agreement shall be as follows:

(a) TGTX shall solely own (or retain ownership of) all Inventions discovered, created, acquired, conceived or reduced to practice, solely by or on behalf of TGTX or any of its Affiliates in the course of performing activities under this Agreement, except to the extent constituting Precision Sole IP ("***TGTX Sole IP***").

(b) Precision shall solely own (or retain ownership of) (i) all Inventions discovered, created, acquired, conceived or reduced to practice, solely by or on behalf of Precision or any of its Affiliates in the course of performing activities under this Agreement, and (ii) all Inventions that relate to the [***], whether discovered, created, conceived or reduced to practice by or on behalf of TGTX or Precision or any of their respective Affiliates in the course of performing activities under this Agreement ("***Precision Sole IP***"). TGTX agrees to assign and hereby assigns to Precision all of its and its Affiliates' right, title and interests in and to the Precision Sole IP and agrees to execute such documents and perform such other acts as Precision may reasonably request to obtain, perfect and enforce the Precision Sole IP and the assignment thereof.

(c) Except to the extent constituting Precision Sole IP, any Invention discovered, created, conceived, reduced to practice or acquired, jointly by or on behalf of the Parties in the course of performing activities under this Agreement ("***Joint IP***"), will be jointly owned by the Parties.

9.1.3 **Inventorship**. Inventorship as between the Parties will be determined in accordance with U.S. patent laws. All such determinations shall be documented to ensure that the Patent claims in any divisional or continuation patent applications reflect appropriate inventorship.

9.1.4 **Rights of Joint Owners**. Subject to the licenses granted hereunder and the payment obligations under Article 8, each Party shall have full rights to exploit and license Joint IP (and any Patents therein), without any obligation or requirement of an accounting to the other Party.

9.1.5 **Independent Development**. Subject to the licenses granted hereunder, nothing in this Agreement shall be construed as limiting either TGTX's or Precision's right to Develop and in-license technology related to the TGTX Background IP (in the case of TGTX) or Precision Background IP (in the case of Precision) outside the scope of this Agreement in its ordinary course of business.

9.1.6 **Assignment Obligation**. Each Party shall cause all of its Affiliates, directors, officers, employees, agents, independent contractors, Sublicensees, consultants, and others who perform activities for such Party under this Agreement (each, a "***Representative***") to be under an appropriate obligation of confidentiality and non-use consistent with the provisions of this Agreement and an obligation to assign (or, if such Party is unable to cause such person or entity to agree to such assignment obligation despite such Party using reasonable efforts to negotiate such assignment obligation, provide a license, preferably exclusive, under) to such Party their rights in and to any Inventions and all intellectual property rights therein such that the Party is able to comply with its obligations under this Agreement as if such Invention had been discovered, created, acquired, conceived or reduced to practice by such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a Party shall obtain a suitable license, preferably exclusive, or right to obtain such a license). Each Party shall use reasonable efforts to promptly disclose to the other Party in writing all Inventions arising under this Agreement that are owned by the other Party, including any invention disclosures, or other similar documents, submitted to it by its Representatives describing such Inventions, and all information relating to such Inventions to the extent necessary or useful for the preparation, filing and maintenance of any Patent with respect to such Invention.

9.2 **Patent Prosecution and Maintenance**.

9.2.1 **Rights to Prosecute and Maintain Patents**. As between the Parties:

(a) TGTX has the sole right, but not the obligation, to Prosecute and Maintain any Patents constituting or claiming any TGTX Background IP or TGTX Sole IP, at TGTX's sole cost and expense.

(b) Precision (or Precision's designee, as applicable) has the first right, but not the obligation, to Prosecute and Maintain any Patents constituting or claiming any Precision Background IP or Precision Sole IP, at Precision's (or its designee's, as applicable) sole cost and expense. Precision will give TGTX the opportunity to review (i) the text of any Precision Product-Specific Claim and (ii) responses to office actions related thereto, in each case, before filing of the relevant application or responding to such office action. Precision will reasonably consider any input or feedback from TGTX with respect to the foregoing, *provided*, that Precision shall have the final authority with respect to any such decisions. In the event that Precision (or Precision's designee, as applicable) elects not to conduct a Patent Defense Matter with respect to a Precision Patent, Precision may, in Precision's sole discretion, elect to permit TGTX to conduct such Patent Defense Matter, at TGTX's sole cost and expense. In the event that Precision elects in writing to permit TGTX to conduct a Patent Defense Matter with respect to any Precision Patent, TGTX shall keep Precision reasonably informed of the status of such Patent Defense Matter and shall consider in good faith Precision's comments thereon. TGTX shall provide Precision with drafts of all material papers and statements to be filed in connection with such Patent Defense Matter in sufficient time to allow Precision to review, consider and substantively comment thereon, and shall in good faith consider all reasonable comments thereto by Precision before filing such papers or statements. Precision may, at its own expense, join as a party to such Patent Defense Matter and be represented in any such action by counsel of its own choice.

(c) TGTX has the first right, but not the obligation, to Prosecute and Maintain any Patents constituting or claiming any Joint IP, at TGTX's sole cost and expense, and Precision shall have the secondary right, at Precision's sole cost and expense, to Prosecute and Maintain any Patents constituting or claiming any Joint IP, subject to and in accordance with Section 9.2.2.

(d) TGTX acknowledges and agrees that Precision has no rights or responsibility for preparing, filing, Prosecuting or Maintaining the Cellectis Patents. For clarity, TGTX shall have no rights with respect to preparing, filing Prosecuting or Maintaining the Cellectis Patents.

9.2.2 **Prosecution and Maintenance Procedures for Joint IP**. The Party handling the Prosecution and Maintenance of a Patent claiming or constituting Joint IP under Section 9.2.1(c) (the "***Prosecuting Party***") shall keep the other Party reasonably informed of the status of the applicable Patent and shall promptly provide the other Party with all material correspondence received from any patent authority in connection therewith. In addition, the Prosecuting Party shall promptly provide the other Party with drafts of all proposed material filings and correspondence to any patent authority with respect to the applicable Patent for the other Party's review and comment prior to the submission of such proposed filings and correspondences, and the Prosecuting Party shall consider the other Party's reasonable comments in good faith. The Prosecuting Party shall notify the other Party of its intention to suspend or cease any Prosecution and Maintenance of any such Patent. The Prosecuting Party shall provide such notice at least [***] prior to any filing or payment due date, or any other due date that requires action, in connection with such Patent. In such event, the Prosecuting Party shall permit the other Party, at the other Party's discretion and at its sole expense, to continue Prosecution and Maintenance of such Patent.

9.2.3 **Separation of Patent Claims**.

(a) If a Party determines that an application for a Patent filed, or sought to be filed, by the other Party claims [***], then the Parties agree that, to the extent practicable, such application shall be divided into two (2) or more Patent applications, so that each application shall contain claims that cover only [***].

(b) If the division contemplated in Section 9.2.3(a) is not practicable, or a single claim covers [***], then such Patent application shall be subject to the provisions of this Agreement relating to [***].

(c) Similarly, an attempt shall be made to divide Patent applications into those that claim Inventions [***].

9.2.4 **Cooperation of the Parties**. Each Party shall, at the other Party's reasonable request, cooperate with the other Party in the Prosecution and Maintenance of Patents under this Section 9.2 at [***] cost (except as expressly set forth otherwise in this Article 9), including by: (a) executing all papers and instruments, or requiring its Representatives, to execute such papers and instruments, to enable the other Party to apply for and to Prosecute and Maintain such Patents in any country as permitted by this Section 9.2; and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the Prosecution and Maintenance of any such Patents. [***]. Each Party will use reasonable efforts via good faith consultation with the other to avoid creating potential issues in Prosecution and Maintenance of Patents under this Section 9.2.

9.2.5 **Patent Working Group**. Each Party shall designate to the other Party in writing a patent Prosecution and Maintenance representative to liaise with the other Party's patent Prosecution and Maintenance representative with respect to the Prosecution and Maintenance of Patents under this Section 9.2; such representatives will meet no less frequently than quarterly during the Term, by means of teleconference, Internet conference, videoconference, or other similar communication method, to discuss matters relevant to the Prosecution and Maintenance of Patents under this Section 9.2, including timing of planned filings and other upcoming Prosecution and Maintenance actions. Each Party may update its patent Prosecution and Maintenance representative at any time upon written notice to the other Party.

9.3 **Infringement or Misappropriation by Third Parties**.

9.3.1 **Notice**. Each Party shall notify the other within [ten (10) Business Days] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Precision Patents or Joint Patents, in each case in the Licensed Field in the Territory, and any related declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Precision Patents or Joint Patents (collectively "***Infringement***").

9.3.2 **Joint IP and Precision Product Patents**.

(a) As between the Parties, TGTX has the first right, but not the obligation, to bring and control any legal action, at [***] cost and expense, in connection with (i) any Infringement of any [***] or (ii) any Infringement of any Joint IP (other than any [***]) that is competitive with the Licensed Product. TGTX shall keep Precision reasonably informed of the status of such enforcement efforts for such Joint IP or [***] and shall consider in good faith Precision's comments thereon. TGTX shall provide Precision with drafts of all material papers and statements to be filed with the court in sufficient time to allow Precision to review, consider and substantively comment thereon, and shall in good faith consider all reasonable comments thereto by Precision before filing such papers or statements. Precision may, at [***] expense, join as a party to such claim, suit, or proceeding and be represented in any such action by counsel of its own choice. If TGTX does not bring such legal action within [***] after the notice provided pursuant to Section 9.3.1 (or within such shorter period prior to the next deadline for any action that must be taken in order to bring such legal action), Precision may bring and control any legal action in connection with such Infringement, at [***] cost and expense as it reasonably determines appropriate so long as TGTX does not reasonably object to such action.

(b) As between the Parties, Precision shall have the first right, but not the obligation, to bring and control any legal action, at [***] cost and expense, in connection with any Infringement of any Joint IP (other than any Infringement described in Section 9.3.2(a)). Precision shall keep TGTX reasonably informed of the status of such enforcement efforts for such Joint IP and shall consider in good faith TGTX's comments thereon. Precision shall provide TGTX with drafts of all material papers and statements to be filed with the court in sufficient time to allow TGTX to review, consider and substantively comment thereon, and shall in good faith consider all reasonable comments thereto by TGTX before filing such papers or statements. TGTX may, at its own expense, join as a party to such claim, suit, or proceeding and be represented in any such action by counsel of its own choice. If Precision does not bring such legal action within [***] after the notice provided pursuant to Section 9.3.1, TGTX may bring and control any legal action in connection with such Infringement, at [***] cost and expense as it reasonably determines appropriate.

9.3.3 **Precision Background IP and Precision Sole IP**. Except as set forth in Section 9.3.2(a), as between the Parties, Precision has the sole right to initiate any proceedings or take other appropriate actions against an infringement of any Precision Background IP or Precision Sole IP and to defend against any challenge of any Precision Background IP or Precision Sole IP that are brought by a Third Party in connection with such infringement. TGTX acknowledges and agrees that (a) Precision has no rights or responsibility for enforcing the Cellectis Patents, and therefore all references to Precision Background IP in this Section 9.3 shall be deemed to exclude the Cellectis Patents for all purposes, (b) prior to initiating enforcement actions against a Third Party with respect to certain Precision Patents which are subject to the non-exclusive license granted by Precision to Cellectis S.A. pursuant to the Cellectis Agreement, Precision is required by the Cellectis Agreement to confirm that Cellectis S.A. has not granted a license to such Third Party under such Precision Patents, and TGTX will cooperate with Precision in taking such actions as required by the Cellectis Agreement, and (c) Duke retains discretion as to whether to become a party plaintiff and has certain rights with respect to enforcement of Patents contained within the Duke IP in the event Precision does not enforce such Patents.

