UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2018

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 000-30929

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address including zip code of principal executive offices)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).
☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition 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 ☐ (Do not check if smaller reporting company)	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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

There were 82,818,608 shares of the registrant’s common stock, $0.001 par value, outstanding as of August 3, 2018.

TG THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2018

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “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, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the 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. The words "anticipate," "believe," "estimate," "may," "expect," “plan,” “intend” and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- use of clinical research centers and other contractors;
- expectations as to the timing of commencing or completing pre-clinical and clinical trials and the expected outcomes of those trials;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- expectations for the acceptance of our products by doctors, patients or payors;
- ability to compete against other companies and research institutions;
- ability to secure adequate protection for our intellectual property;
- ability to attract and retain key personnel;
- abilit yto obtain reimbursement for our products;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- stock price volatility; and
- expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements 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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TG Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2018 (Unaudited)	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 105,672	$ 56,718
Short-term investment securities	20,573	27,999
Interest receivable	87	108
Prepaid research and development	8,890	8,056
Other current assets	816	437
Total current assets	136,038	93,318
Restricted cash	1,237	587
Leasehold interest, net	2,376	2,429
Equipment, net	265	248
Goodwill	799	799
Total assets	$ 140,715	$ 97,381
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 35,394	$ 25,877
Accrued compensation	1,182	1,800
Current portion of deferred revenue	152	152
Notes payable	210	128
Total current liabilities	36,938	27,957
Deferred rent	1,411	1,364
Deferred revenue, net of current portion	990	1,067
Total liabilities	39,339	30,388
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of June 30, 2018 and December 31, 2017)	--	--
Common stock, $0.001 par value per share (150,000,000 shares authorized, 82,539,417 and 73,181,750 shares issued, 82,498,108 and 73,140,441 shares outstanding at June 30, 2018 and December 31, 2017, respectively)	82	73
Additional paid-in capital	542,062	422,017
Treasury stock, at cost, 41,309 shares at June 30, 2018 and December 31, 2017	(234)	(234)
Accumulated deficit	(440,534)	(354,863)
Total stockholders' equity	101,376	66,993
Total liabilities and stockholders' equity	$ 140,715	$ 97,381

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

TG Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2018	**2017**	**2018**	**2017**
License revenue	$ 38	$ 38	$ 76	$ 76
Costs and expenses:				
Research and development:				
Non-cash stock expense associated with in–licensing agreements	3,000	-	4,000	-
Noncash compensation	888	1,266	3,747	3,573
Other research and development	34,812	25,440	65,971	45,815
Total research and development	38,700	26,706	73,718	49,388
General and administrative:				
Noncash compensation	3,375	223	7,854	3,913
Other general and administrative	2,308	1,534	4,426	2,867
Total general and administrative	5,683	1,757	12,280	6,780
Total costs and expenses	44,383	28,463	85,998	56,168
Operating loss	(44,345)	(28,425)	(85,922)	(56,092)
Other (income) expense:				
Interest income	(189)	(50)	(333)	(95)
Other (income) expense	(14)	(22)	82	84
Total other income, net	(203)	(72)	(251)	(11)
Net loss	$ (44,142)	$ (28,353)	$ (85,671)	$ (56,081)
Basic and diluted net loss per common share	$ (0.59)	$ (0.45)	$ (1.18)	$ (0.96)
Weighted average shares used in computing basic and diluted net loss per common share	74,256,348	63,288,269	72,456,657	58,251,045

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

TG Therapeutics, Inc.
Condensed Consolidated Statement of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock			Treasury Stock			
	Shares	Amount	Additional paid-in capital	Shares	Amount	Accumulated Deficit	Total
Balance at January 1, 2018	73,181,750	$ 73	$ 422,017	41,309	$ (234)	$ (354,863)	$ 66,993
Issuance of restricted stock	1,420,511	1	(1)	--	--	--	--
Forfeiture of restricted stock	(130,661)	*	*	--	--	--	--
Issuance of common stock in At-the-Market offerings (net of offering costs of $1.9 million)	7,733,949	8	104,445	--	--	--	104,453
Compensation in respect of restricted stock granted to employees, directors and consultants	--	--	11,601	--	--	--	11,601
Shares issued in connection with in-licensing agreements	333,868	*	4,000				4,000
Net loss	--	--	--	--	--	(85,671)	(85,671)
Balance at June 30, 2018	82,539,417	$ 82	$ 542,062	41,309	$ (234)	$ (440,534)	$ 101,376

** Amount less than one thousand dollars.*

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

TG Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Six months ended June 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (85,671)	$ (56,081)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash stock compensation expense	11,601	7,485
Noncash licensing expense	4,000	--
Depreciation	41	41
Amortization of premium on investment securities	(9)	45
Change in fair value of notes payable	82	84
Changes in assets and liabilities:		
Increase in other current assets	(1,213)	(4,252)
Decrease in leasehold interest	53	75
Decrease in accrued interest receivable	22	41
Decrease in other assets	--	395
Increase in accounts payable and accrued expenses	8,898	3,068
Increase in deferred rent	46	45
Decrease in deferred revenue	(76)	(76)
Net cash used in operating activities	(62,226)	(49,130)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(58)	(2)
Investment in held-to-maturity securities	(6,965)	--
Proceeds from maturity of short-term securities	14,400	11,000
Net cash provided by investing activities	7,377	10,998
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the exercise of warrants	--	2,143
Proceeds from sale of common stock, net	104,453	88,562
Net cash provided by financing activities	104,453	90,705
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	49,604	52,573
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	57,305	25,614
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 106,909	$ 78,187
Reconciliation to amounts on consolidated balance sheets:		
Cash and cash equivalents	$ 105,672	$ 77,602
Restricted Cash	1,237	585
Total cash, cash equivalents and restricted cash	$ 106,909	$ 78,187
NONCASH TRANSACTIONS		
Accrued financing cost	$ --	$ 234
Reclassification of deferred financing costs to additional paid-in capital	$ --	$ (3)

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

Unless the context requires otherwise, references in this report to "TG," the "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

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, we have recently brought our anti-PD-L1 monoclonal antibody into Phase 1 development and aim to bring additional pipeline assets into the clinic in the future.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Quarterly Report on Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the condensed consolidated financial statements have been included. Nevertheless, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2017. The accompanying condensed consolidated December 31, 2017 balance sheet has been derived from these statements. The results of operations for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Certain reclassifications have been made to the prior period unaudited condensed consolidated financial statements to conform to the current period presentation, including:

- Presentation of restricted cash on the condensed consolidated statements of cash flows for the six months ended June 30, 2017, as a result of the adoption of Accounting Standards Update No. 2016-18 in the first quarter of 2018.

Liquidity and Capital Resources

We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and, may never become profitable. As of June 30, 2018, we have an accumulated deficit of approximately $440.5 million.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on many factors, including our ability to obtain regulatory approval for our drug candidates; successfully completing any post-approval regulatory obligations; and successfully commercializing our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of June 30, 2018, we had approximately $126.3 million in cash, cash equivalents, investment securities, and interest receivable. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of June 30, 2018 combined with the proceeds raised subsequent to the quarter end will be sufficient to fund the Company's planned operations into the fourth quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current strategic plan, including the commercialization of any of our drug candidates (see Note 5 for further details).

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

Recently Issued Accounting Standards

In July 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (“ASU”) No. 2018-11, “Leases - Targeted Improvements” (“ASU 2018-11”) as an update to ASU 2016-02, Leases (“ASU 2016-02” or “Topic 842”) issued on February 25, 2016. ASU 2016-02 is effective for public business entities for fiscal years beginning January 1, 2019. ASU 2016-02 required companies to adopt the new leases standard at the beginning of the earliest period presented in the financial statements, which is January 1, 2017, using a modified retrospective transition method where lessees must recognize lease assets and liabilities for all leases even though those leases may have expired before the effective date of January 1, 2017. Lessees must also provide the new and enhanced disclosures for each period presented, including the comparative periods.

ASU 2018-11 provides an entity with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity’s reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases). An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments do not change the existing disclosure requirements in Topic 840. An entity shall apply the effects of modification using one of the following two methods:

- Retrospectively to each prior reporting period presented in the financial statements with the cumulative effect of initially applying ASU 2018-11 recognized at the beginning of the earliest comparative period presented. Under this transition method, the application date shall be the later of the beginning of the earliest period presented in the financial statements and the commencement date of the lease.

- Retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. Under this transition method, the application date shall be the beginning of the reporting period in which the entity first applies ASU 2018-11.

ASU 2018-11 is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier adoption permitted. We are currently evaluating the impact the adoption of ASU 2018-11 will have on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, “Improvements to Nonemployee Share-Based Payment Accounting” (“ASU 2018-07”). ASU 2018-07 expands the scope of FASB Topic 718, Compensation – Stock Compensation (“Topic 718”) to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. Disclosures required at transition include the nature of and reason for the change in accounting principle and, if applicable, quantitative information about the cumulative effect of the change on retained earnings or other components of equity.

ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. We are currently evaluating the impact the adoption of ASU 2018-07 will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, “Scope of Modification Accounting” (“ASU 2017-09”). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

- The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

- The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

- The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In January 2017, the FASB issued ASU No. 2017-01, “FASB Clarifies the Definition of a Business” (“ASU 2017-01”). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

- Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.

- Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.

- Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of ASU 2017-01 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In November 2016, the FASB issued ASU No. 2016-18, “Statement of Cash Flows – Restricted Cash” (“ASU 2016-18”). ASU 2016-18 requires that a statement of cash flows explain the change during the period for the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 does not provide a definition of restricted cash or restricted cash equivalents, and does not change the balance sheet presentation for such items. The Company adopted ASU 2016-18 on January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers” (Topic 606) (“ASU 2014-09” or “ASC 606”), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity’s promise to the customer. To determine whether the entity’s promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material effect on our condensed consolidated financial statements as of June 30, 2018.

Other pronouncements issued by the FASB or other authoritative accounting standards with future effective dates are either not applicable or not significant to our consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with 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. Actual results could differ from those estimates. Such differences could be material to the consolidated financial statements.

Cash and Cash Equivalents

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

Restricted Cash

We record cash pledged or held in trust as restricted cash. As of June 30, 2018 and December 31, 2017, we have approximately $1.2 million and $0.6 million, respectively, of restricted cash pledged to secure a line of credit as a security deposit for an Office Agreement (see Note 8).

Investment Securities

Investment securities at June 30, 2018 and December 31, 2017 consist of short-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 would be 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

We recognize license revenue in accordance with the revenue recognition guidance of ASC 606. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for a promise to transfer more than one good or service to the customer, in which case the Company would account for each promised good or service as a performance obligation only if it is (1) distinct or (2) a series of distinct goods or services that are substantially the same and have the same pattern of transfer. For each performance obligation, the Company would determine whether we satisfy the performance obligation over time by transferring control of a good or service over time. To determine whether the Company's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the Company would consider the nature of the intellectual property to which the customer will have rights. The Company has symbolic intellectual property, derived from its association with the Company's ongoing activities, including its ordinary business activities. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

Research and Development Costs

Generally, research and development costs are expensed as incurred. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued liability balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to 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. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion 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 CRO's, 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 June 30, 2018 and December 31, 2017, we recorded approximately $8.9 million and $8.1 million, respectively, 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.

Stock-Based Compensation

We recognize all share-based payments to employees and non-employee directors (as compensation for service) as noncash compensation expense in the condensed 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.

For share-based payments to consultants and other third-parties (including related parties), noncash compensation expense is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties (including related parties) are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

In addition, because some of the restricted stock 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.

Basic and Diluted Net Loss Per Common Share

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The following outstanding shares of common stock equivalents were excluded from the computation of net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three and Six Months Ended June 30,	
	2018	**2017**
Unvested restricted shares	4,589,940	4,275,762
Stock options	560,000	--
Shares issuable upon note conversion	15,950	15,181
Total	5,165,890	4,290,943

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 is reviewed for impairment annually, or earlier when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

Rent Expense and Deferred Rent

Rent expense and lease incentives, including landlord construction allowances, are recognized on a straight-line basis over the lease term, commencing generally on the date the Company takes possession of the leased property. The Company records lease incentives as deferred rent and recognizes the lease incentives as reductions of rental expense. The unamortized portion of deferred rent is included in deferred rent in the condensed consolidated balance sheets.

NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at June 30, 2018 and December 31, 2017:

(in thousands)	June 30, 2018	December 31, 2017
Checking and bank deposits	$ 96,995	$ 55,682
Money market funds	8,677	1,036
Total	$ 105,672	$ 56,718

NOTE 3 – INVESTMENT SECURITIES

Our investments as of June 30, 2018 and December 31, 2017 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at June 30, 2018 and December 31, 2017:

(in thousands)	June 30, 2018			
	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 July 2018 and April 2019) (held-to-maturity)	$ 20,573	$ --	$ 17	$ 20,556
Total short-term investment securities	$ 20,573	$ --	$ 17	$ 20,556

	December 31, 2017			
	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 2018 and November 2018) (held-to-maturity)	$ 27,999	--	$ 35	$ 27,964
Total short-term investment securities	$ 27,999	--	$ 35	$ 27,964

NOTE 4 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the condensed consolidated 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.

As of June 30, 2018 and December 31, 2017, the fair values of cash and cash equivalents, restricted cash, accounts payable, and notes and interest payable, approximate their carrying value.

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. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston's product candidates, AST-726 and AST-915. We have no obligations under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston's product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above.

The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately $17.9 million at June 30, 2018 and $17.5 million at December 31, 2017. No payments have been made on the 5% Notes as of June 30, 2018.

In December 2011, we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes' fair value as of June 30, 2018 and December 31, 2017. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our condensed consolidated financial statements.

The following tables provide the fair value measurements of applicable financial liabilities as of June 30, 2018 and December 31, 2017:

(in thousands)	Financial liabilities at fair value as of June 30, 2018			
	Level 1	Level 2	Level 3	Total
5% Notes	$ --	$ --	$ 210	$ 210
Total	$ --	$ --	$ 210	$ 210

	Financial liabilities at fair value as of December 31, 2017			
	Level 1	Level 2	Level 3	Total
5% Notes	$ --	$ --	$ 128	$ 128
Total	$ --	$ --	$ 128	$ 128

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

The following table summarizes the changes in Level 3 instruments during the six months ended June 30, 2018:

(in thousands)

Fair value at December 31, 2017	$ 128
Interest accrued on face value of 5% Notes	436
Change in fair value of Level 3 liabilities	(354)
Fair value at June 30, 2018	$ 210

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

NOTE 5 - 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.

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 150,000,000 shares of $0.001 par value common stock.

In May 2017, we filed a shelf registration statement on Form S-3 (the "2017 S-3"), which was declared effective in June 2017, replacing the 2015 S-3. Under the 2017 S-3, the Company may sell up to a total of $300 million of its securities. In connection with the 2017 S-3, we entered into an At-the-Market Issuance Sales Agreement (the "2017 ATM") with Jefferies LLC, Cantor Fitzgerald & Co., FBR Capital Markets & Co., SunTrust Robinson Humphrey, Inc., Raymond James & Associates, Inc., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each a "2017 Agent" and collectively, the "2017 Agents"), relating to the sale of shares of our common stock. Under the 2017 ATM we pay the 2017 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

In July 2018, we filed a shelf registration statement on Form S-3 (the “2018 S-3”) pursuant to the Joint Venture and License Option Agreement, dated June 18, 2018, by and between TG Therapeutics, Inc. and Novimmune S.A. (“Novimmune”), pursuant to which we issued 216,294 common shares to Novimmune. The 2018 S-3 was declared effective in July 2018.

During the six months ended June 30, 2018, we sold a total of 7,733,949 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately $106.3 million at an average selling price of $13.75 per share, resulting in net proceeds of approximately $104.5 million after deducting commissions and other transactions costs.

Subsequent to the second quarter, from July 1, 2018 through August 7, 2018, we sold an aggregate of 358,000 shares of common stock pursuant to the 2017 ATM for total gross proceeds of approximately $4.7 million at an average selling price of $13.00 per share, resulting in net proceeds of approximately $4.6 million after deducting commissions and other transactions costs.

The 2017 S-3 is currently our only active shelf registration statement, pursuant to which we can issue shares in an offering. After deducting shares already sold there is approximately $145.9 million of common stock that remains available for sale under the 2017 S-3. We may offer the securities under the 2017 S-3 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 believe that the 2017 S-3 provides us with the flexibility to raise additional capital to finance our operations as needed.

Equity Incentive Plans

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan ("2012 Incentive Plan") was approved by stockholders in June 2018. Pursuant to this amendment, 6,000,000 shares were added to the 2012 Incentive Plan. As of June 30, 2018, 560,000 options were outstanding and up to an additional 4,654,278 shares may be issued under the 2012 Incentive Plan.

Effective as of January 1, 2017, we entered into an amendment (the "Amendment") to the employment agreement entered as of December 15, 2011 (together with the Amendment, the "Employment Agreement") with Michael S. Weiss, our Executive Chairman and Chief Executive Officer and President of the Company. Under the Amendment, Mr. Weiss will remain as Chief Executive Officer and President, removing the interim status. Simultaneously, we entered into a Strategic Advisory Agreement (the "Advisory Agreement") with Caribe BioAdvisors, LLC (the "Advisor") owned by Mr. Weiss to provide the services of Mr. Weiss as Chairman of the Board and as Executive Chairman. As part of the Amendment, Mr. Weiss also agreed to forfeit 3,381,866 restricted shares previously granted under the Employment Agreement that were predominantly subject to time-based vesting over the next three years. Simultaneously, (i) Mr. Weiss was issued 418,371 restricted shares under the Employment Agreement that vest in 2018 and 2019 and (ii) the Advisor was issued 2,960,000 restricted shares under the Advisory Agreement that vested on market capitalization thresholds ranging from $375 million to $750 million. In accordance with GAAP, there was no incremental stock compensation expense recognition as a result of the modification.

Stock Options

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. We granted 560,000 and zero stock options during the six months ended June 30, 2018 and 2017, respectively.

The following table summarizes stock option activity for the three months ended June 30, 2018:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term	Aggregate Intrinsic Value
			(in years)	
Outstanding at December 31, 2017	--	$ --	--	$ --
Granted	560,000	11.56		
Exercised	--	--		
Forfeited	--	--		
Expired	--	--		
Outstanding at June 30, 2018	560,000	$ 11.56	9.65	$ 897,250
Exercisable at June 30, 2018	--	$ 11.56	--	$ --

As of June 30, 2018, the stock options outstanding include options granted to both employees and non-employees which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be recorded if and when a milestone occurs.

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 six months ended June 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2017	6,321,643	$ 7.17
Granted	1,420,511	13.32
Vested	(1,521,550)	9.46
Forfeited	(130,661)	8.30
Outstanding at June 30, 2018	6,089,943	$ 8.01

Total expense associated with restricted stock grants was approximately $4.3 million and $1.5 million during the three months ended June 30, 2018 and 2017, respectively, and $11.6 million, and $7.5 million during the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, there was approximately $11.0 million of total unrecognized compensation cost related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 1.2 years. The unrecognized compensation amount does not include, as of June 30, 2018, 1,128,011 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,224,167 shares of restricted stock outstanding issued to non-employees, the expense for which is determined each reporting period at the measurement date. The expense for non-employee awards is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date.

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

	June 30, 2018			December 31, 2017		
(in thousands)	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	$ 210	$ -	$ 210	$ 128	$ -	$ 128
Total	$ 210	$ -	$ 210	$ 128	$ -	$ 128

Convertible 5% Notes Payable

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 obligation under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston's product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity, which was March 8, 2015 (see Note 4 for further details).

The cumulative liability including accrued and unpaid interest of these notes was approximately $17.9 million at June 30, 2018 and $17.5 million at December 31, 2017. No payments have been made on the 5% Notes as of June 30, 2018.

In December 2011, we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments (see Note 4 for further details).

NOTE 7 – LICENSE AGREEMENTS

TG-1101

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of TG-1101 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 TG-1101 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 $38,000 for each of the three months ended June 30, 2018 and 2017, and $76,000 for each of the six months ended June 30, 2018 and 2017 and, at June 30, 2018 and December 31, 2017, have deferred revenue of approximately $1.1 million and $1.2 million, respectively, associated with this $2.0 million payment (approximately $152,000 of which has been classified in current liabilities at June 30, 2018 and December 31, 2017).

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 TG-1101 in the sublicense territory.

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co. ("Jiangsu"), 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 Jiangsu's Bruton's Tyrosine Kinase inhibitors containing the compounds of either TG1701 (SHR1459 or EBI1459) or TG1702 (SHR1266 or EBI1266). Pursuant to the agreement, in April 2018, we paid Jiangsu an upfront fee of $1.0 million in our common stock. Jiangsu 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. 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 SA ("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. Pursuant to the agreement, in June 2018 we paid Novimmnue an upfront payment of $3.0 million in our common stock. Further 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.

NOTE 8 – RELATED PARTY TRANSACTIONS

LFB Biotechnologies

On January 30, 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"). In connection with the LFB License Agreement, LFB Group was issued 5,000,000 shares of common stock, and a warrant to purchase 2,500,000 shares of common stock at a purchase price of $0.001 per share.

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred expenses of approximately $38,000 and $400,000 during the three months ended June 30, 2018 and 2017, respectively, and $0.2 million and $0.5 million during the six months ended June 30, 2018 and 2017, respectively, which have been included in other research and development expenses in the accompanying condensed consolidated statements of operations. As of June 30, 2018 and December 31, 2017, we had approximately $37,000 and zero, respectively, recorded in accounts payable related to the LFB License Agreement.

Other Parties

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, which is now our corporate headquarters. 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 $1.1 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. During the three and six months ended June 30, 2018, we recorded rent expense of approximately $0.3 million and $0.7 million, respectively, and at June 30, 2018, have deferred rent of approximately $1.4 million. As of June 30, 2018 and December 31, 2017, we have approximately $1.2 million and $0.6 million, respectively, of restricted cash pledged to secure a line of credit as a security deposit related to the Office Agreement. Mr. Weiss, our Executive Chairman and CEO, is also Executive Vice Chairman of FBIO.

Under the Office Agreement, we agreed to pay FBIO our portion of the build out costs, which have been allocated to us at the 45% rate mentioned above. The allocated buildout costs have been recorded in Leasehold Interest and will be amortized over the 15 year term of the Office Agreement. After an initial commitment of the 45% rate for a period of three (3) years, we and FBIO will determine actual office space utilization annually and if our utilization differs from the amount we have been billed, we will either receive credits or be assessed incremental utilization charges. As of June 30, 2018, we had approximately $0.4 million recorded in accounts payable related to FBIO, none of which related to rent and build-out costs.

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 $1.1 million and $0.7 million for shared services for the six months ended June 30, 2018 and 2017, respectively, and expenses of approximately $0.7 million and $0.4 million for the three months ended June 30, 2018 and 2017, primarily related to shared personnel.

In May 2016, as part of a broader agreement with Jubilant Biosys ("Jubilant"), an India-based biotechnology company, we entered into a sublicense agreement ("JBET Agreement") with Checkpoint Therapeutics, Inc. ("Checkpoint"), a subsidiary of FBIO, for the development and commercialization of Jubilant's novel BET inhibitor program in the field of hematological malignancies. We paid Checkpoint an up-front licensing fee of $1.0 million in July 2016 and incurred expenses of $0.2 million in March 2017 for the first milestone achievement as part of the JBET Agreement which is recorded in other research and development in the accompanying consolidated statement of operations. As of June 30, 2018 and 2017, we had approximately $0.1 million and $0.8 million, respectively, recorded in accounts payable, related mostly to the JBET Agreement. Mr. Weiss is also the Executive Chairman of Checkpoint.

ITEM 2. 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 the unaudited condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for patients with multiple sclerosis. Additionally, we have recently brought our anti-PD-L1 monoclonal antibody into Phase 1 development and aim to bring additional pipeline assets into the clinic in the future.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

TG-1101 (ublituximab)

Overview

TG-1101 (ublituximab) is a chimeric, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights to develop and commercialize TG-1101 for all indications, except for the territories of France and Belgium which have been retained by LFB Biotechnologies, and South Korea and Southeast Asia which were licensed by us to Ildong in November 2012.

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms: antibody dependent cell-mediated cytotoxicity ("ADCC"), complement dependent cytotoxicity ("CDC"), and direct or programmed cell death ("DCD" or "PCD"). TG-1101 has been specifically glycoengineered to enhance ADCC activity, which should enhance its ability to deplete B-cells and may improve its anti-cancer effects when compared to Rituxan®, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2016 of more than $7 billion.

Clinical Trials Overview and Recent Developments

Two single-agent, dose-escalation, Phase I studies were undertaken with TG-1101 to establish an optimal dose in patients with Non-Hodgkin's Lymphoma ("NHL") and Chronic Lymphocytic Leukemia ("CLL"). A two part first-in-human Phase I clinical trial was first completed in France in which TG-1101 was evaluated in relapsed or refractory CLL. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL. In both studies, single agent therapy with TG-1101 was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients.

In oncology settings, anti-CD20 therapy is generally used in combination with other anti-cancer agents where it demonstrates maximum activity as opposed to single agent usage. As a result, subsequent clinical development for TG-1101 has focused on combination therapy. Currently, our priority combination trials for TG-1101 are:

- The GENUINE Trial – a randomized controlled Phase 3 trial evaluating TG-1101 in combination with ibrutinib, for previously treated CLL patients with high risk cytogenetics;
- The UNITY-CLL Trial – a randomized controlled Phase 3 trial under Special Protocol Assessment ("SPA") evaluating TG-1101 in combination with TGR-1202, the Company's development stage PI3K delta inhibitor, for patients with front line and previously treated CLL;
- The UNITY-NHL Trial – registration-directed Phase 2b clinical study evaluating TGR-1202 alone and in combination with TG-1101 with or without bendamustine, in patients with previously treated Non-Hodgkin's Lymphoma ("NHL"); and
- TG-1101 + TGR-1202 + Pembrolizumab for patients with CLL.

In non-oncology settings, anti-CD20 therapy has generally been used as monotherapy. In addition to the above oncology studies, TG-1101 is being evaluated in a Phase 2 study for the treatment of Multiple Sclerosis ("MS") and in an investigator initiated Phase 1 study for the treatment of acute neuromyelitis optica ("NMO") relapses, with additional autoimmune related indications planned to be studied. On August 1, 2017, we announced we had reached an agreement with the U.S. Food and Drug Administration ("FDA") regarding an SPA on the design of two global Phase 3 clinical trials for TG-1101, referred to as the ULTIMATE I and ULTIMATE II Phase 3 clinical trials.

Manufacturing of TG-1101 is currently performed by a contract manufacturer based in the US.

Further details on our priority ongoing trials for TG-1101 are as follows:

TG-1101 + Ibrutinib Phase 3 Study Program – The GENUINE Trial

The GENUINE trial is a randomized controlled clinical trial in patients with previously treated CLL with specific high-risk cytogenetic abnormalities, with patients randomized to receive either TG-1101 plus ibrutinib or ibrutinib alone. In October 2016, we announced revisions to the design of the GENUINE study to accelerate its completion. Initially the study was being conducted pursuant to an SPA with the FDA, and was designed to enroll approximately 330 patients, with a two-part analysis of both overall response rate ("ORR") and progression-free survival ("PFS"). The trial was amended in October 2016 to enroll approximately 120 patients, with the PFS analysis component removed. Following the revisions, the sole primary endpoint of the study is ORR, and the SPA is no longer in effect.

In June 2017, the positive results from our Phase 3 GENUINE trial were presented by Dr. Jeff Sharman, Medical Director, Hematology Research, US Oncology in an oral session during the 53rd American Society of Clinical Oncology ("ASCO") Annual Meeting in Chicago, IL.

This presentation included data from the GENUINE Phase 3 trial, a multicenter, randomized trial, which assessed the efficacy and safety of TG-1101 plus ibrutinib versus ibrutinib alone in patients with high risk CLL. For the trial, high-risk was defined as having any one or more of the following centrally confirmed features: 17p deletion, 11q deletion or p53 mutation. The GENUINE study was designed to demonstrate the value of adding TG-1101 to ibrutinib monotherapy in high-risk CLL, and was powered to show a statistically significant improvement in ORR of 30%, with a minimal absolute detectable difference between the two arms of approximately 20%.

We continue to follow patients in the GENUINE study for safety and efficacy including Overall Response, MRD and Progression Free Survival ("PFS"). We are currently working on preparing a Biologics License Application for a potential accelerated approval filing for TG-1101 in combination with ibrutinib in previously treated CLL patients with high-risk cytogenetics, which filing could occur in 2018.

TG-1101 in Combination with TGR-1202 Phase 3 Study Program – The UNITY-CLL Trial

In September 2015, we reached an agreement with the FDA regarding an SPA on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for the proprietary combination of TG-1101 plus TGR-1202, for the treatment of CLL. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the regulatory submission for drug approval of both TG-1101 and TGR-1202 in combination.

The Phase 3 trial, called the UNITY-CLL trial, is a randomized controlled clinical trial that includes two key objectives: first, to demonstrate contribution of each agent in the TG-1101 + TGR-1202 regimen (the combination sometimes referred to as "U2"), and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. The study will randomize patients into four treatment arms: TG-1101 + TGR-1202, TG-1101 alone, TGR-1202 alone, and an active control arm of obinutuzumab (GAZYVA®) + chlorambucil. An early interim analysis will assess contribution of each single agent in the TG-1101 + TGR-1202 combination regimen, which, if successful, will allow early termination of both single agent arms. A second interim analysis will be conducted following full enrollment into the study, which, if positive, we plan to utilize for accelerated approval.

In September 2017, we announced that target enrollment in the UNITY-CLL trial was met and that we were extending enrollment until October 2017 for any additional identified study patients to be allowed in the trial. We expect top-line ORR data from this study to be reported in 2018.

TG-1101 in Combination with TGR-1202 with or without bendamustine Phase 2b Registration-Directed Program – The UNITY-NHL Trial

In June 2016, we commenced a registration-directed UNITY-DLBCL Phase 2b clinical study evaluating TG-1101 in combination with TGR-1202, as well as TGR-1202 alone, in patients with previously treated DLBCL. In mid-2017, this study was expanded to allow enrollment of patients with follicular lymphoma (FL), small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) and marginal zone lymphoma (MZL), as well as to add a cohort evaluating the triplet regimen of TG-1101 + TGR-1202 + bendamustine which has previously been explored in Phase 1. The cohorts of DLBCL, FL/SLL, MCL, and MZL are each being enrolled to and evaluated independently.

The updated study, called UNITY-NHL, is entitled "A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 with or without bendamustine and TGR-1202 alone in Patients with Previously Treated Non-Hodgkin’s Lymphoma.” The DLBCL component is being led by Owen A. O'Connor, MD, PhD, Professor of Medicine and Experimental Therapeutics, and Director of the Center for Lymphoid Malignancies at Columbia University Medical Center, while the indolent NHL component of the study is being led by Nathan H. Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma at the University of Texas MD Anderson Cancer Center, and the MCL component of the study is being led by Michael Wang MD, Director of Mantle Cell Lymphoma (MCL) Program of Excellence and Co-Director of Clinical Trials at The University of Texas MD Anderson Cancer Center. The primary objective of the study is to assess the efficacy of TGR-1202 alone, in combination with TG-1101, or in combination with TG-1101 and bendamustine in patients with previously treated NHL as measured by Overall Response Rate (ORR). The study will also provide important information as to the contribution of each agent, TGR-1202 and TG-1101, to the combination regimen of both agents, as well as the contribution of bendamustine to the combination regimen of both agents.

Single Agent TG-1101 in Relapsing Forms of Multiple Sclerosis

In May 2016, we commenced our first study of TG-1101 in patients with relapsing remitting multiple sclerosis (RRMS), a chronic demyelinating disease of the central nervous system (CNS).

The study, entitled "A Placebo-Controlled Multi-Center Phase 2 Dose Finding Study of Ublituximab, a Third-Generation Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis," is being led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX. The primary objective of the study is to determine the optimal dosing regimen for TG-1101 with a focus on accelerating infusion times. In addition to monitoring for safety and tolerability at each dosing cohort, B-cell depletion and established MS efficacy endpoints will also be evaluated.

Data from this study was most recently presented at the 4th Congress of the European Academy of Neurology (EAN) in Lisbon, Portugal and at the American Academy of Neurology (AAN) 70th Annual Meeting in Los Angeles, California Additional data presentations are to be expected at upcoming medical conferences.

TG-1101 in relapsing forms of Multiple Sclerosis Phase 3 Study Program – The ULITIMATE I and ULTIMATE II Trial

In August 2017, we reached an agreement with the FDA regarding an SPA on the design of two Phase 3 clinical trials for TG-1101, for the treatment of relapsing forms of Multiple Sclerosis (RMS). The SPA provides agreement that the two Phase 3 trial designs adequately address objectives that, if met, would support the regulatory submission for approval of TG-1101.

The RMS Phase 3 program consists of two trials, called the ULTIMATE I and ULTIMATE II trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing TG-1101 (ublituximab) to teriflunomide in subjects with RMS. The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. Each trial is ongoing and was designed to enroll approximately 440 subjects, randomized in a 1:1 ratio.

In August 2018, we announced that target enrollment into the ULTIMATE I and II trials has been achieved, and that enrollment would continue into September 2018 to allow identified patients to participate in the study.

TGR-1202

Overview

The phosphoinositide-3-kinases (“PI3Ks”) are a family of enzymes involved in various cellular functions, including cell proliferation and survival, cell differentiation, intracellular trafficking, and immunity. There are four isoforms of PI3K (alpha, beta, delta, and gamma), of which the delta isoform is strongly expressed in cells of hematopoietic origin, and often implicated in B-cell related lymphomas.

TGR-1202 (also referred to as umbralisib) is an orally available PI3K delta inhibitor with nanomolar potency to the delta isoform and high selectivity over the alpha, beta, and gamma isoforms. TGR-1202 has demonstrated activity in several pre-clinical models and primary cells from patients with hematologic malignancies.

We hold exclusive worldwide rights to develop and commercialize TGR-1202 for all indications worldwide, except for India which has been retained by Rhizen Pharmaceuticals S A.

The Company’s Investigational New Drug (“IND”) application for TGR-1202 was accepted by the FDA in December 2012 and a first in-human Phase I clinical trial was initiated in January 2013.

Clinical Trials Overview and Recent Developments

Initial clinical development of TGR-1202 was focused on establishing preliminary safety and efficacy in a wide variety of hematologic malignancies. Upon identification of safe and active doses of TGR-1202, a combination clinical trial program was opened, exploring TGR-1202 in combination with a variety of agents. In addition to the previously described study in combination with TG-1101 with or without the BTK inhibitor, ibrutinib, our current priority clinical trials for TGR-1202 include:

- TGR-1202 as a single agent in CLL patients who are intolerant to prior BTK inhibitor or PI3K-delta inhibitor therapy;
- TGR-1202 in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL; and
- TGR-1202 in combination with the JAK inhibitor, ruxolitinib (JAKAFI®), in patients with previously treated Myelofibrosis or Polycythemia Vera.

Single Agent TGR-1202 in Patients with Relapsed/Refractory Hematologic Malignancies

In January 2013, the Company initiated a Phase I, open label, multi-center, first-in-human clinical trial of TGR-1202 in patients with hematologic malignancies. The study entitled TGR-1202-101, "A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies," is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Howard “Skip” Burris, MD, Executive Director, Drug Development as the acting Study Chair. Enrollment is open to patients with relapsed or refractory NHL, CLL, and other select hematologic malignancies. As of February 2016, this study has closed to enrollment

Data from this ongoing Phase I study was published in full in *The Lancet Oncology* in February 2018, including safety and efficacy information from 90 patients with relapsed or refractory b-cell malignancies, including patients with CLL and various forms of lymphoma treated with single agent umbralisib.

TGR-1202 Long-term Follow-up Integrated Analysis in Patients with Relapsed/Refractory Hematologic Malignancies

In December 2017, at the 59th American Society of Hematology ("ASH") Annual Meeting, the Company presented integrated data with long term follow-up from 347 patients exposed to TGR-1202 across 5 studies, which continued to demonstrate high response rates in CLL, and FL coupled with a favorable safety profile distinct from other PI3K delta inhibitors.

In June 2018, an update on the data was presented at the 23rd Congress of the European Hematology Association (EHA). The presentation included data pooled from 4 completed or ongoing Phase 1 or 2 studies containing umbralisib, focusing on 177 patients who have been on daily umbralisib for a minimum of 6 months. Patients were heavily pretreated, with 45% of patients having seen 3 or more prior lines of therapy. Umbralisib continued to exhibit a differentiated safety profile compared to prior generation PI3K delta inhibitors. Serious adverse events occurring in >1% of patients after 6 months on therapy were limited to pneumonia (3%), diarrhea (2%), and cellulitis (2%) with only 2% of patients discontinuing umbralisib as a result of diarrhea/colitis after being on umbralisib for more than 6 months.

TGR-1202 TKI Intolerance Study

In June 2018, at the 23rd Congress of the European Hematology Association (EHA), the Company presented data from 47 patients with CLL who were intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent TGR-1202. TGR-1202 appeared to demonstrate a favorable safety profile in patients intolerant to prior ibrutinib (BTK) or idelalisib (PI3K) with only 13% discontinuing due to an adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) also experienced with prior kinase inhibitor therapy. The median progression free survival (PFS) and overall survival has not been reached with a median follow-up of 9.5 months. Enrollment is now closed with patients continuing to be followed.

TGR-1202 Combination Trials

TGR-1202 is being evaluated in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma; in combination with the BTK inhibitor, ibrutinib, in patients with CLL and MCL; and in combination with the JAK inhibitor, ruxolitinib, in patients with Myelofibrosis or Polycythemia Vera. Additional investigator sponsored trials are also underway which are combining TGR-1202 with other approved agents for the treatment of B-cell malignancies.

It is anticipated that updated results from these studies will be presented or updated at future medical conferences.

TGR-1202 in Solid Tumors

In addition to the exploration of TGR-1202 in various hematologic malignancies, a study was opened in October 2015 to evaluate TGR-1202 as a single agent as well as in combination with various chemotherapies for the treatment of select solid tumors. The study, entitled TGR-1202-102, "A Phase I Study Evaluating the Safety and Efficacy of TGR-1202 Alone and in Combination with either nab-paclitaxel + Gemcitabine or with FOLFOX in Patients with Select Relapsed or Refractory Solid Tumors" is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Johanna Bendell, MD, Director of GI Oncology Research as the acting study chair. The study is currently closed to enrollment with patients continuing to be followed for safety and efficacy.

IRAK4

We hold global rights to develop and commercialize the IRAK4 program, which was licensed from Ligand Pharmaceuticals. Our IRAK4 program is currently in pre-clinical development.

PD-L1 and GITR

In March 2015, we entered into a global collaboration agreement for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Our anti-PD-L1 recently entered the clinic and our anti-GITR program is currently in pre-clinical development, with pre-clinical data most recently presented at the American Association for Cancer Research Annual Meeting in March 2017.

In October 2017, we announced that the first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of our anti-PD-L1 monoclonal antibody, enrolling patients across sites in Australia and New Zealand.

BET

In May 2016, as part of a broader agreement with Jubilant Biosys ("Jubilant"), an India-based biotechnology company, we entered into a sub-license agreement ("JBET Agreement") with Checkpoint Therapeutics, Inc. ("Checkpoint"), a subsidiary of FBIO, for the development and commercialization of Jubilant's novel BET inhibitor program in the field of hematological malignancies. The BET inhibitor program is the subject of a family of patents covering compounds that inhibit BRD4, a member of the BET (Bromodomain and Extra Terminal) domain for cancer treatment. Our BET inhibitor program is currently in pre-clinical development.

In April 2018, pre-clinical data for TG-1601, the BET inhibitor, was announced at the American Association for Cancer Research ("AACR") Annual Meeting in Chicago, IL.

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co., or Jiangsu ("BTK Agreement"), pursuant to which we obtained worldwide rights, excluding Asia but including Japan, for the development of Hengrui's Bruton's Tyrosine Kinase ("BTK") inhibitor program, including lead candidate TG-1701 (known in China as SHR-1459), as monotherapy and in combination with TG-1101 and TGR-1202. In addition to TG-1701, the global license agreement covers TG-1702 (SHR-1266), another BTK inhibitor in pre-clinical development. BTK is an essential component of the B-cell receptor signaling pathways that regulate the survival, activation, proliferation, and differentiation of B lymphocytes. Targeting BTK with small molecule inhibitors has been demonstrated to be an effective treatment option for B-cell lymphomas and autoimmune diseases.

In June 2018, pre-clinical data for TG-1701, the BTK inhibitor, was presented at the 23rd Congress of the European Hematology Association in Stockholm, Sweden. TG-1701 is expected to enter the clinic in the second half of 2018.

TG-1801: anti-CD47/anti-CD19

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune SA ("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.

GENERAL CORPORATE

Our license revenues currently consist of license fees arising from our agreement with Ildong. We recognize upfront license fee revenues ratably over the estimated period in which we will have certain significant ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue.

We have not earned any revenues from the commercial sale of any of our drug candidates.

Our research and development expenses consist primarily of expenses related to in-licensing of new product candidates, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, manufacture, testing and enhancement of our drug candidates and technologies. We expense our research and development costs as they are incurred.

Our general and administrative expenses consist primarily of salaries and related expenses for 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 non-cash compensation expenses as a result of the grants of stock options and restricted stock. Compensation expense for awards of options and restricted stock 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 condensed consolidated statements of operations. We expect to continue to incur significant non-cash compensation expenses.

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

In addition, certain restricted stock issued to employees vest upon the achievement of certain milestones; therefore, the total expense is uncertain until the milestone is probable.

Our clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we fund in-licensing and development of new drug candidates. As we further our development efforts, we may enter into additional third-party collaborative agreements and incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish a commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA or a foreign health authority, which would result in incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

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RESULTS OF OPERATIONS

Three months ended June 30, 2018 and 2017

License Revenue. License revenue was approximately $38,000 for each of the three months ended June 30, 2018 and 2017. License revenue is related to the amortization of an upfront payment of $2.0 million received in 2012 associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to $3.0 million for the three months ended June 30, 2018, as compared to zero during the comparable period in 2017. The expense during the three months ended June 30, 2018 was recorded in conjunction with the stock issued to Novimmune as an upfront payment for the license to the CD47/CD-19 program.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled $0.9 million for the three months ended June 30, 2018, as compared to $1.3 million during the comparable period in 2017. The decrease in noncash compensation expense was primarily related to a decrease in the measurement date fair value of certain consultant restricted stock during the period ended June 30, 2018.

Other Research and Development Expenses. Other research and development expenses increased by $9.4 million to $34.8 million for the three months ended June 30, 2018, as compared to $25.4 million for the three months ended June 30, 2017. The increase was mainly due to the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the three months ended June 30, 2018. We expect our other research and development costs to remain relatively consistent for the remainder of 2018 as we complete enrollment in our registration directed clinical trials and we prepare for potential commercialization.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $3.2 million to $3.4 million for the three months ended June 30, 2018, as compared to $0.2 million for the three months ended June 30, 2017. The increase in noncash compensation expense was primarily related to greater compensation expense during the three months ended June 30, 2018 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by $0.8 million to $2.3 million for the three months ended June 30, 2018, as compared to $1.5 million for the three months ended June 30, 2017. The increase was due primarily to rent related expenses of our office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2018.

Other (Income) Expense. Other income increased by approximately $0.1 million to approximately $0.2 million for the three months ended June 30, 2018, as compared to approximately $70,000 for the three months ended June 30, 2017. The increase is mainly due to an increase in interest income for the three months ended June 30, 2018.

Six months ended June 30, 2018 and 2017

License Revenue. License revenue was approximately $0.1 million for each of the six months ended June 30, 2018 and 2017. License revenue for the six months ended June 30, 2018 and 2017 was related to the amortization of an upfront payment of $2.0 million received in 2012 associated with our license agreement with Ildong.

Noncash Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to $4.0 million for the six months ended June 30, 2018, as compared to zero during the comparable period in 2017. The expense during the six months ended June 30, 2018 was recorded in conjunction with the stock issued to Novimmune and Jiangsu Hengrui as upfront payments for the licenses to the CD47/CD19 and BTK programs, respectively.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants remained consistent between the two periods totaling $3.7 million for the six months ended June 30, 2018, as compared to $3.6 million during the comparable period in 2017.