9.3.4 **TGTX Background IP and TGTX Sole IP**. TGTX has the sole right to initiate any proceedings or take other appropriate actions against an infringement of any TGTX Background IP or TGTX Sole IP and to defend against any challenge of any TGTX Background IP or TGTX Sole IP that are brought by a Third Party in connection with such infringement.

9.3.5 **Allocation of Recoveries**. Any recoveries resulting from enforcement action relating to a claim of Infringement shall be [***].

9.3.6 **Cooperation**. At the request and expense of the Party bringing an action under this Section 9.3, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action. In connection with any such enforcement action, the Party bringing the action shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in the applicable Patents without the prior written consent of the other Party.

9.4 **Defense and Settlement of Third Party Claims**. Each Party shall promptly notify the other in writing of: (a) any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party; or (b) any declaratory judgment action that is brought naming either Party as a defendant and alleging invalidity of any of the Precision Patents, or Joint Patents. Precision has the sole right to control any defense of any such claim described in (a) involving alleged infringement of Third Party rights by Precision's activities at [***] expense and by counsel of its own choice, and TGTX may, at [***] expense, be represented in any such action by counsel of its own choice. TGTX has the sole right to control any defense of any such claim described in (a) involving alleged infringement of Third Party rights by TGTX's activities at [***] expense and by counsel of its own choice, and Precision may, at [***] expense, be represented in any such action by counsel of its own choice. Neither Party may settle any patent infringement litigation under this Section 9.4 in a manner that admits the invalidity or unenforceability of the other Party's Patents or a Joint Patent or imposes on the other Party restrictions or obligations or other liabilities, without the written consent of such other Party, which consent shall not be unreasonably withheld, conditioned, or delayed. Nothing in this Section 9.4 will limit any indemnification rights or obligations of a Party under Article 11.

9.5 **Patent Extension**. The Parties shall cooperate in determining whether a Joint Patent claiming or covering a Licensed Product should be extended, and thereafter the Parties shall cooperate in obtaining patent term restorations, supplemental protection certificates or their equivalents, and other forms of patent term extensions for a given Licensed Product with respect to any applicable Joint Patent in any country or region where applicable. Precision shall have final decision-making authority with respect to decisions regarding patent term extensions for Precision Patents. TGTX shall have final decision-making authority with respect to decisions regarding patent term extensions for TGTX Patents.

9.6 **CREATE Act**. It is the Parties' intention that this Agreement is a "joint research agreement" as that phrase is defined in 35 U.S.C. § 102(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act, including the provisions of 35 U.S.C. § 102(b)(2)(c). The Parties agree to cooperate and to take reasonable actions to maximize the protections available for the Licensed ARCUS Nuclease and Licensed Products under such safe harbor provisions.

9.7 **Licenses to Third Party Intellectual Property Rights**. If (a) a Party becomes aware of any Patent of a Third Party that (i) claims or embodies the Licensed ARCUS Nuclease or ARCUS Technology as a composition of matter, or a method of making or using the Licensed ARCUS Nuclease or ARCUS Technology and (ii) is not the subject of an agreement with a Party as of or prior to the Effective Date; then (b) such Party shall notify the other in writing, identifying the relevant Patent. Precision shall have the first right (but not the obligation) to negotiate and obtain a license from such Third Party under such Patent described under a notice described in the foregoing (a) for a period of [***] following the date of such notice.

9.8 **Licensed Product Trademarks**. TGTX shall have the right to select, and the right to use and to register in any trademark office in the Territory, any trademark for use with the Licensed Product (the "***Licensed Product Trademarks***"); *provided* that TGTX shall not use, file applications for, or register any trademarks owned by Precision (or its Affiliates or licensees), or that are confusingly similar thereto, whether stand-alone or in combination with a design element, for the benefit of branding (including co-branding) without the prior written consent of Precision. As between the Parties, TGTX shall own all right, title and interest in and to any such Licensed Product Trademarks adopted by TGTX for use with a Licensed Product, and is responsible for the registration, filing, maintenance and enforcement thereof.

ARTICLE 10

REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 **Mutual Representations and Warranties**. Each of TGTX and Precision represent and warrant that, as of the Effective Date:

10.1.1 it is duly organized and validly existing under in the Applicable Laws of the jurisdiction of its incorporation or formation, as applicable, has full corporate, limited liability company or other power and authority, as applicable, to enter into this Agreement and to carry out the provisions hereof, and has sufficient facilities, experienced personnel or other capabilities (including via Affiliates and/or Third Parties) to enable it to perform its obligations under this Agreement;

10.1.2 it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate, limited liability company or other action, as applicable; and

10.1.3 this Agreement is legally binding upon it and enforceable in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity) and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (a) conflict with, or constitute a default or result in a breach under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any Applicable Law; or (b) require any consent or approval of its stockholders or similar.

10.2 **Precision Representations and Warranties**. Precision represents and warrants to TGTX that, as of the Effective Date:

10.2.1 **No Grants that Conflict with this Agreement**. Precision and its Affiliates have not granted any rights (or other encumbrances) to any Third Party under Precision Technology that conflict with the rights granted to TGTX hereunder.

10.2.2 **Existing Patents**.

(a) All Precision Patents Covering the Licensed Product or the Licensed ARCUS Nuclease that exist as of the Effective Date, other than the Cellectis Patents, that are issued or subject to a pending application for issuance are listed on Exhibit 10.2.2 (the "***Existing Patents***").

(b) The Existing Patents and the Cellectis Patents represent all Patents Controlled by Precision that Cover the Licensed Product, the Licensed ARCUS Nuclease, or the Exploitation of any of the foregoing in the Licensed Field.

(c) All Existing Patents are: (i) to the extent issued (unless otherwise indicated on Exhibit 10.2.2), subsisting and, to Precision's Knowledge, not invalid or unenforceable, in whole or in part, or to Precision's Knowledge, confer a valid right to claim priority thereto; (ii) solely and exclusively owned or exclusively licensed to Precision, free of any encumbrance, lien or claim of ownership by any Third Party; (iii) in respect of Existing Patents owned by Precision, to the extent subject to a pending application for issuance, being prosecuted in good faith in the respective patent offices in which such applications have been filed in accordance with Applicable Law and, to Precision's Knowledge, all material references, documents and information have been presented to the relevant patent office in respect of such Existing Patents to the extent required by such patent office; (iv) in respect of Existing Patents owned by Precision, filed and maintained in accordance with applicable Patent office rules, and all applicable fees applicable thereto have been paid on or before any final due date for payment; and (v) in respect of Existing Patents owned by Precision, all Representatives of Precision who have performed any activities on its behalf in connection with the inventions claimed in the Existing Patents have assigned to Precision the whole of their rights in any intellectual property rights thereto conceived or reduced to practice by them, and no such Representative has any rights to any such Existing Patents.

(d) [***].

10.2.3 **[***]**.

10.2.4 **[***]**.

10.2.5 **Other Material Claims and Actions**. There are no claims, actions, or proceedings pending or, to Precision's Knowledge, threatened by any Third Party against Precision or its properties, assets or business, which if adversely decided, would, individually or in the aggregate, have a material adverse effect on, or prevent Precision's ability to grant the licenses or rights granted to TGTX under this Agreement.

10.2.6 **No Government Funding**. Except with respect to the Duke IP, the Inventions claimed or covered by the Precision Patents: (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States of America or any agency thereof; (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401 (the "***Bayh-Dole Act***").

10.2.7 **Regulatory Compliance of the Batch**. The batch of released Clinical Trial material to be delivered pursuant to Section 6.2.1 at the time of delivery to TGTX by Precision: [***].

10.2.8 **Manufacturing Facilities**. To Precision's Knowledge, all facilities used by Precision in connection with the Manufacture of the Licensed Product, including batch number PBCAR0191-2023-0006, are in good operating condition and repair, were designed to be capable to and were utilized by Precision to Manufacture the Licensed Product [***]. To Precision's Knowledge, no inspection of such facilities has resulted in any warning letter, notice of violation letter or other notice, response or commitment made to or with the FDA or any other Governmental Authority.

10.3 **TGTX Representations and Warranties**. TGTX represents and warrants to Precision that, as of the Effective Date, TGTX and its Affiliates have not granted any rights (or other encumbrances) to any Third Party under TGTX Arising IP or TGTX Background IP that conflict with the rights granted to Precision hereunder.

10.4 **Mutual Covenants**.

10.4.1 **Debarment**. Each Party represents and warrants to the other Party that such Party has not, and its Representatives have not been: (a) debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act; (b) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Each Party will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates the services of any such person. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, directly or indirectly, including through Affiliates or Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

10.4.2 **Protection of Information**. Each Party agrees that during the Term of this Agreement, and without limiting its obligations hereunder, such Party shall implement technical and organizational measures to protect all information under the Agreement that are appropriate and that provide no less protection than both (a) good industry practice (i.e., in accordance with ISO 27001 and/or similar industry standards) and (b) such Party's measures to protect its own information of a similar nature or importance.

10.5 **Precision Covenant**. Precision covenants and agrees that during the Term: (1) it shall satisfy all of its obligations under (including making all payments), and take all steps to maintain in full force and effect, the Existing In-License Agreements; (2) it will not assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 15.7), amend, restate, amend and restate, terminate in whole or in part, or otherwise modify an Existing In-License Agreement in any manner that limits TGTX's exercise of the rights granted in this Agreement without the prior written consent of TGTX; and (3) it will provide TGTX with prompt notice of any claim of a breach under an Existing In-License Agreement made by either Precision or Duke or Cellectis S.A., as applicable. Notwithstanding anything herein to the contrary, Precision may, at any time, create a security interest in, pledge or assign, all or any portion of its rights under and interest in the Existing In-License Agreements in favor of any senior secured creditor of Precision, and such senior secured creditor may enforce such pledge or security interest in any manner permitted under applicable law; provided, however, that any such security interest, pledge, or assignment by Precision of all or any portion of its rights under and interest in the Existing In-License Agreements shall not diminish or impair the rights of TGTX under this Agreement.

10.6 **Compliance**.

10.6.1 **Compliance with Applicable Laws**. Each Party covenants to the other that in the performance of its obligations under this Agreement, such Party shall comply with, and shall cause its Affiliates and its and its Affiliates' employees and contractors to comply with, all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Laws.

10.6.2 **Compliance with Internal Compliance Codes**. All Internal Compliance Codes shall apply only to the Party to which they relate. The Parties agree to cooperate with each other to help ensure that each Party is able to comply with the substance of its respective Internal Compliance Codes and, to the extent practicable, each Party shall operate in a manner consistent with its Internal Compliance Codes applicable to its performance under this Agreement. "***Internal Compliance Codes***," as used in this Section 10.6.2, means a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws and such Party's internal ethical, medical and similar standards.

10.6.3 **Compliance with Anti-Corruption Laws**. In connection with this Agreement, the Parties shall comply with all applicable local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and any laws enacted to implement the Organization of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

10.6.4 **Prohibited Conduct**. Without limiting the other obligations of the Parties set forth in this Section 10.6, each Party covenants to the other that, as of the Effective Date and in the performance of its obligations under this Agreement through the expiration and termination of this Agreement, such Party and, to its knowledge, its Affiliates and its and its Affiliates' Representatives, in connection with the performance of their respective obligations under this Agreement, have not made, offered, given, promised to give, or authorized, and will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly through Third Parties, to any Government Official for the purpose of: (a) improperly influencing any act or decision of the Person or Government Official; (b) inducing the Person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (c) securing any improper advantage; or (d) inducing the Person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist any Party in obtaining or retaining business. For the purpose of this Section 10.6.4, "***Government Official***" means: (x) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital; (y) any candidate for political office, any political party or any official of a political party, in each case for the purpose of obtaining or retaining business for or with, or directing business to, any Person, including either Party; or (z) any Person acting in an official capacity on behalf of any of the foregoing.