Other Research and Development Expenses. Other research and development expenses increased by $20.2 million to $66.0 million for the six months ended June 30, 2018, as compared to $45.8 million for the six months ended June 30, 2017. The increase in other research and development expenses was due primarily to new and ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the six months ended June 30, 2018. We expect our other research and development costs to remain relatively consistent for the remainder of 2018 as we complete enrollment in our registration directed clinical trials and we prepare for potential commercialization.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by $4.0 million to $7.9 million for the six months ended June 30, 2018, as compared to $3.9 million for the six months ended June 30, 2017. The increase in noncash compensation expense was primarily related to greater compensation expense during the six months ended June 30, 2018 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses. Other general and administrative expenses increased by $1.5 million to $4.4 million for the six months ended June 30, 2018, as compared to $2.9 million for the six months ended June 30, 2017. The increase was due primarily to rent related expenses of our new office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2018.

Other (Income) Expense. Other income increased by $0.2 million to approximately $0.3 million for the six months ended June 30, 2018, as compared to approximately $11,000 for the six months ended June 30, 2017. The increase is mainly due to an increase in interest income for the six months ended June 30, 2018.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of cash have been from the sale of equity securities, warrant and option exercises, and the upfront payment from our Sublicense Agreement with Ildong. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of June 30, 2018, we had approximately $126.3 million in cash, cash equivalents, investment securities, and interest receivable. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of June 30, 2018 combined with the additional capital raised in the third quarter of 2018 will be sufficient to fund the Company’s planned operations into the fourth quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Cash used in operating activities for the six months ended June 30, 2018 was $62.2 million as compared to $49.1 million for the six months ended June 30, 2017. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for TG-1101 and TGR-1202.

For the six months ended June 30, 2018, net cash provided by investing activities was $7.4 million as compared to $11.0 million for the six months ended June 30, 2017. The decrease in net cash provided by investing activities was primarily due to greater investment in treasury securities during the six months ended June 30, 2018.

For the six months ended June 30, 2018 and 2017, net cash provided by financing activities of $104.5 million and $90.7 million, respectively, related primarily to proceeds from the issuance of common stock as part of our ATM program.

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

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated 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. We recognize license revenue in accordance with the revenue recognition guidance of ASU No. 2014-09, “Revenue from Contracts with Customers” (Topic 606) (“ASC 606”). We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for a promise to transfer more than one good or service to the customer, in which case we would account for each promised good or service as a performance obligation only if it is (1) distinct or (2) a series of distinct goods or services that are substantially the same and have the same pattern of transfer. For each performance obligation, we would determine whether we satisfy the performance obligation over time by transferring control of a good or service over time. To determine whether our promise is to provide a right to access its intellectual property or a right to use its intellectual property, we would consider the nature of the intellectual property to which the customer will have rights. We have symbolic intellectual property, derived from our association with ongoing activities, including our ordinary business activities. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

Stock-Based Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. For employee and director 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, we are required to estimate the expected forfeiture rate and only recognize expense for those equity awards expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

Total compensation expense for options and restricted stock issued to consultants is determined at the “measurement date.” The expense is recognized over the vesting period for the options and restricted stock. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record stock-based compensation expense based on the fair value of the equity awards at the reporting date. These equity awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to 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. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

We are required to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

Accounting For Income Taxes. In preparing our condensed consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statements of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

Fair Value of 5% Notes Payable. We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The 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 three categories.

We elected the fair value option for valuing the 5% Notes. We elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

RECENTLY ISSUED ACCOUNTING STANDARDS

In July 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (“ASU”) No. 2018-11, “Leases - Targeted Improvements” (“ASU 2018-11”) as an update to ASU 2016-02, Leases (“ASU 2016-02” or “Topic 842”) issued on February 25, 2016. ASU 2016-02 is effective for public business entities for fiscal years beginning January 1, 2019. ASU 2016-02 required companies to adopt the new leases standard at the beginning of the earliest period presented in the financial statements, which is January 1, 2017, using a modified retrospective transition method where lessees must recognize lease assets and liabilities for all leases even though those leases may have expired before the effective date of January 1, 2017. Lessees must also provide the new and enhanced disclosures for each period presented, including the comparative periods.

ASU 2018-11 provides an entity with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity’s reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases). An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments do not change the existing disclosure requirements in Topic 840. An entity shall apply the effects of modification using one of the following two methods:

- Retrospectively to each prior reporting period presented in the financial statements with the cumulative effect of initially applying ASU 2018-11 recognized at the beginning of the earliest comparative period presented. Under this transition method, the application date shall be the later of the beginning of the earliest period presented in the financial statements and the commencement date of the lease.

- Retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. Under this transition method, the application date shall be the beginning of the reporting period in which the entity first applies ASU 2018-11.

ASU 2018-11 is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier adoption permitted. We are currently evaluating the impact the adoption of ASU 2018-11 will have on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, “Improvements to Nonemployee Share-Based Payment Accounting” (“ASU 2018-07”). ASU 2018-07 expands the scope of FASB Topic 718, Compensation – Stock Compensation (“Topic 718”) to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. Disclosures required at transition include the nature of and reason for the change in accounting principle and, if applicable, quantitative information about the cumulative effect of the change on retained earnings or other components of equity.

ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. We are currently evaluating the impact the adoption of ASU 2018-07 will have on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, “Scope of Modification Accounting” (“ASU 2017-09”). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

- The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

- The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

- The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In January 2017, the FASB issued ASU No. 2017-04, "Simplifying the Test for Goodwill Impairment" ("ASU 2017-04"). ASU 2017-04 removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, ASU 2017-04:

- Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units in connection with an entity's testing of reporting units for goodwill impairment.

- Clarifies that an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.

- Makes minor changes to the overview and background sections of certain ASC subtopics and topics as part of the Board's initiative to unify and improve those sections throughout the Codification.

ASU 2017-04 is effective prospectively for annual and interim periods beginning on or after December 15, 2019, and early adoption is permitted on testing dates after January 1, 2017. The Company does not expect the adoption of ASU 2017-04 to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, "FASB Clarifies the Definition of a Business" ("ASU 2017-01"). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

- Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.

- Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.

- Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of ASU 2017-01 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows – Restricted Cash" ("ASU 2016-18"). ASU 2016-18 requires that a statement of cash flows explain the change during the period for the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 does not provide a definition of restricted cash or restricted cash equivalents, and does not change the balance sheet presentation for such items. The Company adopted ASU 2016-18 on January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on our consolidated financial statements as of June 30, 2018.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" (Topic 606) ("ASU 2014-09" or "ASC 606"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity's promise to the customer. To determine whether the entity's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material effect on our condensed consolidated financial statements as of June 30, 2018.

Other pronouncements issued by the FASB or other authoritative accounting standards with future effective dates are either not applicable or not significant to our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES 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 invest in government and investment-grade corporate debt in accordance with our investment policy. Some of 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 June 30, 2018, our portfolio of financial instruments consists of cash equivalents, including bank deposits, and investments. Due to the short-term nature of our investments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our investments.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2018, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the 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 Officer and Chief Financial Officer concluded that, as of June 30, 2018, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. 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 1A. RISK FACTORS

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

Because we have in-licensed 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 candidates.

Because we license our intellectual property from third parties and we expect to continue to in-license additional intellectual property rights, if there is any dispute between us and our licensor regarding our rights under a license agreement, our ability to develop and commercialize our product candidates may be adversely affected. Disputes may arise with the third parties from whom we license our intellectual property rights from 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 intellectual property or technology 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 candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We do not have full internal development capabilities, and are thus reliant upon our partners and third parties to generate clinical, preclinical and quality data necessary to support the regulatory applications needed to conduct clinical trials and file for marketing approval.

In order to submit and maintain an Investigational New Drug application (“IND”), Biologics License Application (“BLA”), or New Drug Application (“NDA”) to the United States Food and Drug Administration (“FDA”), it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. We rely on our third party contractors and our licensing partners to provide a significant portion 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. Additionally, an IND must be active in each division in which we intend to conduct clinical trials. Currently we do not have an active IND for any of the IRAK4, BTK, or BET inhibitors, nor for our anti-GITR or anti-CD47/ anti-CD-19 antibodies. Additionally, there can be no assurance given that any of the molecules under development in our IRAK4, BTK, or BET inhibitor program or in our anti-GITR or anti-CD47/ anti-CD-19 antibody research programs will demonstrate sufficient pharmacologic properties during pre-clinical evaluation to advance to IND enabling studies, or that such IND enabling studies, if any are conducted, will provide data sufficient to support the filing of an IND, or that such IND, if filed, would be accepted by any FDA division under which we would seek to develop any product candidate. While we maintain an active IND for TG-1101 and TGR-1202 enabling the conduct of studies in the FDA’s Division of Hematology and Oncology, and an active IND for TG-1101 under the FDA’s Division of Neurology, there can be no assurance that we will be successful in obtaining an active IND for these drugs in any other division under whose supervision we may seek to develop our product candidates, or that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

We are highly dependent on the success of our product candidates and cannot give any assurance that these or any future product candidates will be successfully commercialized.

We are a development-stage biopharmaceutical company, and do not currently have any commercial products that generate revenues or any other sources of revenue. We may never be able to successfully develop marketable products. Our pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons.

If we are unable to develop, or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues. Even if we are able to develop or receive regulatory approval for or successfully commercialize any of our product candidates, we may not be able to gain market acceptance for our product candidates and future products and may never become profitable.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical development has inherent risk. 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 diverse populations for their target indications before we can seek regulatory approvals for their commercial sale. 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 suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, there is typically an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

We plan on conducting additional Phase I, II and III clinical trials for TG-1101 and TGR-1202. Early clinical results seen with TG-1101 and TGR-1202 in a small number of patients may not be reproduced in expanded or larger clinical trials. Additionally, individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. Further, larger scale Phase III 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 study's outcome or the opinion of the validity of the study results by applicable regulatory agencies. Early clinical trial results from interim analysis or from the review of a Data Safety Monitoring Board ("DSMB") or similar safety committee may not be reflective of the results of the entire study, when completed. Additionally, many of the results reported in our early clinical trials rely on local investigator assessed safety and efficacy outcomes which may differ from results assessed in a blinded, independent, centrally reviewed manner, often required of adequate and well controlled registration directed clinical trials which may be undertaken at a later date. If the results from expansion cohorts or later trials are different from those found in the earlier studies of TG-1101 and TGR-1202, 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. Our IRAK4, BTK, BET, anti-CD47/ anti-CD-19, and anti-GITR programs are all in pre-clinical development and no assurance can be given that they will advance into clinical development. If the results from additional pre-clinical studies or early clinical trials differ from those found in earlier studies, our clinical development plans and timelines for this program could be adversely affected which could have a material adverse effect on our business. Many drugs fail in the early stages of clinical development for safety and tolerability issues and accordingly if our pre-clinical assets advance into clinical development, no assurance can be made that a safe and efficacious dose can be found.

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate 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. 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. They may also incur additional costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner. In addition, conducting multi-national studies adds another level of complexity and risk. We are subject to events affecting countries outside the United States. Negative or inconclusive results from the clinical trials we conduct or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials.

In September 2015 we announced a Phase 3 clinical trial for the combination of TG-1101 + TGR-1202 for patients with Chronic Lymphocytic Leukemia ("CLL"), which is being conducted pursuant to a Special Protocol Assessment ("SPA") with the FDA and in August 2017 we announced an SPA for our registration program for TG-1101 in relapsing forms of Multiple Sclerosis ("MS"). Many companies which have been granted SPAs and/or the right to utilize the FDA's Fast Track or accelerated approval process have ultimately failed to obtain final approval to market their drugs. Since we are seeking approvals under SPAs for some of our product registration strategies, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Further, any changes or amendments to a protocol that is being conducted under SPA will have to be reviewed and approved by the FDA to verify that the SPA agreement is still valid. Even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. 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 data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

The sufficiency of our GENUINE trial results for approval are subject to FDA's discretion.

Obtaining accelerated approval for an agent requires demonstration of meaningful benefit over available therapies. While we believe we have an understanding of what is considered available therapy today, ultimately the determination of what constitutes available therapy is wholly up to the FDA and is subject to change. In October 2017, we announced the outcome of a meeting with the FDA regarding the use of the results from the GENUINE Phase 3 trial to support a BLA filing for accelerated approval of TG-1101 in combination with ibrutinib. As part of the discussion, the FDA also guided that if one or more agents obtained full approval before we could obtain accelerated approval, those agents could be considered available therapy, and we would need to show meaningful benefit over those agents as well. No assurance can be given that other agents will not receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved drugs. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving accelerated approval.

While we wait to see if any drugs receive full approval and can evaluate the data associated with any such agents, we are continuing to make preparations for a BLA filing for accelerated approval. Whether or not we ultimately file such application will be subject to multiple factors and no assurance can be given that a filing will be made. If a filing is made, the FDA acceptance of such a filing will depend on the FDA's views on the adequacy of the filing, and further even if the filing is accepted, approval of such a filing is a question wholly within the FDA's discretion to determine. In addition, if we were to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

The GENUINE study in its final form was not powered for progression-free survival ("PFS"). There can be no assurance given that we will reach agreement with the FDA on an acceptable use of PFS data from GENUINE to support approval of TG-1101, or even if an agreement is reached, that the PFS results of TG-1101 will be positive and/or sufficient to support a regulatory approval of TG-1101.

Any 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 or "fast track" or "priority review" status to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities worldwide. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA or NDA from the FDA. The process of obtaining BLA and NDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Even with "fast track" or "priority review" status which we intend to seek for our product candidates, where possible, including with regard to TG-1101, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. In addition, the FDA may require post-approval clinical trials or studies which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a Risk Evaluation and Mitigation Strategy ("REMS") requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States. As a result, we would be subject to regulation by the European Medicines Agency ("EMA"), as well as the other regulatory agencies in these countries.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. As in the United States, the regulatory approval process in Europe and in other countries is a lengthy and challenging process. The FDA, and any other regulatory body around the world can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from 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 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 submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, raising questions about the safety of marketed pharmaceuticals may result in increased cautiousness by the FDA and other regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Regulatory approvals for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we take into clinical trials could cause either us or regulatory authorities to interrupt, delay, modify or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using TG-1101 and TGR-1202 have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of TG-1101 and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to both TG-1101 and TGR-1202, the toxicity when manufactured under different conditions and in different formulations is not known, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. Should we not be able to adequately demonstrate analytical comparability between drug product manufactured under different conditions, the introduction of such new drug product into ongoing trials also has the potential to confound the interpretation of the results or complicate the statistical analysis of such trial. Further, with respect to TGR-1202, although approximately one thousand patients have been dosed amongst all ongoing TGR-1202 studies, the full adverse effect profile of TGR-1202 is not known. It is also unknown as additional patients are exposed for longer durations to TGR-1202, whether greater frequency and/or severity of adverse events are likely to occur. Common toxicities of other drugs in the same class as TGR-1202 include high levels of liver toxicity, infections and colitis, the latter of which notably has presented with later onset, with incidence increasing with duration of exposure. To date, the incidence of these events has been limited for TGR-1202, however no assurance can be given that this safety and tolerability profile will continue to be demonstrated in the future as higher doses, longer durations of exposure, and multiple drug combinations are explored. 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.

Additionally, in combination clinical development, there is an inherent risk of drug-drug interactions between combination agents which may affect each component's individual pharmacologic properties and the overall efficacy and safety of the combination regimen. Both TG-1101 and TGR-1202 are being evaluated in combination together, as well as with a variety of other active anti-cancer agents, which may cause unforeseen toxicity, or impact the severity, duration, and incidence of adverse events observed compared to those seen in the single agent studies of these agents. Further, with multi-drug combinations, it is often difficult to interpret or properly assign attribution of an adverse event to any one particular agent, introducing the risk that toxicity caused by a component of a combination regimen could have a material adverse impact on the development of our product candidates. There can be no assurances given that the combination regimens being studied will display tolerability or efficacy suitable to warrant further testing or produce data that is sufficient to obtain marketing approval.

If any of our product candidates receives marketing approval and we, or others, later identify unacceptable adverse events caused by the product, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the affected product;
- regulatory authorities may require a more significant clinical benefit for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements 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 the product is administered or, conduct additional clinical trials;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model; and
- our reputation may suffer.

Any one or a combination of these events could prevent us from obtaining or 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 delay or prevent us from generating any revenues from the sale of the affected product.

We may experience delays in the commencement of our clinical trials or in the receipt of data from preclinical and clinical trials conducted by third parties, which could result in increased costs and delay our ability to pursue regulatory approval.

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact our product development costs. Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing, usually in animals, to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and its proposed clinical trial protocol for our product candidates.

We plan to rely on preclinical and clinical trial data from third parties, if any, for the IND submissions for our product candidates. If receipt of that data is delayed for any reason, including reasons outside of our control, it will delay our plans for IND filings, and clinical trial plans. This, in turn, will delay our ability to make subsequent regulatory filings and ultimately, to commercialize our products if regulatory approval is obtained. If those third parties do not make this data available to us, we will likely, on our own, have to develop all the necessary preclinical and clinical data which will lead to additional delays and increase the costs of our development of our product candidates.

Before we can test any product candidate in human clinical trials the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as in-vitro and animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices ("GLP").

We must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, we must work with the FDA to resolve any outstanding concerns before the clinical trials can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

The FDA may require that we conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development.

Even assuming an active IND for a product candidate, we do not know whether our planned clinical trials for any such product candidate will begin on time, or at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board ("IRB") or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial;
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues; and
- unexpected safety findings.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in the completion of clinical testing could result in increased costs and delay our ability to generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a DSMC overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities 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 clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of any product candidate that we advance into clinical trials, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may be harmed. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize any of our product candidates, other therapies for the same indications may have been introduced to the market during the period we have been delayed and such therapies may have established a competitive advantage over our product candidates.

We intend to rely on third parties to help conduct our planned clinical trials. If these third parties do not meet their deadlines or otherwise conduct the trials as required, we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We intend to use CROs to assist in the conduct of our planned clinical trials and will rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties may play a significant role in the conduct of these 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 candidates.

If any of our clinical trial sites terminate 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. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity 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 may be jeopardized.

As all of our product candidates are still under development, manufacturing and process improvements implemented in the production of those product candidates may affect their ultimate activity or function.

Our product candidates are in the initial stages of development and are currently manufactured in 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 profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made. In addition, we have engaged a secondary manufacturer for TG-1101 to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for TGR-1202 to meet expanded clinical trial and commercial needs. While material produced from this secondary manufacturer for TG-1101 has to date demonstrated acceptable comparability to enable introduction into our clinical trials, no assurance can be given that any additional manufacturers will be successful or that material manufactured by the additional manufacturers will perform comparably to TG-1101 or TGR-1202 as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing, or that the relevant regulatory agencies will agree with our interpretation of comparability. If a secondary 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.

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 and marketing 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, we are exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

If our competitors develop treatments for the target indications for which any of our product candidates may be approved, and they are approved more quickly, marketed more effectively or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

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 marketing resources. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. Additionally, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We may also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The cancer indications for which we are developing our products have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of Non-Hodgkin's Lymphoma ("NHL"), CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action. Additionally, numerous established therapies exist for the autoimmune disorders for which we are developing TG-1101, including and in particular, MS.

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (rituximab) and Gazyva® (obinutuzumab or GA-101), and Novartis' Arzerra® (ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing antibodies targeting CD20, CD19, and other B-cell associated targets, chimeric antigen receptor T-cell ("CAR-T") immunotherapy, and other B-cell ablative therapy which, if approved, would potentially compete with TG-1101 both in oncology settings as well as in autoimmune disorders. In 2017, the Roche Group's anti-CD20 antibody ocrelizumab was approved for the treatment of MS. Genmab and GSK's (ofatumumab) is also under clinical development for patients with MS. 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.

With respect to TGR-1202, there are several PI3K delta targeted compounds both approved, such as Gilead's Zydelig® (idelalisib) and Bayer's Aliqopa™ (copanlisib), and in development, including, but not limited to, Verastem's duvelisib which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 that are both approved and in development, which could also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (FDA approved for MCL, CLL, Marginal Zone Lymphoma and WM and marketed by AbbVie and Janssen), the BTK inhibitor acalabrutinib (FDA approved for MCL and marketed by AstraZeneca), or the BCL-2 inhibitor venetoclax (FDA approved for CLL and marketed by AbbVie and Roche).

These developments may render our 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.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop products for the treatment of lymphoma, CLL, or other B-cell and autoimmune related disorders that are more effective, better tolerated, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their product candidates sooner than we do for our products.

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

We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and the commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide us with sufficient quantities of pharmaceutical product or fail to do so at acceptable quality levels or prices.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted only after we submit a BLA or NDA to the FDA, if at all. We do not control the manufacturing process of our product candidates and are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of finished pharmaceutical products (good manufacturing practices, or "GMP"). If our contract manufacturers cannot successfully manufacture material that conforms to our target product specifications, patent specifications, and/or the FDA's strict regulatory requirements of safety, purity and potency, we will not be able to secure and/or maintain FDA approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers cannot meet FDA standards, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. No assurance can be given that a long-term, scalable manufacturer can be identified or that they can make clinical and commercial supplies of our product candidates that meets the product specifications of previously manufactured batches, or is of a sufficient quality, or at an appropriate scale and cost to make it commercially feasible. If they are unable to do so, it could have a material adverse impact on our business.

In addition, we do not have the capability to package finished products for distribution to hospitals and other customers. Prior to commercial launch, we intend to enter into agreements with one or more alternate fill/finish pharmaceutical product suppliers so that we can ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. If we receive marketing approval from the FDA, we intend to sell pharmaceutical product finished and packaged by such suppliers. We have not entered into long-term agreements with our current contract manufacturers or with any fill/finish suppliers, and though we intend to do so prior to commercial launch of our product candidates in order to ensure that we maintain adequate supplies of finished product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business.

In most cases, our manufacturing partners are single source suppliers. It is expected that our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Given this, any disruption of supply from these partners could have a material, long-term impact on our ability to supply products for clinical trials or commercial sale. If our suppliers do not deliver sufficient quantities of our product candidates on a timely basis, or at all, and in accordance with applicable specifications, there could be a significant interruption of our supply, which would adversely affect clinical development and commercialization of our products. In addition, if our current or future supply of any or our product candidates should fail to meet specifications during its stability program there could be a significant interruption of our supply of drug, which would adversely affect the clinical development and commercialization of the product.

Our product candidates may compete with other product candidates and products 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 performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. 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.