10.7 **Disclaimer**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 10 AND IN SECTIONS 8.2.2, 8.2.3, AND 8.14, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS OR THE AVAILABILITY OF ANY LICENSES WITH RESPECT TO INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENTS OR THAT ANY PATENTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT ANY LICENSED PRODUCTS, INCLUDING THE RESEARCH, MANUFACTURE, DEVELOPMENT OR COMMERCIALIZATION THEREOF, WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

ARTICLE 11

INDEMNIFICATION

11.1 **Indemnity**.

11.1.1 **By Precision**. Precision shall defend, indemnify and hold harmless TGTX and its Affiliates, and their respective Representatives (each, a "***TGTX Indemnitee***") from and against any and all costs, fees, expenses, losses, liabilities, and damages, including reasonable legal expenses and attorneys' fees (collectively, "***Losses***") to which any TGTX Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (a "***Claim***") to the extent such Losses arise out of: (a) the gross negligence or willful misconduct of Precision or its Affiliates in connection with its activities under this Agreement; (b) the breach of this Agreement or the representations, warranties, and covenants made hereunder by Precision; except, in each case, to the extent such Losses result from matters subject to clause (a), (b) or (c) of Section 11.1.2.

11.1.2 **By TGTX**. TGTX shall defend, indemnify and hold harmless Precision, its Affiliates, Duke, and its and their respective Representatives (each, a "***Precision Indemnitee***") from and against any and all Losses to which any Precision Indemnitee may become subject as a result of any Claim to the extent such Losses arise out of: (a) the gross negligence or willful misconduct of TGTX, its Affiliates, or its or their respective Sublicensees in connection with its activities under this Agreement; (b) the breach of this Agreement or the representations, warranties and covenants made hereunder by TGTX; or (c) [***]; except, in each case, to the extent such Losses result from matters subject to clause (a) or (b) of Section 11.1.1.

11.1.3 **Procedure**. A Party that intends to claim indemnification under this Article 11 (the "***Indemnitee***") shall promptly notify the Indemnitor (the "***Indemnitor***") in writing of any Claim in respect of which the Indemnitee intends to claim such indemnification. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 11 if and to the extent the Indemnitor is actually and materially prejudiced thereby. The Indemnitor has sole control of the defense or settlement thereof. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification. The Indemnitee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own selection. The Indemnitor shall not settle any Claim in a manner that admits liability of Indemnitee or requires Indemnitee to perform any material obligations (other than payment of money which will be fully satisfied by Indemnitor) without the prior written consent of the Indemnitee, not to be unreasonably withheld, conditioned or delayed. So long as the Indemnitor is actively engaged in activities relating to defending or settling the Claim in good faith, the Indemnitee shall not settle or compromise any such Claim without the prior written consent of the Indemnitor. If the Indemnitor does assume activities in furtherance of the defense and settlement of a Claim as provided above within [***] after written notice from Indemnitee stating intent of the Indemnitor to undertake such activities if Indemnitor does not: (a) the Indemnitee may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnitee may deem reasonably appropriate (and the Indemnitee need not consult with, or obtain any consent from, the Indemnitor in connection therewith); and (b) the Indemnitor shall remain responsible to indemnify the Indemnitee as provided in this Article 11.

11.2 **Insurance**. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term and for a period of [***] thereafter or for otherwise longer as may be required by Applicable Law; but in any event, and without limiting the foregoing, no later than Initiation of the first Clinical Trial for a Licensed Product, TGTX shall procure and maintain product liability insurance in an amount not less than [***] per occurrence and in the annual aggregate. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. The Parties agree that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11 or other obligations under this Agreement.

ARTICLE 12

CONFIDENTIALITY

12.1 **Confidential Proprietary Information**.

12.1.1 **Confidential Proprietary Information**. In connection with this Agreement, each Party may disclose technical, business or other confidential information in connection with this Agreement, whether prior to, on, or after the Effective Date, including (a) any unpublished Patents, and (b) any information regarding the scientific, regulatory or business affairs or other activities of either Party; in each case ((a) and (b)) that is marked or identified at the time of disclosure as confidential or proprietary or is of such a nature that would be understood by a reasonable person to be confidential or proprietary (such confidential information, "***Confidential Proprietary Information***"). Without limiting the foregoing, the terms of this Agreement and all Joint IP are the Confidential Proprietary Information of both Parties and shall be treated confidentially by each of the Parties, subject to the exceptions set forth in this Section 12.1. [***]. Information exchanged by the Parties pursuant to the Confidentiality Agreement shall be treated as Confidential Proprietary Information under this Agreement and governed by the terms of this Agreement.

12.1.2 **Restrictions**. A Party (the "***Receiving Party***") that receives Confidential Proprietary Information from the other Party (the "***Disclosing Party***") shall keep all the Disclosing Party's Confidential Proprietary Information in confidence with the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care), and will not disclose such Confidential Proprietary Information to any Person except as permitted under Section 12.1.4. A Receiving Party shall not use the Disclosing Party's Confidential Proprietary Information except in connection with the performance of its obligations and exercise of its rights under this Agreement.

12.1.3 **Exceptions**. The obligations of confidentiality and restriction on use of Confidential Proprietary Information under Section 12.1.2 do not apply to any information that the Receiving Party can prove by competent written evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available to the public; (b) is known by the Receiving Party at the time of receiving such information, other than by previous disclosure of the Disclosing Party or its Affiliates or Representatives; (c) is hereafter furnished to the Receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the Receiving Party without the use of or reference to Confidential Proprietary Information belonging to the Disclosing Party. Specific information shall not be deemed to be within any of the foregoing exclusions merely because it is embraced by more general information falling within those exclusions. Further, any combination of Confidential Proprietary Information shall not be deemed to be generally known, available to the public or known by the Receiving Party merely because individual elements of such Confidential Proprietary Information are subject to such exclusions unless the combination and its principles are subject to such exclusions.

12.1.4 **Permitted Disclosures**. The Receiving Party may disclose Confidential Proprietary Information belonging to the Disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) made by or on behalf of the Receiving Party to a Patent authority as may be reasonably necessary or useful for purposes of Prosecution and Maintenance of Patents as permitted by this Agreement; *provided*, that neither Party shall file a patent application that discloses TGTX Technology (for disclosures by Precision) or Precision Technology (for disclosures by TGTX) without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed);

(b) made by or on behalf of the Receiving Party to Regulatory Authorities as necessary or reasonably useful in connection with any Regulatory Filings for a product that such Party has a license or right to develop in a given country or jurisdiction;

(c) made by or on behalf of the Receiving Party as may be necessary or reasonably useful for prosecuting or defending litigation as permitted by this Agreement;

(d) made by or on behalf of the Receiving Party for the purpose of complying with a valid order of a court of competent jurisdiction or other Governmental Authority of competent jurisdiction or, if in the opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law;

(e) made by or on behalf of the Receiving Party where such disclosure is required by a Regulatory Authority (including in filings with the Securities and Exchange Commission or other agency) of certain material developments or material information generated under this Agreement; *provided* that, to the extent permitted, the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure; and *provided*, further, that the receiving Party shall afford to the other Party an opportunity to review and comment, which period shall be no less than [***] (*provided* that if the applicable disclosure is required to be made within fewer than [***], then the receiving Party shall afford to the other Party a reasonable opportunity to review and comment consistent with such disclosure requirement), and the Receiving Party shall accept any reasonable comments so provided;

(f) made by or on behalf of Precision to Duke solely as and to the extent necessary to fulfill Precision's reporting obligations under the Duke Agreement as of the Effective Date so long as such information is disclosed subject to the confidentiality provisions of the Duke Agreement as of the Effective Date;

(g) made by or on behalf of the Receiving Party in response to a valid request by a U.S., state, foreign, provincial, or local tax authority, in which case either Party may disclose, a copy of this Agreement (including any Exhibits, Appendices, ancillary agreements, and amendments hereto);

(h) made by the Receiving Party to its and its Affiliates' Representatives, subcontractors, and to Sublicensees (in the case of TGTX) or licensees (in the case of Precision), in each case on a need-to-know basis (as reasonably determined by the Receiving Party) in connection with the Exploitation of the Licensed Product in the Territory, in each case under written obligations of confidentiality and non-use substantially consistent with those herein; and

(i) made by the Receiving Party to potential and actual investors, acquirers, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case so long as such recipients are bound by confidentiality and non-use obligations at least as stringent as those herein; *provided*, however, that with respect to disclosure to actual or bona fide potential investors, such disclosure is under an obligation of confidentiality that is consistent with market terms, including a shorter period of time during which such information must be held confidential.

[***].

12.1.5 **Disclosure of Agreement**. Notwithstanding the foregoing in this Article 12, either Party or its Affiliates may disclose the relevant terms of this Agreement: (a) to the extent required or advisable to comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory, *provided* that such Party shall (i) file a redacted form of this Agreement, if permitted, (ii) before filing, provide the redacted form of the agreement, if any, to the other Party for review and comment, and (iii) consider any comments by the other Party to the redacted form of the Agreement in good faith before filing; (b) upon request from a Governmental Authority (such as a tax authority), *provided* that the disclosing Party uses reasonable efforts to ensure the Governmental Authority maintains such terms as confidential; (c) to applicable licensors, to the extent necessary to comply with the terms of any Third Party license agreement, the rights under which are sublicensed to the other Party under this Agreement; and (d) to the extent necessary to perform obligations or exercise rights under this Agreement, to any sublicensee, collaborator or potential sublicensee or potential collaborator of such Party, *provided* that any sublicensee, collaborator or potential sublicensee or collaborator agree in writing to be bound by obligations of confidentiality and non-use no less protective of the Disclosing Party than those set forth in this Agreement.

12.1.6 **Survival**. Each Party's obligations under this Section 12.1 shall apply during the Term and continue for [***].

12.2 **Publicity**. Neither Party shall issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed; *provided* however, that (a) neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or pursuant to the rules or regulations of any applicable Governmental Authority, national securities exchange or quotation system, subject to the restrictions set forth in Sections 12.1.4 and 12.1.5; and (b) Precision will not be prevented from disclosing publicly the achievement of any Milestone Event and the receipt (and the amount) of any corresponding payment, *provided* that (i) TGTX shall have at least [***] to review and provide edits and comments to any public disclosure proposed by Precision under this Section 12.2(b) and (ii) Precision shall reasonably incorporate any edits and address any comments provided by TGTX in such proposed public disclosure. If either Party desires to issue a press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, the issuing Party will provide the other Party with a copy of the proposed press release or public statement. The issuing Party shall specify with each such proposed press release or public statement, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such proposed press release or public statement. If the reviewing Party provides any comments, the Parties shall consult with one another on such proposed press release or public statement and work in good faith to prepare a mutually acceptable press release or public statement. Each Party may repeat any information relating to this Agreement that has already been publicly disclosed in accordance with this Section 12.2, *provided* that such information continues as of such time to be accurate.

12.3 **Publication**. At least [***] before TGTX or its Affiliate makes any public disclosure (whether by oral presentation, poster, manuscript or abstract) or submits for publication of a proposed publication (such applicable period, the "***Review Period***") relating to any Clinical Trial data, non-clinical or preclinical data, or any associated results or conclusions specific to the Licensed Product or the Licensed ARCUS Nuclease that have not been previously publicly disclosed (collectively, a "***Publication***"), TGTX shall deliver a complete copy of the applicable proposed Publication to Precision. TGTX will provide Precision with a copy of such proposed Publication at least [***] prior to the earlier of its presentation or intended submission for publication. TGTX agrees that it will not submit or present any Publication until (a) Precision has provided written comments during such Review Period on the material in such Publication, or (b) the applicable Review Period has elapsed without written comments from Precision, in which case TGTX may proceed and the Publication will be considered approved in its entirety. If TGTX receives written comments from Precision on any Publication during the applicable Review Period, then it will consider Precision's comments in good faith and incorporate such comments where appropriate. Notwithstanding any provision to the contrary set forth in this Agreement, TGTX will (y) delete any Confidential Proprietary Information of Precision that Precision identifies for deletion, and (z) delay such Publication for a period of up to an additional [***] after the end of the applicable Review Period to enable Precision to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. TGTX will provide Precision a copy of the Publication at the time of the submission or presentation thereof. TGTX agrees to acknowledge the contributions of Precision and the employees of Precision, in each case, in all Publications as scientifically appropriate. TGTX will require its Affiliates and Sublicensees to comply with the obligations of this Section 12.3 as if they were TGTX, and TGTX will be liable for any non-compliance of such Persons. For the avoidance of doubt, neither Party will be prevented by this Section 12.3 from complying with any duty of disclosure it may have pursuant to Applicable Laws or pursuant to the rules or regulations of any applicable Governmental Authority, national securities exchange or quotation system, subject to the restrictions set forth in Sections 12.1.4 and 12.1.5.

ARTICLE 13

TERM & TERMINATION

13.1 **Term**. This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 13 or by mutual written agreement of the Parties, shall continue until the expiration of the last Royalty Term (the "***Term***"). Upon expiration (but not termination of this Agreement) of the Royalty Term with respect to the Licensed Product in any country within the Territory, the licenses under Section 7.1.1 and Section 7.1.2 with respect to such Licensed Product in such country will become perpetual, fully paid-up and royalty-free.

13.2 **Termination**.

13.2.1 **Termination for Material Breach of Agreement**.

(a) Either Party may terminate this Agreement upon written notice to the other Party if such other Party materially breaches its obligations under this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within [***] from the date of such notice [***].

(b) If an allegedly-breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided pursuant to Section 13.2.1(a), and such Party provides notice to the non-breaching Party of such Dispute within the applicable cure period, such Party may refer the Dispute for resolution in accordance with Section 14.3 and 14.4. It is understood and acknowledged that during the pendency of such a Dispute, all of the terms and conditions of this Agreement shall remain in effect, the Parties shall continue to perform all of their respective obligations hereunder in good faith with continued diligence, and the non-breaching Party shall not have the right to terminate this Agreement pursuant to Section 13.2.1(a) on the basis of such disputed breach.

13.2.2 **Termination by Precision**. Without limiting Section 13.2.1, Precision may terminate this Agreement upon written notice to TGTX if (a) TGTX fails to Initiate a Phase I Clinical Trial of the Licensed Product in the Licensed Field by the Initiation Deadline, or (b) [***] TGTX and its Affiliates and Sublicensees have suspended or do not have an active and ongoing Development program with respect to the Licensed Product for [***].

13.2.3 **Termination for Insolvency**. In the event that either Party (a) makes an assignment for the benefit of creditors, (b) appoints or suffers appointment of a receiver or trustee over any or substantially all of its property, where the receiver or trustee appointment is not discharged within [***] after such filing, (c) proposes a written agreement of composition with its creditors, (d) resolves to enter into, or enters into, a scheme of arrangement or a deed of company arrangement, (e) proposes or is a party to any dissolution or liquidation, (f) appoints or suffers the appointment of an administrator, (g) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [***] of the filing thereof, or (h) admits in writing its inability generally to meet its obligations as they fall due in the general course or is otherwise insolvent within the meaning given in Applicable Laws, then such Party will promptly notify the other Party of the occurrence of such Insolvency Event, and Precision (if TGTX becomes subject to a relevant Insolvency Event) or TGTX (if Precision becomes subject to a relevant Insolvency Event) may terminate this Agreement in its entirety effective immediately upon written notice to the other Party.

13.2.4 **Termination for Patent Challenges**. To the extent permitted under Applicable Law, Precision shall have the right to terminate this Agreement upon written notice to TGTX if TGTX or any of its Affiliates or Sublicensees, directly, or indirectly through any Third Party challenges the validity of any Patents Controlled by Precision, including commencing any pre-grant or post-grant action, interference or opposition proceeding with respect to, challenging the patentability, validity or enforceability of, or opposing any extension of or the grant of a Patent Term Adjustment or Extension or supplementary protection certificate with respect to, the Licensed Product in the Territory. Notwithstanding the forgoing, (a) Precision will not have any right to terminate this Agreement pursuant to this Section 13.2.4 on the basis of that act if, within [***] after TGTX's receipt of written notice from Precision, (i) the challenging party permanently withdraws its challenge with respect to any challenge made by a Sublicensee or (ii) TGTX terminates the applicable sublicense agreement; and (b) this Section 13.2.4 shall not apply to any challenge that (i) is required under a court order or subpoena or (ii) is asserted as a defense against a claim, action or proceeding asserted directly or indirectly by Precision or its Affiliates against TGTX, its Affiliates, or any Sublicensee with respect to Exploitation of the Licensed Product in the Licensed Field.

13.3 **Effects of Termination**. Upon any termination of this Agreement, the following provisions will apply, and all Licensed Products will be deemed "***Terminated Products***."

13.3.1 **Termination of Licenses from Precision**. All licenses for Terminated Products granted by Precision under Article 7 terminate automatically as of the termination effective date and all such rights shall revert to Precision; *provided* that, if TGTX (or its Affiliates or Sublicensees) has inventory of usable Terminated Product(s) as of the effective date of termination, then TGTX (and its Affiliates and Sublicensees) may continue to sell off such inventory of Terminated Products in the Licensed Field in the Territory (and fulfill customer orders therefor) until the earlier to occur of [***] after the effective date of termination and the date on which TGTX (or its Affiliates or Sublicensees) no longer has such inventory of Terminated Product(s) and shall pay Precision any applicable Royalties due (and Commercial Milestone Payments for Commercial Milestone Events achieved, as applicable) based on such sales. Any permitted sublicense granted by TGTX or its Affiliate to a Sublicensee under the licenses granted to TGTX under this Agreement shall survive the termination of this Agreement upon written request by the applicable Sublicensee and TGTX shall assign such sublicense to Precision such that such sublicense becomes a direct license between Precision and the Sublicensee on the same terms and conditions as those set forth in this Agreement to the extent applicable to the rights granted by TGTX to such Sublicensee, *provided* that, such sublicense was granted in accordance with the terms of Section 7.3 and in the case where termination of this Agreement was for TGTX's uncured material breach pursuant to Section 13.2.1, such Sublicensee did not cause such uncured material breach and such Sublicensee is, at the time of such termination, otherwise in compliance with the sublicense granted by TGTX to such Sublicensee and the applicable terms and conditions of this Agreement.

13.3.2 **Destruction of Confidential Proprietary Information**. Subject to the potential transfer of any data and information covered below in Section 13.4, each Receiving Party shall destroy (at the Disclosing Party's written request) all such Confidential Proprietary Information of the Receiving Party in its possession as of the effective date of expiration or termination (with the exception of one (1) copy of such Confidential Proprietary Information, which may be retained by the legal department of the Receiving Party to confirm compliance with the non-use and non-disclosure provisions of this Agreement), and any Confidential Proprietary Information of the Disclosing Party contained in its laboratory notebooks or databases, *provided* that each Receiving Party may retain and continue to use such Confidential Proprietary Information of the Disclosing Party only to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Notwithstanding the foregoing, a Receiving Party shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its Representatives who received the Disclosing Party's Confidential Proprietary Information under this Agreement, and neither Party shall be required to destroy any Joint IP.

13.4 **Terminated Product Reversion.**

13.4.1 In the event of any termination of this Agreement, upon Precision's request, TGTX shall perform the following obligations, and Precision shall reimburse TGTX for the actual, reasonable costs associated with the performance of such obligations:

(a) to the extent permitted by Applicable Laws or the terms of any applicable Third Party agreements (including Third Party agreements under which TGTX or any of its Affiliates are granted a license related to the Exploitation of any Terminated Product), (i) assign to Precision (A) TGTX's and its Affiliates' entire right, title and interest in and to all materials, preclinical and clinical data, safety data and all other supporting data, in each case, relating to such Terminated Product that is in TGTX's or its Affiliates' Control, and (B) TGTX's and its Affiliates' entire right, title and interest in and to all such Third Party agreements that are freely assignable and relate to the Exploitation of any applicable Terminated Product and for which such Third Party agrees to release TGTX for obligations and liabilities arising from and after such assignment, *provided*, that TGTX will retain the right to use any of the assigned materials or data as necessary for legal or compliance purposes, (ii) with respect to any Third Party agreements that are not assigned under (i) and under which TGTX or any of its Affiliates are granted a license related to Exploitation of any Terminated Product and pursuant to which TGTX or its Affiliates have a right or ability to grant sublicenses to Precision, grant a sublicense to Precision of all license rights granted to TGTX thereunder, on and subject to the same terms and conditions (including financial terms) set forth in the applicable Third Party agreement solely to Exploit such Terminated Product in all fields in the Territory, and (iii) deliver to Precision a copy of all relevant Know-How, in each case that relates to, and to the extent necessary or reasonably useful for, Precision to continue the Exploitation of such Terminated Product;

(b) to the extent permitted by Applicable Laws and the terms of any applicable Third Party agreements, transfer to Precision ongoing Clinical Trials or other studies being conducted by or under authority of TGTX related to such Terminated Product as of the date of the applicable termination notice and furnish Precision with reasonable cooperation to transition to Precision the management and continued performance of such Clinical Trials or other studies or, if requested by Precision, terminate such Clinical Trials or other studies, in each case in a manner in compliance with Applicable Laws and ethical guidelines;

(c) to the extent permitted by Applicable Laws and the terms of any applicable Third Party agreements, transfer to Precision any and all Regulatory Filings and related regulatory data (including pharmacovigilance databases, adverse drug experience reports and associated documents) and nonclinical, clinical and other data contained or referenced in or supporting any Regulatory Filings and related Know-How, manufacturing records, Regulatory Approvals, Marketing Authorizations and all other correspondence (including minutes and official contact reports relating to any communications with any Regulatory Authority), filings and submissions with and to Regulatory Authorities with respect to such Terminated Product; and, to this end, TGTX shall file for transfer with the relevant Regulatory Authorities and to give all other notifications and approvals necessary under Applicable Laws for the transfer of such Regulatory Filings and related regulatory data and Know-How, Regulatory Approvals, Marketing Authorizations and such other filings and submissions;

(d) after fulfillment of TGTX's existing commitments to its customers (including its Distributors) (which fulfillment period shall not in any event exceed [***] following termination of this Agreement as set forth in Section 13.3.1), sell to Precision TGTX's then-existing inventory of such Terminated Product, at TGTX's cost of goods sold for such Terminated Product as calculated in accordance with U.S. GAAP without mark-up; *provided* that Precision shall not be obligated to purchase such inventory;

(e) if an application seeking Marketing Authorization for a given Terminated Product has been filed as of the effective date of termination of this Agreement, assign to Precision all right, title and interest in and to the Licensed Product Trademarks that have been used in commerce solely with such Terminated Product, together with all goodwill relevant thereto, throughout the Territory; *provided*, however, that such obligation to assign will not extend to (i) any corporate name or logo of TGTX or any of its Affiliates, or (ii) any trademarks used by TGTX or any of its Affiliates on products that are not a Terminated Product;

(f) TGTX shall not withdraw or cancel any such Terminated Product's Regulatory Approval or Marketing Authorization or application for either, unless expressly instructed so by Precision in writing or required by Applicable Laws or any Regulatory Authority; *provided* that Precision shall be responsible for all costs and expenses for the maintenance of all Regulatory Approvals and Marketing Authorizations following receipt of notice of termination;

(g) TGTX shall thereafter refrain from making any statement, public or otherwise, regarding any Terminated Product unless TGTX is required to make such statement pursuant to Applicable Law or requirements of any Regulatory Authority and such statement is limited to the fact that TGTX is no longer Developing or Commercializing such Terminated Product or Precision shall have approved any such statement in writing; and

(h) following written request by Precision, TGTX shall take such other actions and execute such other instruments, assignments and documents that are reasonably necessary to effect the transfers and grants of rights under this Section 13.4.1 to Precision.