We currently have no marketing and sales organization and no experience in marketing pharmaceutical products. If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any products we may develop, we may not be able to effectively market and sell our products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of our biotechnology products, and we must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize our products. We plan to either develop internally or enter into collaborations or other commercial arrangements to develop further, promote and sell all or a portion of our product candidates.

The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we or our development partners would be able to successfully develop this capability. If we or our development partners are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell such products. We currently possess limited resources and may not be successful in establishing our own internal sales force or in establishing arrangements with third parties on acceptable terms, if at all.

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.

Any future product candidate development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For any current or future product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any additional collaborations 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 clinical trials, the likelihood of approval by FDA 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 any future product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. 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. If we are unable to negotiate and enter into new collaborations, 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 reduce or delay any other future development programs.

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 will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product candidate cannot be marketed in the United States or other countries until we have completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for TG-1101, TGR-1202 or any future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office("USPTO"). The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for TG-1101, TGR-1202 or any future product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize TG-1101, TGR-1202, or any future product candidates.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from its sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

If any product candidate is approved but does 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.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer.

Our projections of both the number of people who are affected by disease within our target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend our self against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- impairment to our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- loss of revenues.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, we may be unable to obtain this product liability insurance on commercially reasonable terms and with insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits relating to marketed pharmaceuticals. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

We intend to seek approval to market our future products in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to our product. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals.

Most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "ACA," was enacted. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- 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, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. Any remaining legal challenges to the ACA are viewed generally as not significantly impacting the implementation of the law if the plaintiffs prevail.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the United States House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful.

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

- 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;
- our ability to generate revenues and achieve or maintain profitability;
- 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.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing this growth.

As of August 1, 2018, we had 96 full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

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 its 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, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may not be successful in our efforts to identify or discover additional product candidates and 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.

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our programs. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources.

Additionally, 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 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. 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.

If any of these 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.

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

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts for our product candidates and future product candidates. We are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management. The loss of the services of any of our senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. We do not maintain “key man” insurance policies on the lives of these individuals. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

In addition to FDA restrictions on the marketing of pharmaceutical and biotechnology products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries, as well as consulting or other service agreements with physicians or other potential referral sources and regulate the use and disclosure of identifiable patient information. These laws include anti-kickback statutes and false claims statutes that prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or, in return for, purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally-financed healthcare programs, and knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and any practices we adopt may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Any challenge to its business practices under these laws could have a material adverse effect on our business, financial condition, and results of operations. Finally, the Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or ("HITECH"), their respective implementing regulations and similar state laws and regulations, impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In the event our operations result in our receiving such information, we could become subject to the requirements of these laws and regulations, including potential civil and criminal penalties.

Our employees, consultants, or third party partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third party partners 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, 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. Employee, consultant, or third party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. 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 be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We use biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We use hazardous materials, including chemicals and biological agents and compounds, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our pharmaceutical development efforts.

In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, or operations otherwise affected.

All product candidate development timelines and projections in this report are based on the assumption of further financing.

The timelines and projections in this report are predicated upon the assumption that we will raise additional financing in the future to continue the development of our product candidates. In the event we do not successfully raise subsequent financing, our product development activities will necessarily be curtailed commensurate with the magnitude of the shortfall. If our product development activities are slowed or stopped, we would be unable to meet the timelines and projections outlined in this filing. Failure to progress our product candidates as anticipated will have a negative effect on our business, future prospects, and ability to obtain further financing on acceptable terms, if at all, and the value of the enterprise.

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 Securities and Exchange Commission ("SEC"), and the rules of any stock exchange on which we may become 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. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees or as executive officers.

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, which could have an adverse effect on the market price of our stock.

Risks Relating to Acquisitions

Acquisitions, investments and strategic alliances that we may make in the future may use significant resources, result in disruptions to our business or distractions of our management, may not proceed as planned, and could expose us to unforeseen liabilities.

We may seek to expand our business through the acquisition of, investments in and strategic alliances with companies, technologies, products, and services. Acquisitions, investments and strategic alliances involve a number of special problems and risks, including, but not limited to:

- difficulty integrating acquired technologies, products, services, operations and personnel with the existing businesses;
- diversion of management's attention in connection with both negotiating the acquisitions and integrating the businesses;
- strain on managerial and operational resources as management tries to oversee larger operations;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;
- exposure to unforeseen liabilities of acquired companies;
- potential costly and time-consuming litigation, including stockholder lawsuits;
- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our common stock or which may have a dilutive effect on our stockholders;
- risk of loss of invested capital;
- the need to incur additional debt or use cash; and
- the requirement to record potentially significant additional future operating costs for the amortization of intangible assets.

As a result of these or other problems and risks, businesses we acquire may not produce the revenues, earnings, or business synergies that we anticipated, and acquired products, services, or technologies might not perform as we expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We may not be able to successfully address these problems and we cannot assure you that the acquisitions will be successfully identified and completed or that, if acquisitions are completed, the acquired businesses, products, services, or technologies will generate sufficient revenue to offset the associated costs or other negative effects on our business.

Any of these risks can be greater if an acquisition is large relative to our size. Failure to effectively manage our growth through acquisitions could adversely affect our growth prospects, business, results of operations, financial condition and cash flows.

Risks Relating to Our Intellectual Property

Our success depends upon our ability to protect our intellectual property and proprietary technologies, and the intellectual property protection for our product candidates depends significantly on third parties.

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection in the United States and other countries with respect to our product candidates or any future product candidate that we may license or acquire, 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 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. 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. If any of our licensors or partners fails to appropriately prosecute and maintain patent protection for these product candidates, our ability to develop and commercialize these product candidates 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 these product candidates could have a material adverse effect on our financial condition and results of operations.

Currently, the composition of matter patent and several method of use patents for TG-1101 and TGR-1202 in various indications and settings have been applied for but have not yet been issued, or have been issued in certain territories but not under all jurisdictions in which such applications have been filed. While composition of matter patents have been granted in the United States for TG-1101 and TGR-1202, no patents to date have been issued for our IRAK4 inhibitor, BET inhibitor, BTK inhibitor and anti-PD-L1 and anti-GITR programs. There can be no guarantee that any of these patents for which an application has already been filed, nor any patents filed in the future for our product candidates will be granted in any or all jurisdictions in which there were filed, or that all claims initially included in such patent applications will be allowed in the final patent that is issued. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents.

These risks and uncertainties include the following:

- the patent applications that we or our partners file may not result in any patents being issued;
- 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 which have substantially greater resources than we do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate its ability to make, use, and sell our potential 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; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

If patents are not issued that protect our product candidates, it could have a material adverse effect on our financial condition and results of operations. 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. 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 the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and 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 laws of foreign countries may not protect our 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 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 United States 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 third-party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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 changes to transition from a “first-to-invent” system to a “first-to-file” system and 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.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. 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 United States 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 our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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 United States 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 sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect its rights. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, 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 any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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.

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 also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. 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. For example, Roche has the Cabilly patents in the United States that block the commercialization of antibody products derived from a single cell line, like TG-1101. Also, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the United States. While these patents have been challenged, to the best of our knowledge, those matters were settled in a way that permitted additional anti-CD20 antibodies to be marketed for CLL. If those patents are still enforced at the time we are intending to launch TG-1101, then we will need to either prevail in a litigation to challenge those patents or negotiate a settlement agreement with the patent holders. If we are unable to do so we may be forced to delay the launch of TG-1101 or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

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 candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our 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.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any collaborators of ours infringe their intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign its products or processes to avoid infringement;
- pay substantial damages, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- 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.

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 its 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 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, or our business could be harmed, possibly materially.

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 of day-to-day business operations. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging 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 patent 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 patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Furthermore, adverse results on United States patents may affect related patents in our global portfolio. The adverse result could also put related patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our 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 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to it.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Even if frivolous or unsubstantiated in nature, litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, day-to-day business operations, and the implicated employee(s).

Risks Relating to Our Finances and Capital Requirements

We will need to raise additional capital to continue to operate our business.

As of June 30, 2018, we had approximately $126.3 million in cash, cash equivalents, investment securities, and interest receivable, which in addition to the capital raised in the third quarter of 2018, will be sufficient to fund our planned operations into the fourth quarter of 2019. As a result, we will need additional capital to continue our operations beyond that time. 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 might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which would have a dilutive effect to stockholders.

Currently, none of our product candidates have been approved by the FDA or any foreign regulatory authority for sale. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand and amounts raised in future offerings or financings.

We have a history of operating losses, expect to continue to incur losses, and are unable to predict the extent of future losses or when we will become profitable, if ever.

We have not yet applied for or demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Our short operating history makes it difficult to evaluate our business prospects and consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical or biotechnology products. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of operations and the competitive environment in which we operate.

We have never been profitable and, as of June 30, 2018, we had an accumulated deficit of $440.5 million. We have generated operating losses in all periods since we were incorporated. We expect to make substantial expenditures resulting in increased operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We have not generated any revenue from our product candidates and may never become profitable.

Our ability to become profitable depends upon our ability to generate significant continuing revenues. To obtain significant continuing revenues, we must succeed, either alone or with others, in developing, obtaining regulatory approval for and manufacturing and marketing our product candidates (or utilize early access programs to generate such revenue). To date, our product candidates have not generated any revenues, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- successful completion of preclinical studies of our product candidates;
- successful commencement and completion of clinical trials of our product candidates and any future product candidates we advance into clinical trials;
- achievement of regulatory approval for our product candidates and any future product candidates we advance into clinical trials (unless we successfully utilize early access programs which allow for revenue generation prior to approval);
- manufacturing commercial quantities of our products at acceptable cost levels if regulatory approvals are obtained;
- successful sales, distribution and marketing of our future products, if any; and
- our entry into collaborative arrangements or co-promotion agreements to market and sell our products.

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

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

We will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals, and eventual commercialization. We anticipate that we will incur operating losses for the foreseeable future. We have based these estimates, however, on assumptions that may prove to be wrong, and we could expend our available financial resources much faster than we currently expect. Further, we will need to raise additional capital to fund our operations and continue to conduct clinical trials to support potential regulatory approval of marketing applications. Future capital requirements will also depend on the extent to which we acquire or in-license additional product candidates. We currently have no commitments or agreements relating to any of these types of transactions.

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

- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable under our license agreements;
- the costs and timing of regulatory approvals;
- the costs and timing of clinical and commercial manufacturing supply arrangements for each product candidate;
- the costs of establishing sales or distribution capabilities;
- the success of the commercialization of our products;
- 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.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings or licensing arrangements. To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing we enter into may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions.

In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of one or more of our product candidates.

Our tax position could be affected by recent changes in United States federal income tax laws.

On December 22, 2017, legislation commonly referred to as the "Tax Cuts and Jobs Act" was signed into law and is generally effective after December 31, 2017. The Tax Cuts and Jobs 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 Cuts and Jobs 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 United States federal income tax base. The Tax Cuts and Jobs 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 Cuts and Jobs Act on us and our affiliates, 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 Cuts and Jobs Act and any other regulatory or administrative developments and proposals, and their potential effects on them based on their unique circumstances.

Risks Related to Our Common Stock

We are controlled by current officers, directors and principal stockholders.

Our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 37% of our outstanding voting stock, including shares underlying outstanding options and warrants. Our directors, officers and principal stockholders, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

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 is likely 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:

- publicity regarding actual or potential clinical results relating to 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 our competitors or us;
- 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;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

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.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of your stock.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our stock in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

Certain anti-takeover provisions in our charter 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.

Provisions in our amended and restated certificate of incorporation and restated bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. 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.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

ITEM 6. EXHIBITS

The exhibits listed on the Exhibit Index are included with this report.

10.20	License Agreement between TG Therapeutics, Inc. and Novimmune S.A., dated June 18, 2018. *
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2018.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2018.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2018.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2018.
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders' Equity, (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements (filed herewith).

* Subject to a request for confidential treatment.

SIGNATURES

Pursuant to the requirements 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: August 9, 2018

By: /s/ Sean A. Power

Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

JOINT VENTURE AND LICENSE OPTION AGREEMENT

BY AND BETWEEN

TG THERAPEUTICS, INC.

AND

NOVIMMUNE S.A.

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

This JOINT VENTURE AND LICENSE OPTION AGREEMENT (the "Agreement") is entered into on June 18, 2018 (the "Effective Date") between **Novimmune SA**, a Swiss company having an address at 14 ch. des Aulx, 1228 Plan-Les-Ouates, Geneva, Switzerland ("NOVIMMUNE") and **TG Therapeutics, Inc.**, a Delaware corporation, with a place of business at 2 Gansevoort Street | 9th Floor, New York, NY, USA ("TGTX"). Novimmune and TGTX are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, NOVIMMUNE is a pharmaceutical company focused on the discovery and development of antibody-based drugs for the treatment of inflammatory diseases, immune-related disorders and cancer.

WHEREAS, TGTX is a biopharmaceutical company engaged in the development, manufacturing and marketing of pharmaceutical products directed toward the treatment of B-cell proliferative diseases;

WHEREAS, NOVIMMUNE and TGTX desire to establish a contractual Joint Venture (the "JV") with an aim for broad collaboration under this Agreement for the joint development and commercialization of the Product (as defined below) on a worldwide basis, for the treatment of B-cell proliferative diseases and such other indications as the Parties may jointly or unilaterally develop with TGTX serving as the primary responsible Party for the development, manufacturing and commercialization;

WHEREAS, TGTX will be responsible for the manufacture or will have manufactured clinical and commercial supplies of the Finished Product, in addition to the *g of ready-to-be-labelled Product initially supplied by NOVIMMUNE (the "Novimmune Initial Drug Supply") for use by TGTX according to the Development Plan, as described below;

WHEREAS, TGTX will be responsible for the development and commercialization of the Product in the Territory (see section 1.89) and the Parties shall share equally (subject to adjustment as more fully described in this Agreement) in the costs and expense of and in the profits resulting from marketing and sales of the Product in the Territory in accordance with the terms set forth below; and

WHEREAS, NOVIMMUNE desires to grant to TGTX exclusive rights to the Product for the joint development and commercialization of the Product, under this Agreement, and TGTX desires to obtain such rights for the joint development and commercialization of the Product in each case on the terms set forth below;

NOW THEREFORE, in consideration of the foregoing premises and mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

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* Confidential material redacted and filed separately with the Commission

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ARTICLE I. ARTICLE 1

SECTION 1.01 DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "Adverse Event" means any untoward medical occurrence in a human clinical trial subject or in a patient who is administered a Product, whether or not considered related to the Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease associated with the use of a Product, as defined more fully in 21 CFR §312.32.

1.2 "Affiliate" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

1.3 "Alliance Representative" has the meaning set forth in Section 2.4.

1.4 "Bulk API" means the Product in bulk form.

1.5 "Business Day" means any day other than (i) Saturday or Sunday or (ii) any other day on which banks in New York, New York, United States or Geneva, Switzerland are permitted or required to be closed.

1.6 "Cause" means, for purposes of Section 13.2(b), any failure of TGTX, following good-faith efforts, to get clearance from the appropriate Regulatory Authority to commence Phase 1 Clinical Trials under an active IND or CTA or any unfavorable result (interim or final) from a Clinical Trial (or non-clinical toxicology study) that, as reasonably determined by TGTX, causes material concerns regarding the tolerability, safety or effectiveness of the Product.

1.7 "Change of Control" means (i) the acquisition, directly or indirectly, by any person, entity or "group" (within meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) by means of a transaction or series of related transactions, of (a) beneficial ownership of fifty percent (50%) or more of the outstanding voting securities of a Party (or the surviving entity, as applicable, whether by merger, consolidation, reorganization, tender offer or other similar means), or (b) all, or substantially all, of the assets of a Party; or (ii) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of the Party immediately prior to such consolidation, merger or reorganization (or prior to any series of related transactions leading up to such event) own fifty (50%) or less of the surviving entity's voting power immediately after such consolidation, merger or reorganization

1.8 "Claims" has the meaning set forth in Section 11.1.

1.9 "Clinical Trial" means, collectively, any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, or Phase IV Clinical Trial using the Product, as applicable.

1.10 "CTA" means an application for Clinical Trial Authorization filed with a Regulatory Authority in the Territory to undertake clinical trials of an investigational new drug, the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in the Territory outside the U.S.

1.11 "Commercial Expenses" means those expenses incurred for the purpose of the Commercialization of the Finished Product which are consistent with the budget set forth in the Commercialization Plan and are specifically attributable to the Commercialization of Finished Products, and shall consist of (i) Cost of Goods Sold, (ii) Pre-Marketing Expenses, (iii) Marketing Expenses, (iv) Distribution Expenses, (v) Clinical Phase IV and Related Expenses, (vi) Regulatory Expenses, (vii) the Launch Expenses, (viii) Medical Science Liaison Expenses, and (ix) amounts paid to Third Party licensors as described in Section 8.4 (as such terms are defined in Exhibit H). Commercial Expenses shall exclude Development Expenses, even if incurred after the first commercial launch of a Finished Product, and shall exclude any costs that are deductible from Net Sales under the definition thereof (*e.g.*, distributor fees). For avoidance of doubt, any cost deducted in the calculation of Net Sales shall not be included in the calculation of the Commercial Expenses.

1.12 "Commercialization", with a correlative meaning for "Commercialize", means all activities undertaken before and after obtaining Regulatory Approval relating specifically to the pre-marketing, launch, promotion, marketing, sale, and distribution of a pharmaceutical product, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and product support; and (b) any Phase IV Clinical Trials, and (c) all customer support and Product distribution, invoicing and sales activities.

1.13 "Combination" shall mean a co-administration of Product combined with any other active pharmaceutical ingredient.

1.14 "Commercialization Plan" has the meaning set forth in Section 5.2(b).

1.15 "Confidential Information" means, with respect to a Party, all confidential Information of such Party that is disclosed to the other Party under this Agreement, which may include, but is not limited to specifications, know-how, trade secrets, legal information, technical information, drawings, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, in each case whether disclosed in oral, written, graphic, or electronic form. All Confidential Information disclosed by either Party pursuant to the Mutual Confidential Disclosure Agreement between the Parties dated February 15, 2018 shall be deemed to be such Party's Confidential Information disclosed hereunder.

1.16 "Control" means, with respect to any material, Information, or intellectual property right, that a Party owns or has a license to such material, Information, or intellectual property right and has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be first required hereunder to grant to the other Party such access, license, or sublicense.

1.17 "Detail" or "Detailing" means, with respect to the Product, the communication by a Sales Representative during a sales call (a) involving face-to-face contact, (b) describing in a fair and balanced manner the Regulatory Authority-approved indicated uses and other relevant characteristics of the Product, (c) using promotional materials in an effort to increase the prescribing and/or hospital ordering preferences of the Product for its approved indicated uses, and (d) made at such medical professional's office, in a hospital, at marketing meetings sponsored by a Party for the Product or other appropriate venues conducive to pharmaceutical product informational communication where the principal objective is to place an emphasis, either primary or secondary, on the Product with such medical professional.

1.18 "Develop" or "Development" means all activities relating to preparing and conducting preclinical testing, toxicology testing, human clinical studies and regulatory affairs for obtaining the Regulatory Approvals, process development for manufacture and associated validation, quality assurance and quality control activities (including qualification lots). Development shall exclude all Phase IV Clinical Trials.

1.19 "Development Budget" means the budget of Development Expenses expected to be incurred by the Parties in connection with the performance of the Development Plan.

1.20 "Development Expenses" means (i) any amounts payable by a Party for the Development or Manufacturing of Finished Product (excluding the cost of the NOVIMMUNE Initial Drug Supply), (ii) any amounts payable by a Party for obligation to a third party for non-clinical studies and Clinical Trials, (iii) the cost of supply of Finished Product or bulk API used for the Development of the Product as well as the freight, postage, shipping, transportation, insurance, warehousing and handling charges paid with regard to such Finished Product or Bulk API.

1.21 "Development Plan" means the plan for Development in the Territory. The initial Development Plan is attached hereto as Exhibit D and covers through the completion of the Phase I clinical study. Exhibit D may be from time to time added or modified by the Joint Steering Committee (JSC), as per section 2.2.

1.22 "Diligent Efforts" means, with respect to a Party's obligation under this Agreement to Develop or Commercialize a Product, the level of efforts and resources required to carry out such obligation in a sustained manner consistent with the efforts and resources a similarly situated biopharmaceutical company devotes to a product of similar market potential, profit potential or strategic value within its portfolio, based on conditions then prevailing i.e. it shall mean the efforts required in order to carry out a task or objective in a diligent and sustained manner without undue interruption, pause or delay, which level is at least commensurate with the level of efforts that a pharmaceutical company would devote to a product of similar potential and having similar commercial and scientific advantages and disadvantages as compared to the Product hereunder. Diligent Efforts requires (without limitation) that the Party exerting such efforts (i) promptly assign responsibility for its obligations to specific employee(s) or contractor(s) who are held accountable for progress and monitor such progress, on an ongoing basis, (ii) set and continue to seek to achieve specific and meaningful objectives for carrying out such obligations, and (iii) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives, in each case in a diligent manner.

1.23 "Dollar" means a U.S. dollar, and "$" shall be interpreted accordingly.

1.24 "EMA" means the European Medicines Agency, or any successor thereto, which is responsible for coordinating the centralized system for Regulatory Approval of pharmaceutical products in the European Union and the European Economic Area and recommending to the European Commission (the "EC") that the EC grant Regulatory Approval of certain pharmaceutical products in the EU and EEA under such centralized system.

1.25 "European Union" or "EU" means all of the European Union member states as of the applicable time during the Term.

1.26 "FDA" means the U.S. Food and Drug Administration or its successor.

1.27 "FD&C Act" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.28 "Field" means the prevention, diagnosis, treatment or amelioration of any disease or condition in humans or animals.

1.29 "Finished Manufacture" means the manufacture (and all reasonably necessary testing, including release and, as appropriate, stability testing) of Finished Product from Bulk API.

1.30 "Finished Product" means a Product that has been filled into vials, syringes or manufactured into other pharmaceutical presentations for administration; finished and labeled for use in clinical trials or for commercial purposes in accordance with the applicable specifications and legal requirements.

1.31 "Financial Force Majeure" shall mean any situation outside of either Party's control that causes either Party to be unable to raise capital to continue the Development of the Product for some period of time, including without limitation, poor financing environment for biotech companies, product failure or delay or any similar factors forcing a delay in appropriate financing for either Party.

1.32 "First Commercial Sale" means, with respect to a particular country, the first sale to a Third Party of the Product in such country after Regulatory Approval has been obtained in such country.

1.33 "Fiscal Year" means the twelve (12)-month period commencing on January 1 of a given year and ending on December 31 of the same year.

1.34 "Biosimilar Product" means a biologic product that (i) is highly similar to the active ingredient in the Product where the Product is the reference-listed biologic, and (ii) is approved by a Governmental Authority pursuant to a Biosimilar License Application an application under 42 U.S.C. §262(k), or similar application.

1.35 "Good Clinical Practices" or "GCP" means the then-current good clinical practice standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA, and comparable regulatory standards, practices and procedures in jurisdictions outside the U.S., in each case as they may be updated from time to time.

1.36 "Good Laboratory Practices" or "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards in jurisdictions outside the U.S., in each case as they may be updated from time to time.

1.37 "Good Manufacturing Practices" or "GMP" means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical and biological materials, and comparable Laws applicable to the manufacture and testing of pharmaceutical and biological materials in jurisdictions outside the U.S., including without limitation 21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals) and the guideline promulgated by the International Conference on Harmonization designated ICH Q7A, entitled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and associated guidelines and regulations, in each case as they may be updated from time to time.

1.38 "Governmental Authority" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.39 "IND" means (a) an Investigational New Drug application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA or any successor application or procedure required to initiate clinical testing of a Product in humans in the Territory; and (b) all supplements and amendments to the foregoing.

1.40 "IND/CTA Filing Conditions" means the delivery to TGTX by Novimmune of all the data and reports necessary and required to file an IND in the United States, with the exception of the Investigator's Brochure. The Parties will work together diligently to ensure that all such data and reports are indeed delivered to TGTX, including a reasonable search by Novimmune of specific items believed to be in the possession of Novimmune at the request of TGTX.

1.41 "IND/CTA Filing Deadline" means the date that is the greater of twelve months from the Effective date or six months from the delivery of the thirteen week toxicity report, subject to a reasonable extension of up to an additional twelve months in the discretion of the JSC.

1.42 "Information" means any data, results, technology, business information, and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

1.43 "Internal Expenses" means any costs for employees, overhead, or other internal handling incurred by a Party.

1.44 "Joint Know-How": shall mean all Know-How developed or acquired by either Party in performing its obligations pursuant to this Agreement that is necessary or useful for the Development, manufacture or Commercialization of the Product.

1.45 "Joint Steering Committee" or "JSC" means the committee formed by the Parties as described in Section 2.2.

1.46 "Joint Inventions" has the meaning set forth in Section 9.1.

1.47 "Joint Patent" has the meaning set forth in Section 9.3(c).

1.48 "Laws" means all relevant laws, statutes, rules, regulations, guidelines having the binding effect of law, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.49 "License Options" shall collectively refer to the TGTX License Option and to the NOVIMMUNE License Option.

1.50 "Major Market(s)": shall mean any of the following countries or groups of countries: (i) the *; (ii) *; (iii) *, *, *, *, and the * (each, a " * "); (iv) *; and (v) *, * or * (each, a " * ").

1.51 "Manufacturing Costs" shall mean Manufacturing Development Expenses plus any costs incurred by TGTX to supply clinical trial material and commercial supply (excluding the cost of the Novimmune Initial Drug Supply).

1.52 "Manufacturing Development" means any of the following with respect to Bulk API or Finished Product: manufacturing process development and validation, process improvements, associated analytical development and validation and the manufacture and testing of clinical and stability or consistency lots (including process development, qualification, QA, and test batches).

1.53 "Manufacturing Development Expenses" means any costs incurred by a Party to a Third Party after the Effective Date for the Manufacturing Development.

1.54 "Marketing Authorization Application" or "MAA" means an application for Regulatory Approval (but excluding Pricing Approval) in any particular jurisdiction other than the U.S.

1.55 "Minimum Phase 1 Patients" shall mean the lesser of (i) * patients enrolled into the Phase I Clinical Trial or (ii) the maximum number of patients that are enrolled at the time the quantity of ready-to-be-labeled Product that NOVIMMUNE has supplied runs out.

1.56 "BLA" means a "Biologics License Application" (as more fully defined in 21 C.F.R. 601 *et seq.*) filed with the FDA or the equivalent application filed with any other Regulatory Authority to obtain Regulatory Approval for a Product in a country or jurisdiction in the Territory.

1.57 "Net Sales" means, with respect to a particular time period, the total amounts received or invoiced by TGTX and its Affiliates and Subcontractors for sales of Finished Product made during such time period to unaffiliated Third Parties, less the following deductions to the extent actually allowed or incurred with respect to such sales:

(a) discounts, including cash, trade, and quantity discounts, retroactive price reductions, charge-back payments, and rebates actually granted or administrative fees actually paid to trade customers, patients (including those in the form of a coupon or voucher), managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, federal, state, or local government and the agencies, purchasers and reimbursers of managed health organizations, pharmaceutical benefit managers, group purchasing organizations, or federal, state or local government;;

(b) credits or allowances actually granted upon prompt payment or losses actually incurred as a result of damaged goods, rejections or returns of such Product, including in connection with recalls, and all other reasonable and customary allowances and adjustments actually credited to customers.

(c) packaging, freight, postage, shipping, transportation, warehousing, handling and insurance charges, credit card processing fees and any customary payments with respect to the Products actually made to wholesalers or other distributors, in each case actually allowed or paid for distribution and delivery of Product, to the extent billed or recognized; and

(d) taxes, including sales taxes, excise taxes, value-added taxes, and other taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of such Product, including, without limitation, value-added and sales taxes.

Notwithstanding the foregoing, amounts received or invoiced by TGTX and its Affiliates, and Subcontractors for the sale of Finished Product among TGTX, its Affiliates and Subcontractors shall not be included in the computation of Net Sales hereunder. In any event, any amounts received or invoiced by TGTX and its Affiliates, or their Subcontractors shall be accounted for only once. Net Sales shall be accounted for in accordance with US Generally Accepted Accounting Principles ("GAAP") consistently applied. Net Sales shall exclude any samples of Product transferred or disposed of at no cost for promotional or educational purposes, and the cost for such samples transferred or disposed of shall be deemed to be included in the Commercial Expenses.

Further, the Parties agree to negotiate in good faith for an equitable determination of the Net Sales of the Product in the event TGTX or its Affiliates or its Subcontractors sells the Product in such a manner that gross sales of the Product are not readily identifiable (*e.g.*, for Product to be sold as a Combination product or bundling with other products). In addition, for purposes of this Agreement, "sale" shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of Product at no charge for academic research, preclinical, clinical, or regulatory purposes (including the use of a Product in Clinical Trials) or in connection with patient assistance programs or other charitable purposes or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry and/or which is reasonably proportional to the market for such Product).

1.58 " "Patents" means (a) pending patent applications, including provisional patents, issued patents, utility models and designs; and (b) extensions, reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, requests for continued examination, continuations-in-part, or divisions of or to any patents, patent applications, utility models or designs.

1.59 "Patent Term Extension" means any term extensions, supplementary protection certificates and equivalents thereof offering patent protection beyond the initial term with respect to any issued patents.

1.60 "Patient" means any subject enrolled into any Phase I, II, or III Clinical Trial and administered at least one dose of the Product.

1.61 "Phase I Clinical Trial" means a small scale trial of a pharmaceutical product on subjects that generally provides for the first introduction into humans of such product with the primary purpose of determining safety, metabolism and pharmacokinetic properties, clinical pharmacology and any other properties of such product as per the study protocol design, as required by 21 C.F.R. 312(a) or a similar study in other countries.

1.62 "Phase II Clinical Trial" means a small scale clinical trial of a pharmaceutical product on patients, including possibly pharmacokinetic studies, the principal purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain sufficient information about such product's efficacy to permit the design of further clinical trials, as required by 21 C.F.R. 312(b) or a similar study in other countries.

1.63 "Phase III Clinical Trial" means one or more clinical trials on sufficient numbers of patients, which trial(s) are designed to (a) establish that a drug is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed; and (c) support Regulatory Approval of such drug, as required by 21 C.F.R. 312(c) or a similar study in other countries.

1.64 "Phase IV Clinical Trial" means a clinical trial of a Product, possibly including pharmacokinetic studies, which trial is (a) not required in order to obtain Regulatory Approval; (b) required by the Regulatory Authority as mandatory to be conducted on or after the Regulatory Approval, and (c) conducted voluntarily by a Party to enhance marketing or scientific knowledge of the Product (*e.g.*, providing additional drug profile, safety data or marketing support information, or supporting expansion of Product Labeling) or conducted due to a request or requirement of a Regulatory Authority.

1.65 "Pivotal Data" shall mean results from any Phase II Clinical Trial or Phase III Clinical Trial that is designed to form the primary basis to support Regulatory Approval for the Product.

1.66 "Pivotal Trial" shall mean any Phase II Clinical Trial or Phase III Clinical Trial designed to yield Pivotal Data.

1.67 "P/L Share Percentage" shall be the percentage that each Party contributes to Development Expenses and Commercial Expenses and shares in Product Profit/Loss, pursuant to Section 3.4(a) and Section 8.2.

1.68 "Pricing Approval" means such approval, agreement, determination or governmental decision establishing prices for the Product that can be charged to consumers and shall be reimbursed by Governmental Authorities in regulatory jurisdictions where the Governmental Authorities or Regulatory Authorities approve or determine pricing of pharmaceutical products for reimbursement or otherwise.

1.69 "Product" means a pharmaceutical preparation in any formulation that contains the anti-CD47/anti-CD19 bispecific antibody, NI-1701 (whose sequence is depicted in Exhibit C), or any antibody sequence that shares at least * % or greater sequence identity to all the complementarity determining regions (CDRs) in the sequence in Exhibit C, as an active ingredient.

1.70 "Product Infringement" has the meaning set forth in Section 9.5(b).

1.71 "Product Labeling" means (a) the full prescribing information for the Product approved by the applicable Regulatory Authority, and (b) all labels and other written, printed or graphic information included in or placed upon any container, wrapper or package insert used with or for the Product.

1.72 "Product Profit/Loss" means the profits or losses resulting from the Commercialization of the Product in the Territory and shall be equal to Net Sales of the Product in the Territory less Commercial Expenses. For avoidance of doubt, any cost deducted in the calculation of Net Sales shall not be included in the calculation of the Commercial Expenses.

1.73 "Regulatory Approvals" means all approvals (including without limitation supplements, amendments, and Pricing Approvals), licenses, registrations or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the manufacture, storage, import, transport, distribution, marketing, use or sale of a pharmaceutical product in a given regulatory jurisdiction.

1.74 "Regulatory Authority" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including without limitation, in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over the Product, and, in the European Union, the EMA and any other applicable Governmental Authority having jurisdiction over the Product.

1.75 "Regulatory Materials" means regulatory applications, submissions, notifications, registrations, Regulatory Approvals or other submissions made to or with a Regulatory Authority that are necessary or reasonably desirable in order to develop, manufacture, market, sell or otherwise commercialize the Product in a particular country, territory or possession. Regulatory Materials include, without limitation, INDs, CTAs and MAAs, BLAs, and amendments and supplements for any of the foregoing, and applications for Pricing Approvals.

1.76 "NOVIMMUNE Know-How": shall mean (i) all Know-How that is Controlled by NOVIMMUNE or its Affiliates on the Effective Date and during the Term, and (ii) NOVIMMUNE'S interest in any Joint Know-How, in each case that is necessary or useful for the Development, manufacture or Commercialization of the Product. For clarity, NOVIMMUNE Know-How excludes the NOVIMMUNE Patents.

1.77 "NOVIMMUNE License Option" means the one time option that NOVIMMUNE has to supplant this Agreement with a Licensing Agreement in favor of TGTX in a form as substantially shown in Exhibit F (attached hereto), and as further described in Section 6.3, below.

1.78 "NOVIMMUNE Product Patent" means any Patent, including NOVIMMUNE'S interest in any Joint Patent, that (a) is Controlled by NOVIMMUNE or its Affiliates at any time during the Term, and (b) specifically claims the Product or its specific manufacture or specific use. The list of NOVIMMUNE Product Patents as of the Effective Date is attached hereto as Exhibit B(1), and shall be from time to time amended and updated during the Term to incorporate the then-current NOVIMMUNE Product Patents.

1.79 "NOVIMMUNE Platform Patent" means any Patent, including NOVIMMUNE'S interest in any Joint Patent, that (a) is Controlled by NOVIMMUNE or its Affiliates at any time during the Term, and (b) generically claims the Product or its manufacture or use, or any other invention that is otherwise necessary for the Development, Finished Manufacture or Commercialization of the Product. The list of NOVIMMUNE Platform Patents as of the Effective Date is attached hereto as Exhibit B(2), and shall be from time to time amended and updated during the Term to incorporate the then-current NOVIMMUNE Platform Patents.

1.80 "NOVIMMUNE Technology" means the NOVIMMUNE Platform Patents and NOVIMMUNE Know-How.

1.81 "Sales Representative" means a pharmaceutical sales representative conducting Detailing and other promotional efforts with respect to the Product, including through a contract sales organizations.

1.82 "Subcontractor": means a Third Party service provider engaged by TGTX to perform contract services on behalf of TGTX or its Affiliates, where TGTX retains a meaningful participatory role in the overall development and commercialization of the Product (*e.g.*, contract research or development organizations, clinical sites performing clinical trials, universities and scientific institutes, distributors in certain countries in the Territory, or contract manufacturing organizations).

1.83 "Sole Inventions" has the meaning set forth in Section 9.1.

1.84 "Territory" means worldwide.

1.85 "TGTX Know-How": shall mean (i) all Know-How that is Controlled by TGTX or its Affiliates on the Effective Date and during the Term, and (ii) TGTX's interest in the Joint Know-How, in each case that is necessary or useful for the Development, manufacture or Commercialization of the Product. For clarity, TGTX Know-How excludes TGTX Patents.

1.86 "TGTX Patent" means any Patent, including TGTX's interest in any Joint Patent, that (a) is Controlled by TGTX or its Affiliates at any time during the Term, and (b) claims the Product or its manufacture or use, or any invention that is otherwise necessary for the Development, Finished Manufacture or Commercialization of the Product. The list of TGTX Patents as of the Effective Date is attached hereto as Exhibit B, and shall be from time to time amended and updated during the Term to incorporate the then-current TGTX Patents.

1.87 "TGTX Technology" means the TGTX Patents and TGTX Know-How.

1.88 "Term" means the term of this Agreement, as determined in accordance with Article 13.

1.89 "Third Party" means any entity other than NOVIMMUNE or TGTX or an Affiliate of either of them.

1.90 "TGTX License Option" means the one time option that TGTX has to supplant this Agreement with a Licensing Agreement in favor of TGTX in a form as substantially shown in Exhibit F (attached hereto), and as further described in Section 6.2, below.

1.91 "U.S." means the United States of America and its possessions and territories.

1.92 "Valid Claim" means (a) any claim of an issued unexpired patent that (i) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, and (ii) is not lost through an interference proceeding that is unappealable or unappealed within the time allowed for appeal; or (b) provided there is no Biosimilar Product available in the market, a claim of a pending Patent application, which claim has not been abandoned or finally disallowed without the possibility of appeal or which has not been pending for more than * years from its filing date.

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* Confidential material redacted and filed separately with the Commission.

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ARTICLE II. ARTICLE 2

SECTION 2.01 MANAGEMENT

Collaboration Overview. The Parties desire and intend to form this JV to collaborate with respect to the Development and Commercialization of the Product as a single agent and/or as a Combination in the Territory, as and to the extent set forth in this Agreement in two steps: (i) the First Step shall be from the date hereof up to the start of a Phase III Clinical Trial, i.e. first patient dosed, and (ii) the Second Step being the continuation of the JV, unless and until one of the Parties exercises its License Option (as set forth in Article 6). During the First Step, TGTX shall carry-out the activities set forth in Exhibit D at its own cost and expense under the supervision and guidance of the JSC. Following the completion of the First Step and prior to either Party exercising its License Option, the Parties shall participate in the joint development of the Product as set forth in this Agreement, including sharing of Development and Commercial Expenses incurred in connection with the performance of the Development Plan in accordance with Article 3.

TGTX shall be responsible for obtaining and maintaining Regulatory Approval of the Product in the Territory. TGTX also shall be responsible for Commercializing the Product in the Territory and share Product Profits/Losses based on each Party's P/L Share Percentage.

2.1 Commitment to Development and Commercialization. Each Party agrees and acknowledges that, by entering into this Agreement, it shall fund, as and to the extent set forth in this Agreement, the Development Expenses and Commercial Expenses, and shall use Diligent Efforts to conduct the activities assigned to such Party in this Agreement and in the Development Plan, with the JSC overseeing the implementation of such plan.

2.2 Joint Steering Committee.

(a) Formation and Role. The Parties hereby establish a Joint Steering Committee (sometimes referred to hereinafter as "JSC") that shall monitor and coordinate communication regarding the Parties' performance under this Agreement to Develop, obtain Regulatory Approval for and Commercialize the Product. The role of the JSC shall be:

(i) to discuss and agree upon the Development Plan and Commercialization Plan, and any proposed changes or amendments thereto that are not inconsistent with this Agreement;

(ii) to review the overall strategy for Developing and seeking Regulatory Approval for, manufacturing of, and Commercializing the Product in the Territory;

(iii) to facilitate the exchange of information between the Parties with respect to the activities hereunder for the Territory and to establish procedures for the efficient sharing of information and materials necessary for each Party's Development, Product Development and Commercialization of the Product hereunder, consistent with this Agreement;

(iv) to review the plan and the summary budget for the Development with respect to the applicable countries in the Territory and provide comments regarding the content and implementation of such plans;

(v) to monitor the Parties' performance against the then-current Development Plan and Commercialization Plans;

(vi) to inform the other Party of up-coming material internal events and decisions related to the Product and its Development;

(vii) to discuss material submissions to FDA and any other Regulatory Authorities;

(viii) to create subcommittees as the JSC may find necessary or desirable from time to time for implementation of the Development and Commercialization hereunder;

(ix) to oversee the activities of subcommittees created under this Agreement, and to seek to resolve any issues that such subcommittees cannot resolve;

(x) to provide a forum to evaluate strategies for obtaining, maintaining and enforcing patent and trademark protection for the Product in the Territory; and

(xi) to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties.

(b) Powers. The JSC shall have only the powers assigned expressly to it in this Article 2 and elsewhere in this Agreement. The JSC shall not have any power to amend, modify or waive compliance with this Agreement.

(c) JSC Membership. Each Party shall have an equal number of representatives on the JSC, who initially shall be * (*) individuals. The JSC may change its size from time to time by mutual consent of the Parties, provided that the JSC shall at all times consist of an equal number of representatives of each of Party. Either Party may designate substitutes for its representatives if * (*) or more of such Party's designated representatives are unable to be present at a meeting. From time to time each Party may replace its representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). TGTX shall select * (*) of its representatives as the initial chairperson of the JSC. The chairperson shall be responsible for (i) calling meetings, and (ii) preparing and circulating an agenda for the upcoming meeting, but shall have no special authority over the other members of the JSC, and shall have no additional voting rights.

2.3 JSC Meetings, Decisions and Actions.

(a) Meetings. The JSC shall hold at least * (*) meetings per year during the First Step and * (*) meetings per year during the Second Step (at least * (*) of which shall be held in person) on such dates at such times each year as it elects. Meetings of the JSC shall be effective only if at least * (*) representatives of each Party are present or participating. Each Party shall bear the expense of its respective members' participation in JSC meetings. The Chairperson of the JSC shall be responsible for preparing and issuing minutes of each such meeting within * (*) days thereafter. Such minutes shall not be finalized until each Party reviews and confirms the accuracy of such minutes in writing; provided that any minutes shall be deemed approved unless a member of the JSC objects to the accuracy of such minutes within * (*) days after the circulation of the minutes by the Chairperson. With the prior consent of both Parties' representatives (such consent not to be unreasonably withheld or delayed), other representatives of each Party or Third Parties involved with the Products may attend meetings as nonvoting participants, subject to appropriate agreements of confidentiality. All final JSC minutes must be signed by both Parties.

(b) Decision Making. Except as expressly provided in this Section 2.3, actions to be taken by the JSC shall be taken only following * vote during the Second Step, with each Party having * (*) vote, with the caveat that during the First Step, in the event of disagreement, * shall have the final decision.

(c) Disputes. If the members of the JSC cannot reach a unanimous decision with respect to matters delegated to it under this Article 2 for a period in excess of * (*) days from the discussion at the JSC, unless the Parties agree to prolong such time period, the matter shall be referred to * appropriately qualified senior executive officers of the Parties, who shall attempt resolution by good faith negotiations for at least * (*) days after such referral. If the senior executive officers designated by the Parties are not able to resolve such dispute within such * (*) day period, then such dispute shall be finally decided by an independent advisory board to the JSC, the members of which shall be agreed upon by both Parties at the time of the dispute. Notwithstanding anything else to the contrary herein, any decision with respect to the Development Plan or the Commercialization Plan that disproportionately allocates a burden to or disproportionately limits the profits of one Party relative to the other Party (e.g., one Party is required to bear more than * % of the cost) shall not be made without the consent of the disproportionately burdened Party.

(d) Location of in-person meetings. Meetings to be held in person shall be held either (i) in a US city which is hosting a medical conference that the Parties are otherwise attending or (ii) alternating between home cities of each of the Parties.

2.4 Alliance Representative. Each Party will appoint an appropriate employee to facilitate communication and coordination of the Parties' activities under this Agreement relating to the Product and to provide support and guidance to the JSC (each, an "Alliance Representative"). From time to time each Party may replace its Alliance Representative by prior written notice to the other Party specifying the replacement.

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ARTICLE III. ARTICLE 3

SECTION 3.01 CLINICAL AND NON-CLINICAL PRODUCT DEVELOPMENT

Overview. TGTX shall Develop the Product in the Territory as provided in this Article 3 and in accordance with the then-current Development Plan. The initial Development Plan sets forth the Development activities to be performed by TGTX under this Agreement during the First Step and, for which the Development plan up to the end of Phase I is attached hereto as Exhibit D. Within * days following the completion of Phase I, TGTX shall provide the JSC with an updated Development Plan and any future updates thereof shall be submitted to the JSC for review and approval in accordance with Article 2.