Following the foregoing assignments and transfer, all information and Know-How so assigned or transferred that was previously Confidential Proprietary Information of TGTX shall thereafter be deemed the Confidential Proprietary Information of Precision under Article 12.

13.4.2 **Other Rights and Obligations**. Upon any termination of this Agreement, all other rights granted under this Agreement and all obligations of the Parties will automatically terminate except as expressly set forth in Section 13.3, this Section 13.4 or Section 13.5.

13.5 **Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive (including, with respect to any covenants or other obligations, until such covenants have been fully performed and discharged) expiration or termination of this Agreement: Articles 1 (to the extent such definitions are used in surviving provisions) and 14 and Sections 3.2.2, 4.1.1 (only upon expiration, and not termination, of this Agreement), 4.3 (first sentence only, and only upon expiration, and not termination, of this Agreement), 4.4.1 (other than the second and third sentences, and only upon expiration, and not termination, of this Agreement), 4.4.2 (only upon expiration, and not termination, of this Agreement), 4.5 (only upon expiration, and not termination, of this Agreement), 4.6 (only upon expiration, and not termination, of this Agreement), 5.1.4 (only upon expiration, and not termination, of this Agreement), 5.3, 7.2, 7.4 (first sentence only), 8.1, 8.2.1(a), 8.2.1(b), 8.2.1(c) (in the event that Milestone Event 1 has been achieved prior to the effective date of such termination or expiration), 8.2.1(d) (in the event that Milestone Event 2 has been achieved prior to the effective date of such termination or expiration), 8.2.2, 8.2.3, 8.2.4, 8.2.5, 8.2.6, 8.2.7, 8.2.8, 8.3 (with respect to Milestone Events achieved prior to the effective date of such termination or expiration), 8.4 (with respect to Milestone Events achieved prior to the effective date of such termination or expiration), 8.6 (with respect to sales of Licensed Products made before the effective date of such termination or expiration or pursuant to Section 13.3.1), 8.7, 8.8, 8.9, 8.10, 8.11, 8.12, 8.13, 8.14 (with respect to any TGTX Parent Consideration Shares issued or issuable as consideration for any Milestone Events achieved prior to the effective date of such termination or expiration), 9.1.1, 9.1.2, 9.1.3, 9.2.1, 9.2.2, 9.3.2 (with respect to any and all Infringements of Joint IP), 9.3.5 (with respect to actions brought before the effective date of such termination or expiration, or brought with respect to Joint IP after the effective date of such termination or expiration), 9.3.6 (with respect to actions brought with respect to Joint IP), 9.4 (with respect to Joint IP), 9.6, 9.8 (final sentence only), 10.7, 11.1 (with respect to claims for which the cause of action arose prior to the effective date of termination or expiration), 12.1 (to the extent and as described in Section 12.1.6), 13.1 (only upon expiration, and not termination, of this Agreement), 13.3, 13.4, 13.5, 13.6, 15.1, 15.2, 15.4, 15.5, 15.6, 15.8, 15.10, 15.14, 15.15, 15.16, and 15.18.

13.6 **Exercise of Rights to Terminate; Damages; Relief**. The valid use by either Party of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto; *provided*, however, that termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon termination.

13.7 **Bankruptcy Code**. If this Agreement is rejected by a Party as a debtor under Section 365 of the United States Bankruptcy Code or similar provision in the bankruptcy laws of another jurisdiction (the "***Code***"), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code (or similar provision in the bankruptcy laws of another applicable jurisdiction). The Parties agree that a Party that is a licensee of rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against a Party under the Code, the other Party shall be entitled to a complete duplicate of, or complete access to (as such other Party deems appropriate), any such intellectual property to which such other Party is otherwise entitled to have access under this Agreement and all embodiments of such intellectual property, if not already in such other Party's possession, shall be promptly delivered to such other Party: (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by such other Party, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered under the foregoing subclause (a), upon the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party. [***]. The foregoing provisions of this Section 13.7 are without prejudice to any rights a Party may have arising under the Code.

ARTICLE 14

GOVERNING LAW; DISPUTE RESOLUTION

14.1 **Governing Law**. This Agreement shall be interpreted and construed in accordance with the laws of the State of New York. Any and all claims, controversies, and causes of action arising out of or relating to this Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the State of New York, including its statutes of limitations, without giving effect to any conflict-of-laws or other rule that would result in the application of the laws of a different jurisdiction. Notwithstanding the foregoing, any issue relating to the interpretation, construction, validity, enforceability or infringement of Patents shall be determined according to the patent laws of the country (or countries) in which the relevant Patent (or Patents) issued. The United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention) does not apply to this Agreement.

14.2 **Disputes**. The Parties recognize that controversies or claims arising out of, relating to, or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes in an expedient manner by mutual cooperation prior to resort to litigation. To accomplish this objective, the Parties shall follow the procedures set forth in this Article 14 to resolve any dispute, claim or controversy of any nature arising out of or relating to this Agreement, including any action or claim based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement (each, a "***Dispute***"). For the avoidance of doubt, Disputes within the purview of the JSC shall be resolved pursuant to Section 2.6, including through the exercise by a Party of its final decision-making authority in accordance therewith and including the escalation procedures set forth therein; *provided* that Disputes regarding whether a decision is subject to Precision's JSC representatives having final decision-making authority or to TGTX's JSC representatives having final decision-making authority pursuant to Section 2.6 shall be resolved pursuant to the procedures set forth in this Article 14.

14.3 **Executive Officers**. If a Dispute arises between the Parties, either Party may refer the Dispute to Executive Officers of each Party for resolution within [***] of a written request by either Party to the other Party. Each Party, within [***] after a Party has received such written request from the other Party to so refer such Dispute, shall notify the other Party in writing of the Executive Officer to whom such Dispute is referred. If, after an additional [***] after the notice of Dispute, such Executive Officers have not succeeded in negotiating a resolution of the Dispute, and a Party wishes to pursue the matter, the Parties may seek to resolve the Dispute in accordance with Section 14.4.

14.4 **Submission to Jurisdiction**. Each Party hereby (a) submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York or, if such court does not have jurisdiction, any state court sitting in the City of New York, New York in any action or proceeding arising out of or relating to this Agreement, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Either Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 15.4. Nothing in this Section 14.4, however, shall affect the right of either Party to serve legal process in any other manner permitted by law.

14.5 **Waiver of Jury Trial**. TO THE EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY HEREBY IRREVOCABLY WAIVES ALL RIGHTS TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS OR THE ACTIONS OF EITHER PARTY IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT OF THIS AGREEMENT.

14.6 **Equitable Relief**. Either Party may, at any time and without waiving any remedy under this Agreement, seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party. Any final judgment resolving a Dispute may be enforced by either Party in any court having appropriate jurisdiction.

ARTICLE 15

MISCELLANEOUS

15.1 **Entire Agreement; Amendment**. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing may not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 **Limitation of Liability**. NEITHER PARTY MAY RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES; *PROVIDED*, HOWEVER, THAT THIS SECTION 15.2 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 11, EITHER PARTY'S LIABILITY FOR BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12 OR LIABILITY OF A PARTY FOR ITS INFRINGEMENT OR MISAPPROPRIATION OF ANY INTELLECTUAL PROPERTY RIGHTS OR FOR A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD. IN ADDITION, IN NO EVENT SHALL PRECISION'S AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO SUPPLY OF LICENSED PRODUCT UNDER SECTION 6.2.1 OF THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EXCEED [***].

15.3 **Independent Contractors**. The relationship between TGTX and Precision created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party.

15.4 **Notice**. Any notice required or permitted to be given by this Agreement must be in writing, in English. Any and all notices or other communications or deliveries required or permitted to be provided hereunder must be in writing and will be deemed given and effective if: (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered, or certified mail; or (c) delivered by facsimile or electronic mail followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section 15.4, in each case, addressed as set forth below unless changed by notice so given:

If to Precision:

Precision BioSciences, Inc.
302 East Pettigrew Street, Suite A-100
Durham, NC 27701, U.S.A.
Attn: Cindy Atwell, Chief Business Officer
E-mail: [***]

with a copy (which shall not constitute notice) to:

Smith, Anderson, Blount, Dorsett,
Mitchell & Jernigan, LLP
150 Fayetteville Street, Suite 2300
Raleigh, NC 27601, U.S.A.
Attention: John Therien

If to TGTX:

TG Cell Therapy, Inc.
3020 Carrington Mill Blvd, Suite 475
Morrisville, North Carolina 27560
Attention: Michael S. Weiss, Executive Chairman and Chief Executive Officer

with a copy (which shall not constitute notice) to:

DLA Piper LLP
650 South Exeter Street, Suite 1100
Baltimore, MD 21202
Attention: Howard S. Schwartz, Esq.
Email: [***]

If to TGTX Parent:

TG Therapeutics, Inc.
3020 Carrington Mill Blvd, Suite 475
Morrisville, North Carolina 27560
Attention: Michael S. Weiss, Executive Chairman and Chief Executive Officer

with a copy (which shall not constitute notice) to:

DLA Piper LLP
650 South Exeter Street, Suite 1100
Baltimore, MD 21202
Attention: Howard S. Schwartz, Esq.
Email: [***]

15.5 **Severability**. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, (a) such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement, (b) this Agreement shall be construed and enforced as if such invalid, unenforceable or illegal provision had never comprised a part hereof, (c) all remaining portions will remain in full force and effect and shall not be affected by the invalid, unenforceable or illegal provision or by its severance herefrom, and (d) in lieu of such invalid, unenforceable or illegal provision, the Parties shall use reasonable efforts to seek and agree on an alternative valid and enforceable provision that preserves the original purpose and intent of this Agreement.

15.6 **Non-Use of Names**. Except as permitted pursuant to Section 12.2, Precision shall not use the name, trademark, logo, or physical likeness of TGTX or its respective officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without TGTX's prior written consent; *provided* that Precision shall have the right to use the name and logo of TGTX on its website solely for the purpose of referring to TGTX as a partner of Precision. Precision shall require its Affiliates to comply with the foregoing. Except as permitted pursuant to Section 12.2, TGTX shall not use the name, trademark, logo, or physical likeness of Precision or its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Precision's prior written consent; *provided* that TGTX shall have the right to use the name and logo of Precision on its website and in presentation materials solely for the purpose of referring to Precision as licensor of technology used by TGTX. TGTX shall require its Affiliates and Sublicensees to comply with the obligations set forth in this Section 15.6.

15.7 **Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer, without the other Party's consent to: (a) its Affiliate *provided* that (i) such Affiliate has sufficient resources to perform under this Agreement and (ii) such Party shall remain primarily liable for any acts or omissions of such Affiliate; or (b) to an Acquirer in connection with a Change of Control of such Party. For the avoidance of doubt, (y) nothing in this Agreement shall be construed as consent by Precision to assignment of this Agreement by TGTX in the context of a bankruptcy proceeding, and (z) nothing in this Agreement shall be construed as consent by TGTX to assignment of this Agreement, prior to [***], by Precision in the context of a bankruptcy proceeding. Any permitted assignee shall, in writing reasonably satisfactory to the non-assigning party and as a condition to the effectiveness of such assignment, expressly assume performance of such assigning Party's rights and obligations hereunder and unconditionally agree to the terms hereof. Any permitted assignment or transfer is binding on the successors of the assigning or transferring Party and shall inure to their benefit. Any assignment or transfer or attempted or purported assignment or transfer by either Party in violation of the terms of this Section 15.7 is null, void and of no legal effect.

15.8 **Waivers**. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

15.9 **Force Majeure**. Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder (excluding, in each case, the obligation to make payments when due) if such delay or nonperformance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, epidemics, pandemics, the spread of infectious diseases, quarantines, act of God or of the government of any country or of any local government, or by any other cause unavoidable or beyond the control of any Party hereto. In such event, such affected Party shall use Commercially Reasonable Efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto.

15.10 **Interpretation**. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections, Schedules or Exhibits mean the particular Articles, Sections, Schedules or Exhibits to this Agreement and references to this Agreement include all Exhibits and Schedules hereto. In the event of any conflict between the main body of this Agreement and any Exhibit or Schedule hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation"; (b) the word "day" or "year" means a calendar day or Calendar Year unless otherwise specified; (c) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (e) the words "shall" and "will" have interchangeable meanings for purposes of this Agreement; (f) provisions that require that a Party, the Parties or a committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; (j) the phrase "non-refundable" shall not prohibit, limit or restrict either Party's right to obtain damages in connection with a breach of this Agreement; (k) neither Party shall be deemed to be acting on behalf of the other Party; and (l) the words "gene editing" and "genome editing" have interchangeable meanings for purposes of this Agreement and do not include gene therapy activities (other than gene editing).

15.11 **Counterparts; Electronic Signatures**. This Agreement may be executed in any number of counterparts, each of which is deemed an original, but all of which together constitute one instrument. This Agreement may be executed and delivered electronically and upon such delivery such electronic signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

15.12 **Expenses**. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and execution of this Agreement.

15.13 **Further Assurances**. TGTX and Precision hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all documents and take any action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

15.14 **No Third Party Beneficiary Rights**. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

15.15 **Construction**. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

15.16 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

15.17 **Extension to Affiliates**. Except as expressly set forth otherwise in this Agreement, each Party shall have the right, subject to compliance with the applicable terms of this Agreement, to extend the rights and immunities granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement, except this right to extend, shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and immunities. For clarity, the Party extending the rights and immunities granted hereunder shall remain primarily liable for any acts or omissions of its Affiliates.

15.18 **TGTX Parent Guarantee**.

15.18.1 TGTX Parent hereby absolutely, unconditionally and irrevocably guarantees, jointly and severally, as a primary obligor and not merely as a surety, the due and timely payment and performance of all obligations (including payment obligations and other covenants) of TGTX and each of its Affiliates under this Agreement (the "***Parent Obligations***"). TGTX Parent agrees that (a) the Parent Obligations and this Agreement may be extended, modified or renewed, in whole or in part, without notice or further assent from TGTX Parent, and that TGTX Parent will remain bound upon its guarantee notwithstanding any extension, modification or renewal of any Parent Obligation or of this Agreement, any assumption of any such guaranteed Parent Obligation by any other party or any other act or event that might otherwise operate as a legal or equitable discharge of TGTX Parent under this Section 15.18, (b) TGTX Parent shall be bound by all of the terms and conditions of Article 12, Sections 14.1 and 14.4 – 14.6, and this Article 15 (and all of the definitions and capitalized terms contained therein) as if such Sections and Articles applied to TGTX Parent, and (c) so long as the Parent Obligations remain outstanding, TGTX Parent will operate in the ordinary course of business and not dispose of (by dividend, distribution, sale, transfer, or otherwise) all or substantially all of its assets other than to Affiliates that shall also agree in writing to become a guarantor of the Parent Obligations under the terms and conditions of this Section 15.18. TGTX Parent further agrees that its guarantee constitutes an absolute, unconditional and irrevocable guarantee of payment and performance when due (and not just of collection) and waives (y) any right to require that any resort be had by Precision to any other guarantee for any security held for payment or performance of the Parent Obligations and (z) any other circumstance which might otherwise constitute a defense to this guarantee. This guarantee is in no way conditioned upon any requirement that Precision first attempt to collect or enforce any guaranteed obligation from or against TGTX. NOTWITHSTANDING THE FOREGOING, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, ORAL, WRITTEN, EXPRESS, IMPLIED, OR OTHERWISE, IN CONNECTION WITH THIS GUARANTEE, AND EACH PARTY HEREBY DISCLAIMS, AND TGTX PARENT ACKNOWLEDGES AND AGREES TO THE DISCLAIMER BY THE PARTIES OF, ALL REPRESENTATIONS AND WARRANTIES IN CONNECTION WITH THIS GUARANTEE.

15.18.2 TGTX Parent represents and warrants that, as of the Effective Date:

(a) it is duly organized and validly existing under in the Applicable Laws of the jurisdiction of its incorporation or formation, as applicable, has full corporate, limited liability company or other power and authority, as applicable, to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate, limited liability company or other action, as applicable; and

(c) this Agreement is legally binding upon it and enforceable in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity) and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (i) conflict with, or constitute a default or result in a breach under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any Applicable Law; or (ii) require any consent or approval of its stockholders or similar.

[signature page follows]

In Witness Whereof, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

Precision BioSciences, Inc.

By: _____
Name: Michael Amoroso
Title: Chief Executive Officer

[Signature Page to License Agreement]

TG Cell Therapy, Inc.

By: _____
Name:
Title:

In Witness Whereof, TGTX Parent has caused this Agreement to be executed, with respect to Sections 8.14 and 15.18, as of the Effective Date by its duly authorized representative.

TG Therapeutics, Inc.

By: _____
Name:
Title:

Exhibit 1.85

Licensed ARCUS Nuclease
[Omitted]

[***]

Exhibit 10.2.2

Existing Patents
[Omitted]

[***]

Schedule 1.45

Patents within Duke IP as of the Effective Date
[Omitted]

[***]

Insider Trading Policy

I. PURPOSE

TG Therapeutics, Inc. (the "Company") has adopted this Insider Trading Policy (this "Policy") to help its Employees, Consultants, Officers, and Directors, comply with insider trading laws and to prevent the appearance of improper insider trading.

Insider trading laws prohibit a person from:

- using material nonpublic information to make decisions to purchase, sell, give away or otherwise trade the Company's securities,
- providing material nonpublic information to others outside the Company or recommending the purchase or sale of Company securities on the basis of such information (often referred to as "tipping"), or
- assisting someone who is engaged in any of the above activities.

The prohibition against insider trading applies to purchases, sales, tips and recommendations by anyone associated with the Company if the information involved is "material" and "nonpublic" ("Material Nonpublic Information") as defined below. The prohibition on insider trading applies irrespective of the volume of securities at issue.

This Policy is administered by the Chief Financial Officer, the Company's Insider Trading Compliance Officer ("Compliance Officer"). See Section V. for more details.

II. SCOPE

A. **Insiders**. This Policy applies to all Insiders, which includes:

- all Employees, Officers, and members of the Board of Directors (Directors) of the Company (collectively, "Company Personnel");
- family members and others living in the same household as Company Personnel;
- family members of Company Personnel whose transactions in Company securities are subject to the influence or control of Company Personnel;
- any corporations, partnerships, or other entities owned or controlled by the foregoing persons or any corporation in which such persons hold more than 20% of the equity or voting rights;
- any trust or estate over which Company Personnel have control or influence with respect to a transaction in securities (e.g., a trustee or an executor); and
- any Consultants and other third parties who have or may gain access to material nonpublic information concerning the Company.

B. **Transaction Types**. This Policy applies to any and all transactions in the Company's securities, including (unless specifically excluded herein) its common stock and options to purchase common stock. In addition, this Policy applies to any other type of securities that the Company may issue, including but not limited to preferred stock, convertible debentures, warrants and exchange-traded options or other derivative securities.

Transactions subject to this Policy include, but are not limited to:

- purchases,
- sales (including short-selling), whether in the open market or with the Company,
- transfers to anyone or any entity, with or without consideration,
- gifts,
- pledging of shares of options,
- granting of an option to acquire an Insider's interest in Company securities, and
- certain elections made under the Company's 401K plan, if applicable.

III. DEFINITION OF "MATERIAL NONPUBLIC INFORMATION"

A. "Material" Information. Material information is any type of information that could reasonably be expected to affect the price of Company securities, beyond normal daily fluctuations. There is no bright-line rule as to what constitutes "Material" information. Generally speaking, information about the Company is Material if there is a substantial likelihood that a reasonable stockholder would consider the information important in making a decision whether or not to buy or sell the Company's securities, or, stated another way, if the disclosure of the information would be expected to significantly alter the total mix of the information about the Company in the marketplace, the information would be considered Material.

While it is not possible to identify all information that would be deemed Material, the following types of information ordinarily would be considered Material:

- Financial performance, including quarterly and year-end earnings, and significant changes in financial performance or liquidity;
- Company projections and strategic plans;
- Clinical results or presentations of the Company's drug candidates;
- Potential mergers and acquisitions or the sale of Company assets or subsidiaries;
- Partnership agreements for the Company's clinical-stage drug candidates;
- New major contracts, order, suppliers, customer, or finance sources, or the loss thereof;
- Major discoveries or significant changes or developments in products or product lines, clinical trial results, research or technologies;
- Significant changes or developments in supplies or inventory, including significant product defects, recalls or product returns;
- Significant pricing changes;
- Stock splits, public or private securities/debt offerings, or changes in Company dividend policies or amounts;
- Transactions in the Company's securities by the Company's Section 16 Officers and Directors, until such time as the transactions are publicly filed with the Securities and Exchange Commission (SEC);
- Significant changes in senior management;
- Significant labor disputes or negotiations;
- Actual or threatened major litigation or the resolution of such litigation; and
- Content of material formal Food and Drug Administration responses to the Company.

It is important to remember that whether information is Material will be viewed by enforcement authorities with the benefit of hindsight.

B. "Nonpublic" Information. Material information is "Nonpublic" if it has not been widely disseminated to the public in a manner that makes it generally available to investors, including, without limitation, through major newswire services, national news services and financial news services or the filing of public documents as required with the SEC. For the purposes of this Policy, information will be considered public, i.e., no longer Nonpublic, after the close of trading on the second full trading day following the Company's widespread public release of the information.

C. Consult with the Compliance Officer for Guidance. Any Insider who is unsure whether the information that he or she possesses is Material Nonpublic Information should consult the Compliance Officer for guidance before seeking pre-clearance to trade in Company securities.

IV. STATEMENT OF COMPANY POLICY AND PROCEDURES

A. Prohibited Activities For All Insiders:

i. Trading in Company Securities. No Insider may buy, sell, or otherwise trade in Company securities while possessing Material Nonpublic Information concerning the Company. In addition, no Insider may buy, sell, or otherwise trade in Company securities unless the trade(s) have been pre-approved in accordance with the procedures set forth in Section IV.B., below.

ii. Tipping. No Insider may "tip" or disclose Material Nonpublic Information concerning the Company to any person unless required as part of that Insider's regular duties for the Company. In any instance in which such information is disclosed to outsiders, the Company shall take such steps as are necessary to preserve the confidentiality of the information, including requiring the outsider to agree in writing to comply with the terms of this Policy and/or to sign a confidentiality agreement. All inquiries from outsiders regarding Material Nonpublic Information about the Company must be forwarded to Investor Relations.

iii. Giving Trading Advice. No Insider may give trading advice of any kind about the Company to anyone while possessing Material Nonpublic Information about the Company, except that Insiders should advise others not to trade if they have knowledge that doing so might violate the law or this Policy. The Company strongly discourages all Insiders from giving trading advice concerning the Company to third parties even when the Insiders do not possess Material Nonpublic Information about the Company.

iv. Engaging in Short Sales. No Insider may trade in any interest or position relating to the future price of Company securities, such as a put, call or short sale.

v. Trading in Securities of Other Companies. No Insider, while in the possession of Material Nonpublic Information about any other public company gained during the course of employment with the Company, may (a) trade in securities of the other Company, (b) "tip" or disclose such Material Nonpublic Information concerning that company to anyone, or (c) give trading advice of any kind to anyone concerning the other public company.

B. Procedures for Approving Insider Trades. Regardless of the proposed timing or type of trade, no Insider may trade in Company securities until:

- The person trading has notified the Compliance Officer in writing of the amount and nature of the proposed trade(s) by submitting a Notification of Proposed Trade form (see Appendix A);
- The person trading has certified to the Compliance Officer in writing at the time of such proposed trade(s) that (i) he or she is not in possession of Material Nonpublic Information concerning the Company and (ii) the proposed trade(s) do not violate the trading restrictions of Section 16 of the Exchange Act or Rule 144 of the Securities Act;
- The Compliance Officer has approved the trade and has certified such approval in writing (including by email); and
- The person trading has provided the Compliance Officer any other documentation reasonably requested by the Compliance Officer in furtherance of the foregoing procedures. Any failure to provide such requested information may be grounds for denial of a Notification of Proposed Trade by the Compliance Officer.