3.1 Development Plan. The initial Development Plan through end of Phase I has been agreed upon by the Parties and is attached hereto as Exhibit D and incorporated herein by reference. TGTX will be responsible for conducting the activities in the Development Plan. Upon the completion of Phase I, the Development Plan will be updated and presented to the JSC and shall contain the following information for the Product, to the extent such information is available:

(a) the proposed overall plan for further Development for the Product to support Regulatory Approval in the *, * and *;

(b) the Development Budget, which shall include a * (*)-year rolling budget of Development Expenses (including a detailed budget for the first year thereof and an estimated budget for the subsequent year based on the then-current Development Plan);

(c) scope and target timelines for the Parties' performance of all Clinical Trials and activities within the Development, including without limitation, clinical trial protocols, additional preclinical tests (including any and all carcinogenicity and toxicology studies), Finished Product stability studies, enrollment numbers and submission dates; and

(d) TGTX forecast for clinical supply of such Finished Product and/or Bulk API.

3.2 Updates to Development Plan and Development Budget. The JSC shall review the Development Plan on an ongoing basis and may update the Development Plan as the JSC determines consistent with article 2 hereof. As early as necessary in each year, beginning with the first full Fiscal Year after the completion of the First Step, the JSC shall update and prepare the Development Plan and Development Budget for the Product for the following Fiscal Year to take into account completion, commencement or cessation of Development activities not contemplated by the then-current Development Plan, and submit such proposed Development Plan to the JSC no later than November 1 of such year. The JSC shall endeavor to finalize the updated *, * and * Development Plans by December 15 of each year. As necessary throughout the Fiscal Year, the JSC shall review the Development Plan and any changes thereto proposed by either Party through the JSC, and the JSC shall decide on such changes as set forth in Article 2 hereof.

3.3 Development Expenses.

(a) The Parties shall share any and all Development Expenses as follows:

(i) During the First Step, all expenses and activities are the responsibility of *, as per the Development Plan described in Exhibit D, and subsequent activities required to complete the First Step;

(ii) After the First Step, total Development Expenses shall be borne based on each Parties P/L Share Percentage;

The initial P/L Share Percentages of the Parties are as follows:

TGTX: * %

NOVIMMUNE: * %

If either party fails to pay their proportionate share of Development Expenses and Commercial Expenses prior to First Commercial Sale, then the P/L Share Percentages shall be adjusted as set forth herein in Sections 3.3(a)(vi). The adjustment of such Party's P/L Share Percentages shall be the sole remedy for such failure.

(iii) Each Party shall calculate and maintain records of all relevant Development Expenses incurred by it for the Development of the Product, in accordance with procedures to be agreed upon between the Parties. The Parties understand and agree that Internal Expenses shall not be shared, subject to Section 3.3(a)(vii).

(iv) Within * (*) Business Days following the end of each calendar quarter, * shall submit to * a written report setting forth in reasonable detail the Development Expenses it has incurred in such calendar quarter. Within * (*) Business Days following the end of each calendar quarter, * shall submit to * a written report setting forth in reasonable detail the Development Expenses it has incurred in such calendar quarter.

(v) Within * (*) Business Days following the end of each calendar quarter, * shall submit to * a written report setting forth in reasonable detail the calculation of all Development Expenses for the Product, and the calculation of any net amount owed by NOVIMMUNE to TGTX or by TGTX to NOVIMMUNE, as the case may be, in order to ensure the appropriate sharing of Development Expenses in accordance with the provisions of Section 3.3(a) (ii). The net amount payable shall be paid to the other Party, as the case may be, within * (*) days following the receipt of the written report; provided, that, in the event of a dispute, any amounts not in dispute shall be paid and the disputing Party shall provide written notice without undue delay after receipt of the written report in question to the other, specifying such dispute and explaining the basis of the dispute. The Parties shall promptly thereafter meet and negotiate in good faith a resolution to such dispute and, promptly upon resolution of such dispute, the applicable Party shall make the agreed-upon payment. If such dispute is not resolved within * (*) days after delivery of a notice of dispute with respect thereto to the other Party, the disputing Party may audit the other Party in accordance with the provisions of Section 8.7. For clarity, nothing in this Section 3.3(a) (v) shall serve to limit a Party's ability to seek recourse for billing errors discovered after payment is made.

(vi) If hereunder, either Party fails to contribute their portion of the Development Expenses or Commercial Expenses, such Party's P/L Share Percentage shall be reduced pro rata to the extent of the Development Expenses or Commercial Expenses that they do not fund as a percentage of the cumulative Development Expenses and Commercial Expenses to date, however, in no event shall NOVIMMUNE'S P/L Share Percentage be reduced below * %. In the event of failure to pay allocated Development Expenses or Commercial Expenses on time as set forth above, each party shall be afforded * (*) months to make a catch-up payment. However, upon receipt of Pivotal Data for the Product and any time thereafter, no catch-up payments will be allowed by either Party.

(vii) The Parties acknowledge and agree that Internal Expenses * be reimbursed or shared except as set forth in this Section 3.3(a). However, in connection with the Development, either Party may refer to the JSC to provide certain specified Development activities using internal resources as opposed to out-sourcing such activity to a Third Party and to include such Internal Expenses as the Development Expenses to be shared hereunder. Any such referral shall include a sufficiently detailed description of the proposed Development activities, the associated Internal Expenses, and, where possible, the costs and expenses to be paid to Third Party contractors if the same Development activities were contracted out to them. If the JSC approves (which approval shall not be unreasonably withheld) such Internal Expenses as the Development Expenses, then the proposing Party shall obtain reimbursement as the Development Expenses for the Internal Expenses actually incurred (in an amount not to exceed any approved amount) in performing such Development activities for the Product.

(b) Any reimbursement payments made pursuant to this Section 3.3 shall be subject to the general payment procedures set forth in Sections 8.5 and 8.6.

3.4 Performance; Diligence.

(a) Each Party shall devote Diligent Efforts to the Development of the Product consistent with the then-current Development Plan and in accordance with this Agreement.

(b) Without limiting the generality of Section 3.4(a), TGTX shall devote Diligent Efforts to obtaining Regulatory Approval of the Product in the Territory.

(c) TGTX shall conduct its Development activities under this Agreement in a good scientific manner and in compliance with all applicable Laws, including without limitation applicable GCP, GLP, and GMP.

3.5 Records, Reports and Information. Each Party shall maintain complete, current and accurate records of all work conducted by it under the Development Plan and all data and other Information resulting from such work. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development Plan in sufficient detail and in a good scientific manner appropriate for patent and regulatory purposes. Each Party shall have the right to review such records maintained by the other Party at reasonable times, upon written request. Each Party shall provide written reports in English to the JSC on its Development and regulatory activities with the Product pursuant to the Development Plan on a * basis at the end of each calendar * , at a level of detail reasonably sufficient to enable the other Party to determine the reporting Party's compliance with its Diligent Efforts obligation pursuant to Section 3.4.

3.6 Manufacturing Development.

(a) Duties. * shall be responsible for the Manufacturing Development for the Bulk API and Finished Product, (except with regard to the Novimmune Initial Drug Supply), itself or through a Third Party contract manufacturer.

(b) Comparator Drugs. * shall be responsible for procuring all comparator drugs or placebos necessary for conducting non-clinical studies and Clinical Trials and the cost of these agents up to the end of the First Step. After which, the costs and expenses related to the Comparator Drugs or placebos for the Development shall be included in the Development Expenses.

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ARTICLE IV. ARTICLE 4

SECTION 4.01 REGULATORY MATTERS

4.1 Transfer of Data and Regulatory Materials.

(a) Existing Data. Within * (*) of the Effective Date, NOVIMMUNE shall provide copies of all preclinical, non-clinical data and manufacturing reports (Exhibit G), for Product as a single agent, relevant to an IND or CTA submission. * shall have the full right, without any additional consideration, to use any and all such data and reports to support collaborations on their bispecific antibody platform using their anti-CD47 platform arm. * shall have the full right on behalf of JV, without any additional consideration, to use any and all such data and reports in connection with the Development and/or Commercialization of the Product in the Territory, including the incorporation of such data or reports in any regulatory submissions, including MAA and BLA submissions.

(b) Future Data. Novimmune shall, in a timely manner and compliant with requirements of the FDA, the EMA, and any other applicable Regulatory Authority, provide to TGTX copies of all preclinical, non-clinical, analytical, manufacturing, and clinical data relating to the Product either as single agent or in Combination, generated by or on behalf of Novimmune that is related to the Product. TGTX shall provide to Novimmune all completed clinical study reports and Novimmune shall have the right to use these reports solely for the purposes of decision making on Novimmune other programs. Novimmune will treat these reports as TGTX Confidential Information. TGTX shall have the full right, without any additional consideration, to use any and all such data and reports in connection with the Development and/or the Commercialization of the Product in the Territory, including the incorporation of such data or reports in any regulatory submissions including MAA and/or BLA submissions.

4.2 Regulatory Submissions and Approvals.

(a) In General. The Parties intend to seek Regulatory Approval in the first instance in the * , * and * thereafter the remainder of the Territory wherein the JSC determines it is worthwhile to Develop and Commercialize the Product. Subject to the terms of this Article 4:

(i) *, in consultation with JSC, shall be responsible for assembling, submitting and maintaining any source regulatory submission components and compiled submissions of the Regulatory Materials to be used in support of Regulatory Approval for the Product in the Territory in accordance with such regulatory strategy, including without limitation BLAs, MAAs and associated documents;

(1) * shall have primary responsibility for providing components of Regulatory Materials relating to Bulk API and Finished Product in support of Regulatory Approval;

(2) * shall have primary responsibility for providing the content of Regulatory Materials relating to clinical data supporting Regulatory Approval;

(ii) *, in consultation with JSC, shall be primarily responsible for preparing and submitting to Regulatory Authorities INDs, CTAs and all associated submissions (*e.g.*, IMPDs, safety alerts, protocol submissions, etc.) for the Product and for carrying out clinical protocols in support of Regulatory Approval in the Territory under said INDs and CTAs in the *, * and * in accordance with such regulatory strategy.

(b) Costs and Expenses. Until completion of the First Step, all expenses associated with preparation, submission and maintenance of regulatory materials for the Territory will be borne by *. Following the First Step, any Development Expenses to the extent required for the Parties to prepare, submit and maintain all Regulatory Materials in the Territory shall be treated as Development Expenses and * in accordance with Section 3.3.

4.3 Rights of Reference to Regulatory Materials. Each Party hereby grants to the other Party a right of reference to all Regulatory Materials filed by such Party for Product as follows: The right of reference granted to * herein shall be solely for the purpose of * obtaining Regulatory Approval for the Product in the Territory.

4.4 Reporting and Review.

(a) Each Party shall provide the other Party, in a timely manner, with copies of all Regulatory Approvals it receives for the Product.

(b) Each Party shall provide the other Party, in a timely manner, with copies of any notices of non-compliance with Laws in connection with the Product or its activities related to the Product (*e.g.*, warning letters or other notices of alleged non-compliance), audit notices, notices of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Product (or its manufacture, distribution, or facilities connected thereto), notice of violation letters (*i.e.*, an untitled letter), warning letters, service of process or other inquiries and copies of any communication in response to the Regulatory Authority.

4.5 Regulatory Inspection or Audit.

(a) Audit of TGTX.

(i) If a Regulatory Authority desires to conduct an inspection or audit of TGTX's facility, or a facility under contract with TGTX, with regard to Bulk API or the Finished Product, TGTX shall promptly notify NOVIMMUNE and 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. NOVIMMUNE shall have the right to have a representative observe such inspection or audit and NOVIMMUNE shall, if requested by TGTX, assist TGTX in preparing for, facilitating or enabling such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which TGTX shall immediately provide to NOVIMMUNE), TGTX shall prepare a draft response to any such observations in English, in consultation with NOVIMMUNE, and TGTX shall prepare and file the final response with such Regulatory Authority, and shall provide a copy of such response to NOVIMMUNE.

(b) Audit of NOVIMMUNE.

(ii) If a Regulatory Authority desires to conduct an inspection or audit of NOVIMMUNE'S facility, or a facility under contract with NOVIMMUNE, with regard to the Bulk API or Finished Product, NOVIMMUNE shall promptly notify TGTX and 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 have the right to have a representative observe such inspection or audit and TGTX shall, if requested by NOVIMMUNE, assist NOVIMMUNE in preparing for, facilitating or enabling such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which NOVIMMUNE shall immediately provide to TGTX), NOVIMMUNE shall prepare a draft response to any such observations in English, in consultation with TGTX, and NOVIMMUNE shall prepare and file the final response with such Regulatory Authority, and shall provide a copy of such response to TGTX provided, however, if it is a Regulatory Authority in the Territory and the audit is specific to the Product or the Bulk API, then TGTX shall prepare, with the assistance of NOVIMMUNE, and file the final response and provide a copy to NOVIMMUNE.

(c) Audit Procedures. In any event, each Party shall notify the other Party, in writing, within * (*) hours of receipt of notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities being used to conduct manufacture of Bulk API or Finished Manufacture of the Finished Product. Each Party shall also provide the other Party with copies of any written communications received from Regulatory Authorities with respect to such facilities within * (*) hours of receipt.

4.6 Recalls and Voluntary Withdrawals. JSC shall assign responsibility to * for providing its internal standard operating procedures ("SOPs") for conducting any recall, field alert, product withdrawal or other field action relating to the finished product reasonably in advance of the First Commercial Sale of any Product in the Territory to the other party. If either Party becomes aware of information relating to any Product that indicates that a unit or batch of Finished Product or Bulk API may not conform to the specifications therefor, or that potential adulteration, misbranding, or other issues have arisen that relate to the safety or efficacy of the Product, it shall promptly so notify the other Party. The JSC shall meet to discuss such circumstances and to consider and decide appropriate courses of action, which shall be consistent with the internal SOP of *, * shall have the right and responsibility to control any product recall, field correction, or withdrawal of any Product in the Territory that is required by Regulatory Authorities in the Territory, and the allocation of reasonable expenses incurred in connection with such recall between the Parties shall be made as follows: (i) if the recall is primarily due to a failure by * to comply with its obligation under this Agreement or the commercial supply agreement, including with respect to the labeling, possession, storage or distribution of the finished product, then * shall bear all such expenses, and (ii) otherwise, such expenses shall be treated as Commercial Expenses. In addition, * shall have the right, at its discretion, to conduct any product recall, field correction or withdrawal of any Product in the Territory that is not so required by such Regulatory Authorities but that * deems to be appropriate, and the allocation of expenses incurred in connection with such recall between the Parties shall be as set forth in the immediately preceding sentence. * shall maintain complete and accurate records of any recall in the Territory for such periods as may be required by applicable Laws, but in no event for less than * (*) *.

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ARTICLE V. ARTICLE 5

SECTION 5.01 COMMERCIALIZATION

5.1 Commercialization in the Territory. * shall have the sole right and responsibility for Commercializing the Product in the Territory, as provided in this Article 5. * shall book all sales of the Product in the Territory. The Parties shall * all Commercial Expenses incurred by the Parties in connection with such Commercialization in accordance with the procedures described in Section 8. * shall use Diligent Efforts to minimize Commercial Expenses.

5.2 Commercialization Plans. The strategy for the commercial launch of the Product in the Territory shall be described in a comprehensive plan that describes the pre-launch, launch and subsequent Commercialization activities and budget for the Product (including, if available, advertising, education, planning, marketing, sales force training and allocation, distribution, pricing, and reimbursement) (the "Commercialization Plan"). * shall present an initial Commercialization Plan to the JSC at least * (*) months prior to the then current date of expected Regulatory Approval for such Product in the Territory (the "Approval Date"). The initial Commercialization Plan and subsequent revisions thereto, which revisions shall be reviewed and approved by the JSC from time to time, shall contain such information as the JSC believes necessary for the successful commercial launch of such Product and shall generally conform to the level of detail utilized by the Parties in preparation of their own product commercialization plans. The Commercialization Plan shall be deemed Confidential Information of both Parties, and each Party shall use such Commercialization Plan only to the extent necessary to carry out its Commercialization activities for the Product. From time to time as reasonably necessary during the term of Commercialization of a Product in the Territory, the JSC shall update the Commercialization Plan subject to the provisions of article 2 and 3 hereof.

5.3 Pricing Approvals; Pricing. TGTX shall have the responsibility to determine all pricing of the Product in the Territory provided NOVIMMUNE has an opportunity to review and comment upon TGTX's proposed price of the Product or any material modification thereof and shall consider NOVIMMUNE'S comments in good faith. TGTX shall use its Diligent Efforts to maximize Net Sales in the aggregate. Any discounts on sales where the Product is bundled with other products will be apportioned among all of the products in the bundle such that the discount on the Product is not more than the average discount provided to all the products. Both the parties shall keep reasonably informed on an ongoing basis of current Product pricing by regular reports to the JSC no less frequently than such committee is required to meet pursuant to Section 2.3.

5.4 Sales and Distribution. * shall be solely responsible for handling all returns, order processing, invoicing and collection, distribution, and inventory and receivables for the Product throughout the Territory. * shall have the right and responsibility for establishing and modifying the terms and conditions with respect to the sale of the Product throughout the Territory, including any terms and conditions relating to or affecting the price at which the Product shall be sold, discounts available to any third party payers (including, without limitation, managed care providers, indemnity plans, unions, self-insured entities, and government payer, insurance or contracting programs such as Medicare, Medicaid, or the U.S. Dept. of Veterans Affairs), any discount attributable to payments on receivables, distribution of the Product, and credits, price adjustments, or other discounts and allowances to be granted or refused provided that NOVIMMUNE had the opportunity to review and comment on such modifications, within a period of * days, thereof, and TGTX shall consider NOVIMMUNE'S comments in good faith.

5.5 TGTX Performance; Diligence.

(a) Level of Efforts in the Territory. TGTX shall devote Diligent Efforts to obtaining Regulatory Approval and thereafter Commercializing the Product in the Territory. Without limiting the generality of the foregoing, TGTX shall devote Diligent Efforts to Commercialize the Product in the Territory in accordance with the Commercialization Plan.

(b) Time to Launch Product. In addition to the requirements under Section 5.5(a), TGTX shall achieve First Commercial Sale of each Product within a reasonable time after, but in no event more than * months after, the date on which Pricing Approval is granted for such Product in the * , * and *, provided that such Pricing Approval is deemed by *, in consultation with the JSC, to be sufficiently profitable for Commercialization in such country. If, however, despite using diligent efforts it becomes difficult for TGTX to comply with the above-mentioned time limitations, then TGTX shall, without delay, inform NOVIMMUNE of the fact and explain the cause of such delay, and, such time limitations shall be extended to a reasonable extent as agreed between the Parties.

(c) Territory Reports. Following First Commercial Sale, TGTX shall present a written report to NOVIMMUNE at least * (and no later than * and * of each *) summarizing * 's overall Commercialization activities undertaken with respect to the Product in or for the Territory pursuant to this Agreement, covering subject matter at a level of detail reasonably sufficient to enable NOVIMMUNE to determine TGTX's compliance with its Diligent Efforts obligation pursuant to this Section 5.5.

5.6 Compliance. Each Party shall comply with all applicable Laws relating to activities performed or to be performed by such Party (or its Affiliates, contractor(s) or sublicensee(s)) under or in relation to the Commercialization of the Product pursuant to this Agreement. Each Party represents, warrants and covenants to the other Party that, as of the Effective Date and during the Term, such Party and its Affiliates have adequate procedures in place: (i) to ensure their compliance with such Laws; (ii) to bring any noncompliance therewith by any of the foregoing entities to its attention; and (iii) to promptly remedy any such noncompliance. TGTX shall be responsible for ensuring that all government reporting, sales, marketing and promotional practices with respect to the Product comply with applicable Laws. All promotional materials and labeling used by or on behalf of TGTX for the Product shall comply with applicable Laws and regulations.

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ARTICLE VI. ARTICLE 6

SECTION 6.01 LICENSE AND LICENSE OPTIONS

Licenses to TGTX under NOVIMMUNE Technology. Subject to the terms and conditions of this Agreement, NOVIMMUNE hereby grants TGTX an exclusive license under the NOVIMMUNE Product Patents and a non-exclusive license under NOVIMMUNE Technology, without the right to sublicense except as expressly permitted by Section 6.4 hereof, to Develop, manufacture, use, sell and offer for sale, and import the Product in the Territory, in accordance with this Agreement.

6.1 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

6.2 TGTX License Option. Any time prior to the start of *, TGTX shall have the exclusive right to convert this Agreement into a License Agreement. If TGTX exercises this Option, then both Parties will automatically enter into a licensing agreement under the same terms and conditions as set forth in Exhibit F, provided however that the terms of Section 6 of the form of Licensing Agreement shall remain unchanged unless mutually agreed by the Parties.

6.3 Novimmune License Option. Within * (*) days of the start of a Phase III Clinical Trial where the Product is used either as a single agent or in Combination with another active pharmaceutical ingredient, NOVIMMUNE shall have the exclusive right to convert this Agreement into a License Agreement. If NOVIMMUNE exercises this Option, then the Parties will automatically enter into a licensing agreement under the same terms and conditions as set forth in Exhibit F, provided however that the terms of Section 6 of the form of Licensing Agreement shall remain unchanged unless mutually agreed by the Parties.

6.4 Sublicensing and Subcontracting: The license granted to TGTX by NOVIMMUNE hereunder includes the right for TGTX to grant sublicenses to its Affiliates and to Subcontractors in connection with such Subcontractors' performance of subcontracted activities, provided that such subcontracted activities shall be subject to and subordinate to the terms and conditions of this Agreement. TGTX's execution of a subcontracting agreement with any Subcontractor shall not relieve TGTX of any of its obligations under this Agreement. TGTX shall remain directly liable to NOVIMMUNE for any performance or non-performance of a Subcontractor that would be a breach of this Agreement if performed or omitted by TGTX, and TGTX shall be deemed to be in breach of this Agreement as a result of such performance or non-performance of such Subcontractor. TGTX shall use Diligent Efforts to include in any agreement with a Subcontractor express permission to assign all of the rights and obligations under such agreement to NOVIMMUNE without consent from the Subcontractor. TGTX agrees to take Diligent Efforts to enforce the terms of each subcontractor agreement to prevent a breach of any such agreement that would constitute a breach of this Agreement if performed or omitted by TGTX. Any sublicensing under the license granted to TGTX hereunder to any Third Party that is not a Subcontractor is expressly prohibited unless permitted by the JSC (i) following the expiration of the option rights pursuant to Sections 6.2 and 6.3 hereof and (ii) an agreement of the parties on the equitable sharing of any resulting revenues.