C. Period to Trade Upon Receipt of Approval. After receiving written or electronic approval to engage in a trade from the Compliance Officer, the person trading must complete the proposed trade within five (5) business days of receipt of approval ("Authorization Period"), unless an exception is granted. Transactions not effected within the time limit will be subject to Compliance Officer approval again. If the person trading becomes aware of Material Nonpublic Information after Compliance Officer approval but before the trade is executed, the approval is void and the trade must not be completed.

D. **Blackout Period.** The period beginning with the 15th day of the last calendar month of each quarter and ending two (2) Trading Days following the date of public disclosure of the financial results for that quarter (the "Blackout Period") is a particularly sensitive period of time for Company stock transactions from the perspective of compliance with applicable securities laws. This sensitivity is due to the fact that Officers, Directors and certain other Employees and Consultants will, during that period, often possess Material Nonpublic Information about the expected financial results for the quarter.

Except as set forth in Section IV.F. (Trades Made Pursuant to Rule 10b5-1 Plans), the following Company Personnel may not trade in Company Securities during a Blackout Period, and this restriction will not be waived:

- Directors;
- Officers;
- Vice Presidents and above (all functions); and
- All members of the following functions:
  - Finance
  - Commercial Operations
  - Marketing for Approved Products
  - Market Access

The Blackout Periods are as follows:

- From March 15 until the end of the second full trading day following public announcement of first quarter financial results;
- From June 15 until the end of the second trading full day following public announcement of second quarter financial results;
- From September 15 until the end of the second full trading day following public announcement of third quarter financial results; and
- From December 15 until the end of the second full trading day following public announcement of fourth quarter and year-end financial results.

E. **Special Blackout Periods.** Company business may necessitate a blackout period at points in time other than the above (such as for negotiation of mergers, acquisitions or licensing agreements, clinical trial results, manufacturing and supply, which may not be publicly disclosed). While such Material Nonpublic Information is pending disclosure, the Compliance Officer, in consultation with Company Management, may designate special blackout periods ("Special Blackout Periods") during which trading in Company securities by certain Insiders (who the Compliance Officer may designate as subject to a Special Blackout Period because of their position, responsibilities, or their actual or potential access to Material Nonpublic Information) is prohibited. If the Company imposes a Special Blackout Period, the Compliance Officer will notify the Insiders affected in writing. No Notification of Proposed Trade Forms will be approved during the Special Blackout Period.

An Insider may not disclose to any outside third party that a Special Blackout Period has been designated.

F. **Trades Made Pursuant to Rule 10b5-1 Plans.**

i. General Information: Under Rule 10b5-1 of the Securities Exchange Act, an individual has an affirmative defense against an allegation of insider trading if he or she demonstrates that the purchase, sale or trade in question took place pursuant to a binding contract, specific instruction or written plan that was put into place before he or she became aware of Material Nonpublic Information. Such plans are commonly referred to as Rule 10b5-1 Plans.

Rule 10b5-1 Plans require advance commitments that may impact the amounts, prices, or timing of purchases or sales of Company securities. Accordingly, while Rule 10b5-1 Plans have the advantage of protecting against insider trading liability, they limit flexibility and discretion and may not be suitable for all Insiders.

The availability of a Rule 10b5-1 Plan does not in any way obligate the Compliance Officer to approve any Rule 10b5-1 Plans proposed by Insiders. The Compliance Officer may reject any proposed 10b5-1 Plans at his or her sole reasonable discretion.

ii. Specific Requirements: For a Rule 10b5-1 Plan to serve as an affirmative defense to insider trading liability, it must meet the following specific requirements:

- *Preapproval* - The Compliance Officer must pre-approve any Rule 10b5-1 Plan prior to its effectiveness. Preapproval is also required for any modifications to an existing Rule 10b5-1 Plan;

- *Material Nonpublic Information and Blackouts* -The individual desiring to enter into a Rule 10b5-1 Plan must do so at a time when he or she is not aware of any Material Nonpublic Information or is otherwise subject to a Blackout Period or Special Blackout Period. Further, no modifications to an existing Rule 10b5-1 Plan may be made while the individual is aware of any Material Nonpublic Information or is otherwise subject to a Blackout Period or Special Blackout Period;

- *30-day Waiting Period* – The date of the first possible transaction under an approved Rule 10b5-1 Plan may not happen until 30 days after the date the Rule 10b5-1 Plan is approved and becomes effective. A 30-day waiting period is also required following the date of approval of any modifications to an existing 10b5-1 Plan; and

- *Filing of SEC Forms* – The Compliance Officer must ensure that a procedure is in place for guaranteeing prompt filings of Forms 4, 5, and 144 with the SEC for Rule 10b5-1 Plans established by Officers or Directors.

G. Exceptions to Trading Prohibitions. The prohibition on trading in Company securities during Blackout Periods, during SpecialBlackout Periods, or while otherwise in possession of Material Nonpublic Information does not apply to:

- purchases made under an Employee stock purchase plan operated by the Company; provided, however, that the securities so acquired may not be sold during a Blackout Period or any Special Blackout Period;

- exercises of stock options or the surrender of shares to the Company in payment of the exercise price or in satisfaction of any tax withholding obligation, in each case in a manner permitted by the applicable stock option; provided, however, that the securities so acquired may not be sold (either outright or in connection with a "cashless" exercise transaction through a broker) during a Blackout Period or Special Blackout Period or, if outside a Blackout Period or Special Blackout Period, without receiving the approval of the Compliance Officer;

- automatic sales of shares of the Company's common stock through a Company- contracted service provider or broker to cover any taxes due as a result of the vesting of restricted stock or restricted stock units, where the amount of shares sold is based on the Insider's taxable income, the market price of the common stock on the date that the restricted stock or restricted stock units vest (the "Vesting Date") and the market price on the date of the sale, which date shall be as soon as possible after the Vesting Date;

- acquisitions or dispositions of Company common stock under the Company's 401(k) plan, which are made pursuant to standing instructions not entered into or modified during a Blackout Period or Special Blackout Period or while otherwise in possession of Material Nonpublic Information; and

- purchases or sales made pursuant to a Rule 10b5-1 Plan.

H. Priority of Statutory or Regulatory Trading Restrictions. The trading prohibitions and restrictions set forth in this Policy will be superseded by any greater prohibitions or restrictions prescribed by federal or state securities laws and regulations. Any Insider who is uncertain whether other prohibitions or restrictions apply should ask the Compliance Officer.

V. INSIDER TRADING COMPLIANCE OFFICER

A. Responsibilities. The Company has designated the Chief Financial Officer, as its Insider Trading Compliance Officer (the "Compliance Officer") responsible for ensuring compliance with this Policy. In addition to the trading approval duties described in Section IV.B., the duties of the Compliance Officer will also include:

- administering this Policy and monitoring and enforcing compliance with all Policy provisions and procedures;

- responding to all inquiries relating to this Policy and its procedures;

- designating Special Blackout Periods, in consultation with the General Counsel and Chief Executive Officer and announcing such periods, as defined below;

- providing copies of this Policy and other appropriate materials to all current and new directors, officers and employees, and such Outsiders who the Compliance Officer determines have or may gain access to Material Nonpublic Information concerning the Company;

- administering, monitoring and enforcing compliance with all federal and state insider trading laws and regulations, including without limitation Sections 10(b), 15, 20A and 21A of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations promulgated thereunder, and Rule 144 under the Securities Act of 1933 (the "Securities Act") and related regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA") or The Nasdaq Stock Market Inc. ("Nasdaq"); and assisting in the preparation and filing of all reports required to be filed by the Company under the Exchange Act relating to insider trading in the Company's securities, including without limitation Forms 3, 4, 5 and 144 and Schedules 13D and 13G ("SEC Reports");

- revising the Policy as necessary to reflect changes in federal or state insider trading laws and regulations or the regulations of FINRA or Nasdaq; and

- maintaining as Company records originals or copies of all documents required by the provisions of this Policy or the procedures set forth herein, and copies of all SEC Reports.

The Compliance Officer may designate one or more individuals who may perform the Compliance Officer's duties in the event that the Compliance Officer is unable or unavailable to perform such duties.

B. **Compliance Officer Trades.** If the Compliance Officer desires to complete any trades involving Company securities, he or she must first obtain the approval of the Chief Executive Officer of the Company in accordance with the requirements outlined in this Policy.

VI. POTENTIAL CIVIL, CRIMINAL AND DISCIPLINARY SANCTIONS

A. **Civil and Criminal Penalties.** The consequences of prohibited insider trading or tipping can be severe and can include significant fines and imprisonment. The Company and/or the supervisors of the person violating the rules may also face major civil and/or criminal penalties.

B. **Company Discipline.** Violation of this Policy or federal or state insider trading or tipping laws by any director, officer or employee, or other Insider, may subject the director to dismissal proceedings and the officer or employee to disciplinary action by the Company up to and including termination for cause.

C. **Reporting of Violations.** Any Insider who violates this Policy or any federal or state laws governing insider trading or tipping, or knows of such violation by any other Insiders, must report the violation immediately to the Compliance Officer. Upon learning of any such violation, the Compliance Officer, in consultation with the Company's legal counsel, will determine whether the Company should release any Material Nonpublic Information, or whether the Company should report the violation to the SEC, Nasdaq, or other appropriate governmental authority.

VII. ADDITIONAL INFORMATION APPLICABLE TO SECTION 16 OFFICERS AND DIRECTORS.

Officers and Directors of the Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Exchange Act ("Section 16"). Section 16 Officers and Directors must notify the Compliance Officer, by email and/or facsimile transmission, promptly upon the execution of such trade, but in no event later than next business day after the execution of such trade. Such notice shall include all relevant details of such trade, including, but not limited to:

- the name of the entity in whose name the trade was made;
- the type and amount of securities subject to the trade;
- the price at which the securities were traded; and
- the new number of securities owned, directly or indirectly, by the Insider subsequent to the execution of the trade.

The Company has provided, or will provide, separate materials to its Section 16 officers and directors regarding compliance with Section 16 and its related rules.

VIII. INQUIRIES.

Please direct all inquiries regarding this policy to the Compliance Officer.

Notification of Proposed Trade

Section 1: Notification			
From: (Name of Insider)		Date:	

(Please fill out that which is applicable)

I hereby notify you of my intent to trade in securities of TG Therapeutics, Inc. (the "Company"). The amount and nature of the proposed trade is as follows:

- Sell in the open market _____ shares of Company Common Stock currently held at _____ (e.g., Fidelity).
- Exercise _____ non-qualified stock options granted by the Company on _____.
- Purchase in the open market _____ shares of Company Common Stock.
- Gift shares of Company Common Stock to ; or
- Adopt a Rule 10b5-1 Plan as set forth in the Company's Insider Trading Policy (please submit the proposed Plan with this request).

Section 2: Certification

In connection with this proposed trade, I hereby certify that:

1. I am not in possession of any Material Nonpublic Information concerning the Company, as defined in the Company's Insider Trading Policy (the "Policy").

2. To the best of my knowledge, the proposed trade does not violate the trading restrictions of Section 16 of the Securities Exchange Act of 1934, as amended, or Rule 144 of the Securities Act of 1933, as amended.