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ARTICLE VII. ARTICLE 7

SECTION 7.01 MANUFACTURE AND SUPPLY

7.1 Roles of the Parties.

NOVIMMUNE shall supply * g of ready-to-be-labeled Product to the JV to support the Phase I Clinical Trial ("Novimmune Initial Drug Supply") within a maximum of * months after of the Effective Date. TGTX and NOVIMMUNE shall work together to secure a manufacturing slot with * in * (or the next available date), at * expense. If Novimmune secures the manufacturing slot, then on receipt of an invoice from *, * shall invoice * and * shall pay * in full for any payment in connection therewith within * (*) business days from receipt of an invoice from * for such payment. Thereafter *, at * expense, shall be responsible to supply, or cause to be supplied through its Third Party contract manufacturers, in a timely manner consistent with a relevant supply agreement between the parties, JV's entire requirements of Bulk API and Finished Product, in addition to the Product supplied by NOVIMMUNE, for the Development and Commercialization of the Product as a single agent by the Parties in or for the Territory in accordance with this Article 7.

7.2 Clinical Supply. In addition to the NOVIMMUNE Initial Drug Supply to be used in the Phase I Clinical Trial, TGTX by itself or through its Third Party contract manufacturers, will use Diligent Efforts to supply all remaining Product required to complete Phase I and Phase II Clinical Trials. After completion of the First Step, the JV will be responsible for supplying all quantities of Finished Product or Bulk API required by TGTX to Develop the Product in the Territory pursuant to the Development Plan. Such quantities of Finished Product, and the schedule for such supply, shall be confirmed and if necessary updated by the JSC in a manner consistent with the Development Plan.

7.3 Manufacturer Source.

(a) The Parties shall establish an appropriate facility or contract manufacturing organization for handling Finished Manufacture as follows: * shall be responsible for selecting manufacturer(s) to supply the Finished Product required to complete the Phase I and Phase II Clinical Trials, in addition to the quantity of ready-to-be-labeled Product supplied by NOVIMMUNE. This will involve negotiating the applicable supply agreement, and effecting the technology transfer as necessary to establish and qualify Bulk API and Finished Product manufacturers.

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ARTICLE VIII. ARTICLE 8

SECTION 8.01 COMPENSATION

8.1 Initiation Fee.

(a) As initiation fee for the JV, concomitantly with the delivery of the preclinical, non-clinical and manufacturing reports (Exhibit G) as per Section 4.1, TGTX shall pay to NOVIMMUNE a fee of Three Million US Dollars ($3,000,000) in its equivalent of TGTX shares (the "Initiation Fee"). In addition, NOVIMMUNE shall supply TGTX with the Novimmune Initial Drug Supply within a maximum of * (*) months as of the Effective Date.

(b) Furthermore, within * (*) days following written notification by TGTX (the "Notification Date") that the * patient has entered into the Phase I Clinical Trial or at a time that the quantity of ready-to-be-labeled Product that NOVIMMUNE has supplied runs out, whichever is the earliest, TGTX shall pay to NOVIMMUNE an additional collaboration fee of * US Dollars ($ *) in its equivalent in TGTX shares (the "Milestone Payment"), provided that this Agreement has not been terminated pursuant to Section 13.

(c) Such collaboration fees once paid shall be fully earned, non-refundable and non-creditable against any other payments due hereunder.

(d) For payments made in TGTX Shares pursuant to this Section 8.1, the number of shares of Common Stock of TGTX owed shall equal a fraction where the numerator is the * and the denominator is the *. For purposes of this Section 8.1, the " * " means the * (or, *) for the * (*) trading days prior to the Effective Date (in the case of the Initiation Fee) or the Notification Date (in the case of the Milestone Payment); provided, however, that in the event that TGTX effects a stock split, combination or stock dividend at any time during such * trading days or subsequent thereto and prior to the issuance of the TGTX Shares, the number of shares of TGTX Common Stock issuable shall be appropriately adjusted to give effect to such action. TGTX shall issue to Novimmune certificates representing the TGTX Shares as required by Sections 8.1(a) and (b). Within * (*) business days of the issuance of such certificates for the TGTX shares, TGTX shall file a resale registration statement covering such shares and shall use Diligent Efforts to make such resale registration statement effective as quickly as possible. TGTX covenants to use Diligent Efforts to keep such registration statement continuously effective until such time as such shares can be sold without restriction under Rule 144.

8.2 * of Commercial Expenses and Product Profit/Loss. During the Term but post the First Step, assuming none of the License Options have been exercised, the Parties shall * Product Profit/Loss for each Finished Product based on their respective P/L Sharing Percentage. Within * (*) Business Days of the end of each calendar * following the First Commercial Sale of the Finished Product, * shall report to the JSC its revenues and Commercial Expense items (with appropriate supporting information) involved in the computation of Product Profit/Loss and accrued during such quarter with respect to each such Finished Product (the "* P/L Report"). Such * P/L reports shall be in such form as the Parties may agree from time to time. In addition, TGTX shall provide NOVIMMUNE with a * statement of the amount of gross sales of Product by country in the Territory. The Parties shall calculate and * such Product Profit/Losses based on each Party's respective P/L Sharing Percentage on a calendar * basis and shall make reconciliation, if necessary, for this purpose of sharing such Product Profit/Losses, within * (*) Business Days after * provides its * report to the JSC. For the avoidance of doubt, if Commercial Expenses exceed Net Sales, then each party shall reimburse the other party for such Commercial Expenses such that each party's share of the Commercial Expenses is equal to its P/L Sharing Percentage. If either Party fails to contribute their portion of the Product Profit/Loss and Commercial Expenses, such Party's P/L Share Percentage shall be reduced pro rata to the extent of the Product Profit/Loss and Commercial Expenses that they do not fund as a percentage of the total accumulated Commercial Expenses and Product Profit/Loss to date, however, in no event shall NOVIMMUNE'S P/L Share Percentage be reduced below * %. Such adjustment to a party's P/L share % shall be the * remedy hereunder for such failure. Additionally, with regard to Commercial Expenses incurred by either Party before the First Commercial Sale, such expenses shall be included in Development Expenses and shared pursuant to Section 3.4. Alternately, both Parties may devise a feasible legal structure to address Product Profit/Loss for simplified obligations with regard to maintenance of financial records and audits of either party, including tax benefits, if any, and if agreed to by both Parties.

8.3 The * P/L Report will be subject to a true-up adjustment to take into account deductions under the definition of Net Sales either (a) allowed during a calendar quarter that were not accrued during such calendar quarter, or (b) accrued during a calendar quarter but not taken or later subject to a reversal following the end of such calendar quarter (each of (a) and (b), a "True-up Adjustment"). Each * P/L Report provided by TGTX shall set forth the amount of any True-up Adjustment applicable to any prior calendar quarter.

8.4 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective.

(b) Payment of Tax. A Party receiving a payment pursuant to this Article 8 shall pay any and all taxes levied on such payment. If applicable Law requires that taxes be deducted and withheld from a payment made pursuant to this Article 8, the remitting Party shall promptly notify the other Party and provide all relevant information available to it and (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the obligation together with proof of payment to the other Party within * (*) days following that payment.

(c) Tax Residence Certificate. A Party (including any entity to which this Agreement may be assigned, as permitted under Section 15.5) receiving a payment pursuant to this Article 8 shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction (a "Tax Residence Certificate"), if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

(d) Assessment. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by applicable Law. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

8.5 Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed to a Party under this Agreement shall be made at the period-end rate of exchange quoted on the last day of the applicable calendar quarter by Citibank in New York City.

8.6 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of * % over the then-current LIBOR, or the maximum rate allowable by applicable Law, whichever is lower.

8.7 Records; Audits. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of payments to the other Party under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours of audited Party for a period of * (*) years from the creation of individual records for examination at auditing Party's expense, and not more often than once each Fiscal Year, by an independent certified public accountant selected by auditing Party and reasonably acceptable to audited Party, for the sole purpose of verifying the accuracy of the financial reports furnished pursuant to this Agreement. Any such auditor shall not disclose audited Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by audited Party or the amount of payments due by audited Party under this Agreement. Any amounts shown to be owed but unpaid shall be paid within * (*) days from the accountant's report, plus interest (as set forth in Section 8.6) from the original due date. Any amounts determined to be overpaid shall be refunded within * (*) days from the accountant's report. The auditing Party shall bear the full cost of such audit unless such audit discloses an underpayment of the amount actually owed during the applicable Fiscal Year of more than * %, in which case audited Party shall bear the full cost of such audit.

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ARTICLE IX. ARTICLE 9

SECTION 9.01 INTELLECTUAL PROPERTY MATTERS

9.1 Ownership of Inventions and Know How. Any new information, discovery, or invention observed, conceived or made pertaining to the Product, its manufacture, or use during the term of this Agreement will be owned either solely by one Party ("Sole Know-How" or "Sole Invention") or jointly by both Parties ("Joint Know-How" or "Joint Invention") according to a proper determination of inventorship based on U.S. patent laws. Sole or Joint ownership flows to the Party that employs, or otherwise contracts with, a properly named inventor or co-inventor.

Sole Know-How and Sole inventions owned by TGTX and TGTX's interest in all Joint Know-How and Inventions shall be included in the TGTX Technology. Sole Know-How and Sole Inventions owned by NOVIMMUNE and NOVIMMUNE'S interest in all Joint Know-How and Inventions shall be included in the NOVIMMUNE Know-How, NOVIMMUNE Product Patent, or NOVIMMUNE Platform Patent, as the case might be, except that NOVIMMUNE"s interest in a Joint Invention shall be designated as a NOVIMMUNE Product Patent or as a NOVIMMUNE Platform Patent according to the claimed subject matter, provided that if the claimed subject matter includes a claim specifically directed to the Product, NOVIMMUNE's interest in a Joint Invention shall be included in the NOVIMMUNE Product Patent regardless of the presence in the same patent or patent application of claimed subject matter providing generic Product coverage.

9.2 Disclosure of Inventions. Each Party shall promptly disclose to the other any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing inventions that may be either Sole Inventions or Joint Inventions, and all Information relating to such inventions. Any Novimmune Know-How, TGTX Know-How, Novimmune Product Patents or TGTX Patents generated or discovered during the term of this Agreement shall * in this Agreement.

9.3 Prosecution of Patents.

(a) NOVIMMUNE Product Patents Other than Joint Patents. Except as otherwise provided in this Section 9.3(a), NOVIMMUNE shall have the sole right, authority and obligation to file, prosecute and maintain the NOVIMMUNE Product Patents and NOVIMMUNE Platform Patents (other than Joint Patents which shall be prosecuted and maintained in accordance with Section 9.3(b)) on a worldwide basis. NOVIMMUNE shall provide TGTX reasonable opportunity to review and comment on prosecution efforts regarding such NOVIMMUNE Product Patents in the Territory. NOVIMMUNE shall provide TGTX with a copy of material communications from any patent authority in the Territory regarding such NOVIMMUNE Product Patents, and shall provide TGTX with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. Notwithstanding the foregoing, if NOVIMMUNE desires to abandon or not maintain any NOVIMMUNE Product Patent in the Territory, then NOVIMMUNE shall provide TGTX with * (*) days prior written notice of such desire (or such longer period of time as reasonably necessary to allow TGTX to assume such responsibilities) and, if TGTX so requests, shall provide TGTX with the opportunity to prosecute and maintain such NOVIMMUNE Product Patent in the Territory in place of NOVIMMUNE. If TGTX desires NOVIMMUNE to file, in the Territory, a patent application that claims priority from a NOVIMMUNE Product Patent, other than a Joint Patent, in the Territory, TGTX shall provide written notice to NOVIMMUNE requesting that NOVIMMUNE file such patent application in the Territory. If TGTX provides such written notice to NOVIMMUNE, NOVIMMUNE shall either (i) file and prosecute such patent application and maintain any patent issuing thereon in the Territory or (ii) notify TGTX that NOVIMMUNE does not desire to file such patent application and provide TGTX with the opportunity to file and prosecute such patent application and maintain any patent issuing thereon in the Territory in place of NOVIMMUNE. Any patent controlled by or taken over by TGTX under this Section 9.3(a) shall henceforth be automatically assigned by NOVIMMUNE in favor of TGTX.

(b) Joint Patents. Except as otherwise provided in this Section 9.3(b), the JSC shall entrust one Party the right and authority, to prosecute and maintain the Joint Patents on a worldwide basis at its sole discretion herein referred to as an "**Entrusted Party**" (subject to this Section 9.3(b)). The Entrusted Party shall provide the other Party reasonable opportunity to review and comment on such prosecution efforts regarding such Joint Patents. The Entrusted Party shall provide the other Party with a copy of material communications from any patent authority regarding such Joint Patents, and shall provide the other Party with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. If one Party determines in its sole discretion to abandon or not maintain any Patent within the Joint Patents anywhere in the world, then the one Party shall provide the other Party with * (*) days' prior written notice of such determination (or such longer period of time reasonably necessary to allow the other Party to assume such responsibilities) and shall provide the other Party with the opportunity to prosecute and maintain such Patent in place of the one Party at such other Party's * expense, and if the other Party so requests, the one Party shall assign such Patent to the other Party (if the other Party is NOVIMMUNE in which case such Patent shall be included in the NOVIMMUNE Product Patents or NOVIMMUNE Platform Patents, as appropriate, or if the other Party is TGTX, in which case such Patent shall be included in the TGTX patents). If the other Party desires the Entrusted Party to file, in a particular jurisdiction, a patent application that claims priority from a Patent within the Joint Patents, the other Party shall provide written notice to the Entrusted Party expressing its desire to file such patent application in such jurisdiction. If the other Party provides such written notice to the Entrusted Party, the Entrusted Party shall either (i) express its agreement in writing to the other Party and the Entrusted Party shall file and prosecute such patent application and maintain any patent issuing thereon in such jurisdiction at its expense, or (ii) notify the other Party that the Entrusted Party does not desire to file such patent application and provide the other Party with the opportunity to file and prosecute such patent application and maintain any patent issuing thereon at it's sole expense in place of the Entrusted Party, in which case the Entrusted Party shall assign such patent application to the other Party (and in which case such Patent shall be included in the other Party's Patents).

(c) Cooperation in Prosecution. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts of the other Party's Patents and Joint Patents including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

(d) Costs of Prosecution. The costs to prosecute and maintain the Patents related to the Product shall be considered Development Expenses and shared according to Section 3.4; provided, however, if either of the License Options are exercised then the cost of prosecution of any NOVIMMUNE Product Patent, shall be borne by *, and the cost of prosecution of any TGTX Patent, shall be borne by *.

9.4 Patent Term Extensions in the Territory. Each Party shall discuss and recommend to the JSC which, if any, of the NOVIMMUNE Product Patents, TGTX Patents, or Joint Patents the Parties should seek Patent Term Extensions in the Territory, following which the JSC shall recommend to either of the parties which of the NOVIMMUNE Product Patents, TGTX Patents, or Joint Patents should be the subject of such Patent Term Extension application; provided, however, that JSC shall have the final decision-making authority with respect to applying for any such Patent Term Extensions in the Territory. Each party shall cooperate fully with the other in making such filings or actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All activities and expenses thereof of the Parties pursuant to this Section 9.4 for the Territory shall be deemed Development Expenses, unless either of the License Options have been exercised then such expenses shall be borne solely by TGTX.

9.5 Infringement of Patents by Third Parties.

(a) Notification. Each Party shall promptly notify the other Party in writing of any existing or threatened infringement of the NOVIMMUNE Product Patents, Joint Patents or TGTX Patents of which it becomes aware, and shall provide evidence in such Party's possession demonstrating such infringement.

(b) Infringement of Patents in the Territory.

(i) If a Party becomes aware that a Third Party infringes any NOVIMMUNE Product Patent, TGTX Patent, or Joint Patent in the Territory by making, using, importing, offering for sale or selling the Product or any similar anti-CD47/anti-CD19 bispecific antibody covered by any of such Patents (such activities, "Product Infringement"), then such Party shall so notify the other Party as provided in Section 9.5(a), which such notice shall include all Information available to the notifying Party regarding such alleged infringement.

(ii) In the Territory, TGTX shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement, subject to Section 9.5(b)(iii), below, the cost and expense of which will be included in Commercial Expenses (except as otherwise expressly provided in this Section 9.5(b)(ii)); provided, however, if either of the License Options is exercised then the cost and expense will be borne by TGTX. TGTX shall have a period of * (*) days (or shorter period, if required by the nature of the proceeding) after notification by NOVIMMUNE or providing notification to NOVIMMUNE pursuant to section 9.5(a), to elect to so enforce such Patent. In the event TGTX does not so elect, it shall so notify NOVIMMUNE in writing during such * (*) day time period (or the above-mentioned shorter period), and NOVIMMUNE shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such Product Infringement at its sole cost and expense (except as otherwise expressly provided in this Section 9.5(b)(ii). Each Party shall provide to the Party enforcing any such rights under this Section 9.5(b)(ii) reasonable assistance in such enforcement, at such enforcing Party's request, including joining such action as a party plaintiff if required by applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider the other Party's comments on any such efforts. Any recoveries obtained from a suit or an action commenced by TGTX hereunder shall first be applied to the recovery of expenses incurred by TGTX and NOVIMMUNE in bringing the suit or action; and the remaining amounts, if any, shall be shared by the Parties according to Section 8.2; provided, however, if either License Option is exercised, then any recoveries obtained from a suit or an action commenced by TGTX hereunder shall first be applied to the recovery of expenses incurred by TGTX in bringing the suit or action and the remaining amounts, if any, shall be deemed additional Net Sales; provided, further, however, if NOVIMMUNE proceeds with the enforcement after TGTX decides not to move forward, then any amounts recovered shall belong solely to NOVIMMUNE.

(iii) The Party not bringing an action with respect to Product Infringement in the Territory under Section 9.5(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action. Additionally, the Party not bringing an action under this Section 9.5(b) may have an opportunity to participate in such action to the extent that the Parties may mutually agree at the time the other Party elects to bring an action hereunder.

(c) Settlement. TGTX shall not settle any claim, suit or action that it brings under this Section 9.5 involving NOVIMMUNE Product Patents (excluding Joint Patents) in any manner that would negatively impact NOVIMMUNE Product Patents anywhere in the world, or that would limit or restrict the ability of either Party to manufacture, use, sell, offer for sale or import the Product anywhere in the world, without the prior written consent of NOVIMMUNE. NOVIMMUNE shall not settle any claim, suit or action that it brings under this Section 9.5 involving TGTX Patents (excluding Joint Patents) in any manner that would negatively impact the TGTX Patents or that would limit or restrict the ability of either Party to manufacture, use, sell, offer for sale or import the Product anywhere in the world, without the prior written consent of TGTX. Neither Party shall settle any claim, suit or action that it brings under this Section 9.5 involving Joint Patents in any manner that would negatively impact the Joint Patents or that would limit or restrict the ability of either Party to manufacture, use, sell, offer for sale or import the Product anywhere in the world, without the prior written consent of such other Party.

9.6 Infringement of Third Party Rights in the Territory.

(a) Notice. If any Product manufactured, used or sold by either Party, its Affiliates, licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory relating to the manufacture, use, sale, offer for sale or importation of the Product, the Party first having notice of the claim or assertion shall promptly notify the JSC, and the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action for an approval by the JSC.

(b) Defense. The Parties, working through the JSC, shall cooperate to defend any such claims under the strategy, terms and conditions as may be authorized by the JSC. Unless otherwise agreed, TGTX shall be the leading Party for such defense. The Parties shall make decisions with regard to such actions covered by this Section 9.6 jointly through the JSC in accordance with the provisions of Sections 2.3, provided that any unresolved disputes shall not be subject to settlement by expedited arbitration and, in the case of any unresolved dispute, each Party named as a defendant in such action shall be entitled upon written notice to defend itself in such matter independently by counsel of its own choice and at its own expense; provided, that each Party shall inform the other Party of the progress of such defense and, if reasonably requested by the other Party, shall reasonably cooperate with the other Party. For so long as the Parties continue to pursue such matter jointly through the JSC, all costs and expenses of any defense actions under this Section 9.6(b) shall be considered Commercial Expenses and shared as in Section 8.2. In any action pursued jointly by the Parties through the JSC, the non-leading Party shall reasonably cooperate with the leading Party, including if required to conduct such defense, furnishing a power of attorney. The non-leading Party shall have the right to confer, through the JSC, with the leading Party in any such defense and the leading Party shall consider in good faith such input from the non-leading Party.

(c) Settlement. Neither Party shall enter into any settlement of any claim described in this Section 9.6 that affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld, conditioned, or delayed.

(d) Settlement Payment. Any amounts that either Party becomes obligated to pay as a result of any settlement of or decision rendered in any defense pursuant to this Section 9.6 with respect to the manufacture, use, sale, offer for sale or import of the Product in or for the Territory shall be shared as provided in Section 8.2.

9.7 Patent Oppositions and Other Proceedings. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party that covers, in the Territory, the Product, or the manufacture, use, sale, offer for sale or importation of the Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 9.6, in which case the provisions of Section 9.6 shall govern), such Party shall so notify the JSC and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action for the approval by the JSC. The Parties working jointly through the JSC shall cooperate to assert any such claims under the strategy, terms and conditions as may be authorized by the JSC. Unless otherwise agreed, the JSC shall designate * as the leading Party for such claims. The Parties shall make decisions jointly through the JSC in accordance with the provisions of Sections 2.3. For so long as the Parties continue to pursue such matter jointly through the JSC, all costs and expenses of any actions or settlement efforts under this Section 9.7 shall be shared pursuant to Section 8.2. In any action pursued jointly by the Parties through the JSC, the non-leading Party shall cooperate fully with the leading Party, including, if required, to conduct such defense, furnishing a power of attorney. The non-leading Party shall have the right to confer with the leading Party, and the leading Party shall consider in good faith input from the non-leading Party. Any awards or amounts received in bringing any such action, if any, shall be first allocated to reimburse the Parties' respective expenses in such action, and any remaining amounts shall be shared pursuant to Section 8.2; provided, however, if either of the License Options is exercised then the entire cost of the action shall be borne by *, who shall have the final decision making authority over such action, and any awards or amounts received in bringing such action shall first be allocated to reimburse * for their expenses in such action and any remaining amounts shall be deemed additional Net Sales.