I understand that if I trade while possessing Material Nonpublic Information or in violation of the above trading restrictions, including during the Authorization Period (as defined below and in the Policy), I may be subject to severe civil and/or criminal penalties, and may be subject to sanctions by the Company as set forth in the Policy. Furthermore, I understand that I am not authorized to trade in Company securities or adopt a Rule 10b5-1 Plan in reliance upon this Notice until the Compliance Officer has approved it. Following approval by the Compliance Officer, authorization to trade pursuant to the Notice will continue for five (5) business days following the date of the Compliance Officer's approval ("Authorization Period"). I understand that if I have not completed by proposed trade or adopted by Rule 10b5-1 Plan by the last date of the Authorization Period, I must submit a new Notice of Proposed Trade in order to trade in Company securities or adopt a Rule 10b5-1 Plan.

Signature of Insider: _____	Date:

Section 2: Insider Trading Compliance Officer (or Designee) Approval	
Name	
Title	

Signature of Insider Trading Compliance Officer (or Designee): _____	Date:

Exhibit 21.1

Subsidiaries of TG Therapeutics, Inc.

Ariston Pharmaceuticals, Inc.

TG Biologics, Inc.

TG Therapeutics AUS Pty Ltd

TG Cell Therapy, Inc.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-265838) on Form S-8 and registration statement (No. 333-267262) on Form S-3ASR of our reports dated February 29, 2024, with respect to the consolidated financial statements of TG Therapeutics, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

New York, New York
February 29, 2024

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Weiss, certify that:

1. I have reviewed this annual report on Form 10-K of TG Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 29, 2024

/s/ Michael S. Weiss
Michael S. Weiss
Chairman, Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean A. Power, certify that:

1. I have reviewed this annual report on Form 10-K of TG Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 29, 2024

/s/ Sean A. Power
Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF

TG THERAPEUTICS, INC.

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of TG Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Chairman, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 29, 2024

/s/ Michael S. Weiss
Michael S. Weiss
Chairman, Chief Executive Officer and President

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF

TG THERAPEUTICS, INC.

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of TG Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Sean A. Power, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 29, 2024

/s/ Sean A. Power
Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer

TG Therapeutics, Inc.
Incentive Compensation Recovery Policy

1.0 General.

1.1 TG Therapeutics, Inc. (the "Company") has adopted this Policy in accordance with the applicable listing standards of Nasdaq and Rule 10D-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which require listed companies to adopt and comply with a compensation recovery policy. To the extent this Policy is in any manner deemed inconsistent with such listing standards, this Policy shall be treated as retroactively amended to be compliant with such listing standard.

1.2 The effective date of this Policy is October 2, 2023 (the "Effective Date").

2.0 Definitions. The following words and phrases shall have the following meanings for purposes of this Policy:

2.1 Accounting Restatement. An "Accounting Restatement" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

2.2 Board. The "Board" means the Board of Directors of the Company.

2.3 Compensation Committee. The "Compensation Committee" means the Compensation Committee of the Board.

2.4 Erroneously Awarded Compensation. "Erroneously Awarded Compensation" is the amount of Incentive-Based Compensation Received that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid. For Incentive-Based Compensation based on stock price or TSR, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement: (i) the amount shall be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive-Based Compensation was Received, and (ii) the Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq.

2.5 Executive Officer. The term "Executive Officer" means the executive officers identified by the Company in the Company's filings with the SEC pursuant to Item 401(b) of Regulation S-K and the officers required to file reports under Section 16 of the Exchange Act.

2.6 Financial Reporting Measure. A "Financial Reporting Measure" is any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure. Stock price and TSR (and any measures that are derived wholly or in part from stock price and TSR) are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the SEC.

2.7 Incentive-Based Compensation. The term "Incentive-Based Compensation" means any compensation (whether cash-based or equity-based) that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Please refer to Appendix A to this Policy for a list of examples of Incentive-Based Compensation.

2.8 Nasdaq. "Nasdaq" means the Nasdaq Capital Market. In the event the Company's securities become listed on a different national securities exchange or national securities association in the future, then following such new listing, references to Nasdaq shall be deemed to refer to such other national securities exchange or national securities association.

2.9 Policy. "Policy" means this Incentive Compensation Recovery Policy.

2.10 Received. Incentive-Based Compensation is deemed "Received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, Incentive-Based Compensation that is subject both to one or more Financial Reporting Measures and to a service-based vesting condition shall be considered to be "Received" when the relevant Financial Reporting Measures are achieved, even if the Incentive-Based Compensation continues to be subject to the service-based vesting condition.

2.11 SEC. "SEC" means the United States Securities and Exchange Commission.

2.12 TSR. "TSR" means total stockholder return.

3.0 Statement of Policy.

3.1 In the event that the Company is required to prepare an Accounting Restatement, the Company will recover reasonably promptly the amount of all Erroneously Awarded Compensation Received by a person:

i. After beginning service as an Executive Officer;

ii. Who served as an Executive Officer at any time during the performance period for that Incentive-Based Compensation;

iii. While the Company has a class of securities listed on Nasdaq; and

iv. During the three completed fiscal years immediately preceding the date that the Company is required to prepare the Accounting Restatement and any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years. For purposes of this Policy, a transition period between the last day of the Company's previous fiscal year and the first day of its new fiscal year that comprises a period of nine to twelve months would be deemed a completed fiscal year.

Notwithstanding the foregoing, this Policy shall only apply to Incentive-Based Compensation Received on or after the Effective Date.

3.2 The Company's obligation to recover Erroneously Awarded Compensation pursuant to this Policy is not dependent on when the restated financial statements are filed.

3.3 For purposes of determining the relevant recovery period under this Policy, the date that the Company is required to prepare an Accounting Restatement is the earliest to occur of: (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

3.4 The Company must recover Erroneously Awarded Compensation in compliance with this Policy except to the extent that the conditions of paragraphs (i), (ii) or (iii) in this Section 3.4 are met, and the Compensation Committee, or in the absence of such a committee, a majority of the independent directors serving on the Board, has determined that recovery would be impracticable.

i. The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to Nasdaq.

ii. Recovery would violate home country law where that law was adopted prior to November 28, 2022. Before concluding that it would be impractical to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation, and provide such opinion to Nasdaq.

iii. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

3.5 The Company shall not indemnify any Executive Officer or former Executive Officer against (i) the loss of Erroneously Awarded Compensation pursuant to this Policy, or (ii) any claims relating to the Company's enforcement of its rights under this Policy. Similarly, the Company shall not adopt or enter into any plan or agreement that exempts any Incentive-Based Compensation that is granted, paid or awarded to an Executive Officer or former Executive Officer from the application of this Policy. This Policy shall supersede any such plan or agreement, whether entered into before, on or after the Effective Date of this Policy. In addition, the Company shall not reimburse any Executive Officer or former Executive Officer for premiums on, or otherwise subsidize or pay for, an insurance policy that would cover such person's potential clawback obligations under this Policy.

3.6 The Compensation Committee shall determine, in its sole discretion, the appropriate means to seek recovery of any Erroneously Awarded Compensation, which may include, without limitation: (i) requiring cash reimbursement; (ii) seeking recovery or forfeiture of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of equity-based awards; (iii) offsetting the amount to be recouped from any compensation otherwise owed by the Company to the Executive Officer or former Executive Officer; (iv) cancelling outstanding vested or unvested equity awards; or (v) taking any other remedial and recovery action permitted by law, as determined by the Compensation Committee.

3.7 The Compensation Committee shall determine the repayment schedule for any Erroneously Awarded Compensation in a manner that complies with the "reasonably prompt" requirement set forth in Subsection 3.1. The determination with respect to "reasonably prompt" recovery may vary from case to case, and the Compensation Committee may amend or supplement this Policy to further describe what repayment schedule satisfies this requirement.

3.8 The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the U.S. Federal securities laws, including the disclosure required by the applicable SEC filings.

4.0 Application to Additional Persons.

4.1 In addition to the Executive Officers and former Executive Officers, this Policy shall apply to any other employee of the Company or its parent or subsidiaries designated by the Compensation Committee as a person covered by this Policy (each, an "Other Covered Person").

4.2 Unless otherwise determined by the Compensation Committee, this Policy shall apply to an Other Covered Person as if such individual was an Executive Officer during the relevant periods described in Section 3.0.

4.3 Notwithstanding the foregoing, the Compensation Committee may, in its discretion, limit recovery of Erroneously Awarded Compensation from an Other Covered Person to situations in which an Accounting Restatement was caused or contributed to by the Other Covered Person's fraud, willful misconduct or gross negligence.

4.4 In addition, the Compensation Committee shall have discretion as to (i) whether to seek to recover Erroneously Awarded Compensation from an Other Covered Person, (ii) the amount of the Erroneously Awarded Compensation to be recovered from an Other Covered Person, and (iii) the method of recovering any such Erroneously Awarded Compensation from an Other Covered Person. In exercising such discretion, the Compensation Committee may take into account such considerations as it deems appropriate, including whether the assertion of a claim may violate applicable law or prejudice the interests of the Company in any related proceeding or investigation.

5.0 Interpretation; Enforcement

5.1 The Compensation Committee shall have full authority to interpret and enforce this Policy to the fullest extent permitted by law.

5.2 Any determination by the Compensation Committee with respect to this Policy shall be final, conclusive, and binding on all interested parties.

5.3 To the extent an Executive Officer, former Executive Officer or Other Covered Person refuses to pay to the Company any Erroneously Awarded Compensation, the Company shall have the right to sue for repayment or, to the extent legally permitted, to enforce such person's obligation to make payment by withholding unpaid or future compensation.

6.0 Non-Exclusivity

6.1 The Company's rights to recoupment under this Policy are in addition to other rights the Company may have against any Executive Officer, former Executive Officer or Other Covered Person, including any remedies at law or in equity. Application of this Policy does not preclude the Company from taking other actions to enforce the obligations of an Executive Officer, former Executive Officer or Other Covered Person to the Company, including termination of employment or institution of legal proceedings. Nothing in this Policy shall be viewed as limiting the right of the Company or the Compensation Committee to pursue recoupment under or as provided by the Company's plans, awards, policies or agreements or the applicable provisions of any law, rule or regulation (including, without limitation, Section 304 of the Sarbanes-Oxley Act of 2002).

6.2 If the requirement to recover Erroneously Awarded Compensation is triggered under this Policy, then, in the event of any actual or alleged conflict between the provisions of this Policy and a similar clause or provision in any of the Company's plans, awards, policies or agreements, this Policy shall be controlling and determinative; provided that, if such other plan, award, policy or agreement provides that a greater amount of compensation shall be subject to clawback, the provisions of such other plan, award, policy or agreement shall apply to the amount in excess of the amount subject to clawback under this Policy.

7.0 Amendment

7.1 The Compensation Committee may amend this Policy, provided that any such amendment does not cause this Policy to violate applicable listing standards of Nasdaq or Rule 10D-1 under the Exchange Act.

APPENDIX A

Examples of Incentive-Based Compensation

Examples of compensation that constitutes Incentive-Based Compensation for purposes of this Policy include, but are not limited to, the following:

- Non-equity incentive plan awards earned based wholly or in part on satisfying a Financial Reporting Measure performance goal;
- Bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal;
- Other cash awards based wholly or in part on satisfying a Financial Reporting Measure performance goal;
- Equity-based awards (e.g., restricted stock, restricted stock units, performance share units, stock options, and stock appreciation rights) that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure performance goal; and
- Proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure performance goal.

Examples of compensation that does not constitute Incentive-Based Compensation for purposes of this Policy include the following:

- Salaries or salary increases for which the increase is not contingent upon the attainment of a Financial Reporting Measure performance goal;
- Bonuses paid solely at the discretion of the Compensation Committee or Board that are not paid from a bonus pool, the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal;
- Bonuses paid solely upon satisfying one or more subjective standards (e.g., demonstrated leadership) and/or completion of a specified employment period;
- Non-equity incentive plan awards earned solely upon satisfying one or more strategic measures (e.g., consummating a merger or divestiture) or operational measures (e.g., opening a specified number of business locations, completion of a project, or increase in market share); and
- Equity awards for which the grant is not contingent upon achieving any Financial Reporting Measure performance goal and vesting is contingent solely upon completion of a specified employment period and/or attaining one or more non-Financial Reporting Measures.