9.8 Parties' Patent Rights. If a NOVIMMUNE Product Patent, Joint Patent or TGTX Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 9.5, in which case the provisions of Section 9.5 shall govern), then the Party owning or otherwise Controlling such Patent shall promptly notify the other Party of such effect and discuss with the other Party how to defend such proceedings. The Party owning or otherwise Controlling such Patent shall, in close communication and discussion with the other Party, control such defense and shall solely bear the costs of such defense; *provided* that if such action relates to a Joint Patent, the Parties shall confer and determine which Party shall control such action and bear the associated costs. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. Any awards or amounts received in defending any such Third-Party action, if any, shall be first allocated to reimburse the Controlling Party's expenses in such action, and any remaining amounts shall be shared pursuant to Section 8.2; provided, however, if either of the License Options have been exercised, then * shall bear the expense and any remaining amounts shall first be used to reimburse * 's expenses and any remainder shall be deemed additional Net Sales.

9.9 Purple Book Listing, Compendial Listing. NOVIMMUNE shall allow TGTX to file appropriate information with the Regulatory Authority in the Territory listing any NOVIMMUNE Product Patent in the Purple Book or equivalent in the *, * and *, and each other country of the Territory, that JV deems appropriate, if any, as a Patent related to the Product and the Parties shall use Diligent Efforts to obtain and maintain such listing.

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* Confidential material redacted and filed separately with the Commission.

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ARTICLE X. ARTICLE 10

SECTION 10.01 REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows:

a. Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

b. Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

c. No Conflict. It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement. The execution, delivery and performance of this Agreement shall not violate, conflict with or constitute a default under any agreement (including its corporate charter or other organizational documents) to which it is a party or to which it may be bound, or to its best knowledge, any applicable Laws or order of any court or other tribunal.

d. No Debarment. In the course of the Development and Commercialization of the Product, each Party has not used and shall not use, during the term of this Agreement, any employee or consultant who has been debarred by any Regulatory Authority, or is the subject of debarment proceedings by a Regulatory Authority.

10.2 Additional Representations, Warranties and Covenants of NOVIMMUNE. NOVIMMUNE represents, warrants and covenants (as applicable) to TGTX as follows, as of the Effective Date:

a. Regulatory Materials and Studies. To the best of NOVIMMUNE's knowledge, all Regulatory Materials Controlled by NOVIMMUNE in existence as of the Effective Date and to which TGTX has rights of use or reference hereunder (collectively, "NOVIMMUNE Regulatory Materials"), including the Regulatory Materials described in Section 4.1(a), have been prepared, maintained and retained in accordance with applicable Laws. All preclinical studies conducted with respect to the Product in connection with the preparation of the NOVIMMUNE Regulatory Materials, including such studies from which the data described in Section 4.1(a) are derived, have been conducted substantially in accordance with applicable Laws by persons with appropriate education, knowledge and experience. NOVIMMUNE has not been debarred and is not subject to debarment, in each case pursuant to Section 306 of the FD&C Act or any similar law or regulation in any jurisdiction outside the United States.

b. Sufficiency of License Grants.

i. Except as set forth on Schedule 10.2(b)(i) hereto, to NOVIMMUNE's best knowledge at the Effective Date the NOVIMMUNE Product Patents and NOVIMMUNE Platform Patents are not subject to any encumbrance, lien or claim or ownership by any Third Party that is inconsistent with the rights and (sub)licenses granted to TGTX hereunder;

ii. Except as set forth on Schedule 10.2(b)(ii) hereto, NOVIMMUNE owns or possesses adequate right, title and interest in any NOVIMMUNE Product Patents and NOVIMMUNE Platform Patents to grant the licenses thereto to TGTX as provided in Article 6;

iii. No claim or litigation has been brought or, to NOVIMMUNE's best knowledge at the Effective Date, is threatened to be brought, by any person or entity alleging that (A) any of the NOVIMMUNE Product Patents or NOVIMMUNE Platform Patents in the Territory is invalid or unenforceable, or (B) practice of any of the NOVIMMUNE Product Patents or NOVIMMUNE Platform Patents for making, using or selling a Product in the Territory infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party;

iv. To NOVIMMUNE's best knowledge at the Effective Date, no Third Party has infringed or misappropriated any NOVIMMUNE Product Patents or NOVIMMUNE Platform Patents by making, using, importing, offering for sale or selling the Product and, as of the Effective Date, there is no actual or threatened infringement or misappropriation of the NOVIMMUNE Product Patents or NOVIMMUNE Platform Patents by any Third Party by making, using, importing, offering for sale or selling the Product;

v. Except as set forth on Schedule 10.2(b)(v), to the knowledge of NOVIMMUNE, neither (A) TGTX's exercise of its rights hereunder with respect to the NOVIMMUNE Technology, nor (B) TGTX's Development or Commercialization of the Product in the Territory, shall infringe any valid and enforceable Patent or other intellectual property right or other proprietary right of any Third Party;

vi. This Agreement is consistent with all Novimmune's Third Party license agreements in all respects and does not conflict with, violate, breach or otherwise give rise to a default by NOVIMMUNE under, any term of any of Novimumme's Third Party license agreements;

vii. NOVIMMUNE owns or possesses adequate right, title and interest in the NOVIMMUNE Know-How to grant the license thereto to TGTX as provided in Article 6;

c. Supply of Finished Product by NOVIMMUNE. The ready-to-be-labelled Product supplied by NOVIMMUNE to TGTX pursuant to this Agreement ("Novimmune Initial Drug Supply") shall be manufactured, handled and stored by NOVIMMUNE or its Third Party contract manufacture(s) in compliance with applicable Laws and regulations, including without limitation, GMP requirements.

10.3 Additional Representations of TGTX.

a. TGTX represents and warrants that it will comply with the U.K. Bribery Act, the United States Foreign Corrupt Practices Act and any and all other Applicable Laws prohibiting corruption or bribery (collectively referred to as the "Anti-Corruption Laws"); and

b. TGTX agrees, represents and warrants that (i) it (and its Affiliates) shall transport, store, distribute, sell and promote the Product in compliance with all applicable Laws, and (ii) any calculated prices or other data or information that is used by TGTX for reporting purposes pursuant to the rules and regulations of any federal or state government programs, shall be current, accurate and complete and shall comply with applicable Laws.

10.4 Disclaimer. TGTX understands that the Product is the subject of ongoing clinical research and development and that NOVIMMUNE cannot assure the safety or usefulness of the Product. In addition, NOVIMMUNE makes no warranties except as set forth in this Agreement concerning the NOVIMMUNE Technology.

10.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE XI. ARTICLE 11

SECTION 11.01 INDEMNIFICATION

11.1 Indemnification by each Party. Each Party hereby agrees to defend, indemnify, and hold the other Party and its officers, directors, employees, and agents harmless from and against any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses), and recoveries, including product liability claims (collectively, "Claims") to the extent that such Claims arise out of, are based on, or result from (a) a breach by the indemnifying Party of its representations, warranties, and obligations under the Agreement; or (b) the willful misconduct or grossly negligent acts of the indemnifying Party or its Affiliates, or the officers, directors, employees, or agents of such indemnifying Party or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that any Claim arises from, is based on, or results from (i) a breach of any of the representations, warranties, and obligations under the Agreement by the Party seeking indemnity; or (ii) the willful misconduct or grossly negligent acts of the Party seeking indemnity or its Affiliates, or the officers, directors, employees, or agents of such Party. The foregoing indemnity obligation shall not apply if the applicable indemnitees fail to comply with the indemnification procedures set forth in Section 11.2. Expenses relating to any other Claims resulting directly or indirectly from the manufacture, use, handling, storage, sale or other disposition of the Product in the U.S. shall be shared equally by the Parties at the time such expenses are required to be paid.

11.2 Indemnification Procedures. The Party claiming indemnity under this Article 11 (the "Indemnified Party") shall give written notice to the Party from whom indemnity is being sought (the "Indemnifying Party") promptly after learning of such Claim. In the event of a claim relating to the U.S., the Parties shall confer as to whether such claim would result in indemnification under Section 11.1 and in any event how to respond to the claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, such consent not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 11.

11.3 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.3 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE DAMAGES AVAILABLE FOR A PARTY'S BREACH OF THE CONFIDENTIALITY OBLIGATIONS IN ARTICLE 12.

11.4 Insurance. Each Party shall procure and maintain insurance adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold. During the First Step, TGTX shall procure and maintain clinical trial insurance according to the laws and regulations of each country in which the Phase I and Phase II Clinical Trials are performed. It is understood 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. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least * (*) days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

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* Confidential material redacted and filed separately with the Commission.

ARTICLE XII. ARTICLE 12

SECTION 12.01 CONFIDENTIALITY

12.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and until the later of (i) the * (*) anniversary of the Effective Date, or (ii) * (*) years after the expiration or termination of the Term, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality to the disclosing party ,at the time of disclosure by the other Party as evidenced by written documentation;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information of the other Party as evidenced by written documentation; provided, however, that this exception shall not apply to information or materials consisting of data and results generated or resulting from Development activities with respect to the Product, which information and materials shall be deemed Confidential Information of the Party who has developed such information or materials regardless of whether such information and materials were independently discovered or developed by the receiving Party or its Affiliate.

12.2 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting Patents as permitted in this Agreement;

(b) regulatory submissions and other filings with Governmental Authorities, including filings with the Securities and Exchange Commission;

(c) prosecuting or defending litigation or other proceedings or regulatory actions;

(d) complying with applicable Laws;

(e) disclosure to its employees, agents, and consultants, and any Third Parties (and potential licensees and) with which a Party is Developing or Commercializing the Product) only on a need-to-know basis and solely as necessary in connection with the performance of this Agreement, provided that in each case the recipient of such Confidential Information must agree to be bound by similar obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Article 12 prior to any such disclosure; and

(f) disclosure of the material financial terms of this Agreement to any bona fide potential investor, investment banker, acquiror, merger partner, or other potential financial partner; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each recipient of the confidential nature of such Confidential Information and shall cause each recipient of such Confidential Information to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clause (a) through (d) of this Section 12.2, it shall, except where prohibited by applicable Law, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

12.3 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are included within the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 12.3. The Parties have agreed to make a joint public announcement of the execution of this Agreement substantially in the form of the press release attached as Exhibit A on or after the Effective Date.

(b) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld. A Party commenting on such a proposed press release shall provide its comments, if any, within * (*) Business Days after receiving the press release for review. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed or previously agreed to by such Party, or by the other Party, in accordance with this Section 12.3.

(c) The Parties acknowledge that TGTX will be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission (the "SEC"). TGTX shall be entitled to make such a required filing, provided that it requests confidential treatment of certain commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to TGTX. In the event of any such filing, TGTX shall provide NOVIMMUNE with a copy of the Agreement marked to show provisions for which TGTX intends to seek confidential treatment and shall reasonably consider and incorporate NOVIMMUNE'S comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. NOVIMMUNE shall promptly provide any such comments. NOVIMMUNE recognizes that U.S. Laws and SEC policies and regulations to which TGTX is and may become subject may require TGTX to publicly disclose certain terms of this Agreement that NOVIMMUNE may prefer not be disclosed, and that TGTX is, after completing the above mentioned procedures, entitled hereunder to make such required disclosures to the extent legally required.

12.4 Publications. Neither Party may publish peer reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement with respect to the Territory, without the opportunity for prior review by the other Party. Each Party shall provide the other Party the opportunity to review and comment on any proposed manuscripts or presentations which relate to any Product at least * (*) days prior to their intended submission for publication or presentation. Each Party shall consider the comments of the other Party and shall remove any and all of the other Party's Confidential Information at the request of such other Party. A Party seeking publication shall also provide the other Party a copy of the manuscript at the time of the submission. Neither Party shall have the right to publish or present the other Party's Confidential Information without the other Party's prior written consent, except as expressly permitted in this Agreement.

12.5 Injunction. Each Party shall be entitled, in addition to any other right or remedy it may have, at Law or in equity, to seek an injunction in any court of competent jurisdiction, enjoining or restraining the other Party or its Affiliates from any violation or threatened violation of this Article 12.

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* Confidential material redacted and filed separately with the Commission.

* Confidential material redacted and filed separately with the Commission.

* Confidential material redacted and filed separately with the Commission.

ARTICLE XIII. ARTICLE 13

SECTION 13.01 TERM AND TERMINATION

13.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect in the Territory until the earlier to occur of:

(i) the exercise of the TGTX License Option and the effective date of the License Agreement between the Parties with respect thereto;

(ii) the exercise of the NOVIMMUNE License Option and the effective date of the License Agreement between the Parties with respect thereto; and

(iii) the later to occur of (A) the expiration of the last applicable patent of the Joint Patents, the NOVIMMUNE Product Patents or NOVIMMUNE Platform Patents, or (B) the expiry of any other exclusivity right with respect to the Product in a country, including patent term extensions, marketing exclusivity or any other non-patent exclusivity.

13.2 Termination.

(a) Early Withdrawal by TGTX without any cause. TGTX shall have no right to terminate this Agreement until the enrollment of the Minimum Phase 1 Patients in the Phase I Dose Escalation study (see Exhibit D). Thereafter, TGTX shall have the right to terminate this Agreement, in its entirety, upon written notice to NOVIMMUNE by at least * written (*) notice prior to the effective date of termination. If TGTX terminates this Agreement pursuant to this Section 13.2(a), then:

(i) TGTX shall not, during the applicable notice period, take any action that could adversely affect or impair the further Development and Commercialization of the Product.

(ii) The JSC shall coordinate the wind-down of TGTX's efforts under this Agreement.

(iii) TGTX shall not be responsible for any payments that become due to NOVIMMUNE pursuant to this Agreement that are incurred or accrued during the applicable notice period, other than those that relate to reimbursement of Development and Commercial Expenses based on the P/L Sharing Percentage in effect at the time of termination, subject to determination by the JSC.

(iv) If TGTX terminates prior to enrollment of the Minimum Phase 1 Patients then TGTX shall pay NOVIMMUNE an amount equal to * % of the Milestone Payment.

(v) TGTX shall be responsible for any cancellation fees payable to *, incurred on termination of this Agreement.

(b) Withdrawal by TGTX with Cause. Notwithstanding Section 13.2(a), TGTX shall have the right to terminate this Agreement, in its entirety, for Cause upon written notice to NOVIMMUNE by at least * (*) days' written notice prior to the effective date of termination. If TGTX terminates this Agreement pursuant to this Section 13.2(b), then:

(i) TGTX shall not, during the applicable notice period, take any action that could adversely affect or impair the further Development and Commercialization of the Product.

(ii) The JSC shall coordinate the wind-down of TGTX's efforts under this Agreement.

(iii) TGTX shall not be responsible for any payments that become due to NOVIMMUNE pursuant to this Agreement that were incurred or accrued during the applicable notice period, other than those that relate to reimbursement of Development and Commercial Expenses based on the P/L Sharing Percentage in effect at the time of termination, subject to determination by the JSC.

(iv) TGTX shall be responsible for any cancellation fees payable to *, incurred on termination of this Agreement.

(c) Termination for Breach.

(i) NOVIMMUNE shall have the right to terminate this Agreement upon written notice to TGTX if TGTX, after receiving written notice identifying such material breach by TGTX, fails to cure such material breach within * (*) days from the date of such notice; *provided*, that if such breach cannot be remedied within such * -day period (including a breach caused by a Financial Force Majeure) and TGTX has provided NOVIMMUNE with a written plan, reasonably acceptable to NOVIMMUNE, setting forth the activities to be performed by TGTX to remedy such breach, then NOVIMMUNE may not terminate this Agreement during such time as TGTX is diligently pursuing the performance of the activities described in the plan; and provided, further, that if such material breach relates solely to a particular country in the Territory, then NOVIMMUNE may terminate this Agreement only with respect to the applicable country but may not terminate this Agreement with respect to any other countries. Additionally, all the timeframes for curing a breach shall be stayed pending resolution of any disputes related to such purported breach.

(ii) TGTX shall have the right to terminate this Agreement upon written notice to NOVIMMUNE if NOVIMMUNE, after receiving written notice identifying a material breach by NOVIMMUNE of its obligations under this Agreement, fails to cure such material breach within * (*) days from the date of such notice; provided, that if such breach cannot be remedied within such 90-day period (including a breach caused by a Financial Force Majeure) and NOVIMMUNE has provided TGTX with a written plan, reasonably acceptable to TGTX, setting forth the activities to be performed by NOVIMMUNE to remedy such breach, then TGTX may not terminate this Agreement during such time as NOVIMMUNE is diligently pursuing the performance of the activities described in the plan; and provided, further, that if such material breach relates solely to a particular country in the Territory, then TGTX may terminate this Agreement only with respect to the applicable country but may not terminate this Agreement with respect to any other countries. Additionally, all the timeframes for curing a breach shall be stayed pending resolution of any disputes related to such purported breach.

(iii) For clarity, if a Party elects not to exercise its rights to terminate this Agreement pursuant to this Section 13.2(c) for the other Party's uncured material breach or pursuant to Section 13.5, but instead elects to allow this Agreement to continue in effect, then the breaching Party shall continue to be liable to the other Party for any breach of representations, warranties, obligations or agreements made in this Agreement by such breaching Party, and the non-breaching Party shall be entitled to pursue legal and equitable remedies arising from such breach that are available to it.

(d) Termination for Insolvency. In the event that either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within * (*) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

13.3 NOVIMMUNE Termination for TGTX Failure to File IND/CTA: Notwithstanding Section 13.2(b) above if the IND/CTA Filing Conditions are met and TGTX fails to file an IND or CTA in a Major Market on or before the applicable IND/CTA Filing Deadline (other than for reasons beyond the reasonable control of TGTX, such as the requirements of the applicable Regulatory Authority), NOVIMMUNE may terminate this Agreement on * (*) days' written notice to TGTX unless TGTX makes such filing, or is determined by the JSC to be actively in the process of making such filing before the end of * (*) days' written notice to TGTX. Notwithstanding the foregoing, if TGTX decides to conduct the first Phase 1 study outside of the United States or in a Major Market, then this condition shall be satisfied by the enrollment of the first patient in such study.

13.4 Termination for Diligence Failure: Notwithstanding Section 13.2(b) above, if a party does not correct a failure to use Diligent Efforts within the applicable period specified in, or determined in accordance with this Agreement (a "Diligence Failure"), the non-breaching party shall have the right to terminate this Agreement on * (*) days' written notice to the breaching party unless the breaching party cures such Diligence Failure before the end of such * (*) day period, or is actively in the process of curing such Diligence Failure before the end of such * (*) day period.

13.5 Effect of Termination of the Agreement. Upon termination by NOVIMMUNE of the Agreement under Section 13.2(c), Section 13.3, Section 13.4 or Section 13.5, or upon termination by TGTX under Section 13.2(a) and 13.2(b), the following shall apply (in addition to any other rights and obligations under Section 13.7 or 13.8 or otherwise under this Agreement with respect to such termination) with respect to the affected territory or territories:

a. Intellectual Property. NOVIMMUNE shall have the right, exercisable upon written notice by NOVIMMUNE to TGTX given within *[1] (*) days after the effective date of such termination, to obtain, and effective upon such notice, TGTX shall, and it hereby does, grant to NOVIMMUNE, a perpetual, non-exclusive, worldwide, royalty-bearing license, with the right to sublicense, under TGTX Intellectual Property Rights (which, for purposes of this Section 13.5(a) shall not include the Joint Patents or the Joint Know-How, but see below) solely to develop, make, have made, use, sell, offer for sale, have sold and import the Products in the Field of Use, subject to the terms and conditions set forth below in subparagraph (c). TGTX shall provide to NOVIMMUNE when enforcing any such rights under this Section 13.5(a) reasonable assistance in such enforcement, at NOVIMMUNE'S request and cost, including joining such action as a party plaintiff if required by applicable Law to pursue such action. In consideration for such non-exclusive license, NOVIMMUNE shall pay to TGTX a royalty that is * % of the royalty amounts set forth in Exhibit F. The royalty will be paid out of NOVIMMUNE'S gross profits following the first commercial sale of the Product, and which gross profits will be based on all amounts paid to NOVIMMUNE from its sublicensing or from sales directly or indirectly in the particular country or Territory. The term of such royalty will expire on the expiration of the last to expire issued Valid Claim within the TGTX Patents or Joint Patents covering the Product in the particular country or Territory.

TGTX shall, and it hereby does, upon such Termination, grant to NOVIMMUNE, (i) a perpetual, exclusive, worldwide, royalty-free license, with the right to sublicense, under the Joint Patents; and (ii) a perpetual, non-exclusive, royalty-free license to the Joint Know-How, in each case solely to develop, make, have made, use, sell, offer for sale, have sold and import the Products in the Field of Use. TGTX shall provide to NOVIMMUNE when enforcing any such rights under this Section 13.6(a) reasonable assistance in such enforcement, at NOVIMMUNE'S request and cost, including joining such action as a party plaintiff if required by applicable Law to pursue such action.

b. Regulatory Materials. TGTX shall transfer and assign to NOVIMMUNE all Regulatory Materials and Regulatory Approvals for Product for the terminated country(ies) of the Territory, and shall grant NOVIMMUNE a right of reference to all Regulatory Materials filed by TGTX in the Territory solely for the purpose of NOVIMMUNE obtaining Regulatory Approval for the Product in such terminated country(ies). For avoidance of doubt, NOVIMMUNE shall have right to transfer and assign the rights to any of its licensing partners for the terminated country(ies) of the Territory.

c. Transition Assistance. TGTX shall, for a reasonable period of time, provide such assistance, at no cost to NOVIMMUNE, to transfer or transition to NOVIMMUNE all other technology or know-how, including Information generated from the Clinical Trials or other Development activities, or then-existing commercial arrangements, that is, or are, reasonably necessary or useful for NOVIMMUNE to commence or continue Developing, conducting Finished Manufacturing of or Commercializing the Product in or for the terminated country(ies) of the Territory, to the extent TGTX is then performing or having performed such activities. TGTX shall take such other commercially reasonable actions and shall execute such other instruments, assignments and documents as may be necessary to effect the transition of the Development and Commercialization of the Product to NOVIMMUNE, including without limitation assignments of any contracts, including subcontracting agreements, related to the Development and Commercialization of the Product, unless such assignment is prohibited by a contract and the applicable consent cannot be reasonably procured at reasonable cost. TGTX will use commercially reasonable efforts to obtain the consent of any third-party to any contract or agreement related to the Development or Commercialization of the Product, which consent is required for the assignment of any such contract or agreement from TGTX to NOVIMMUNE, provided, however, that any cash payment required by TGTX in order to procure any such consent shall be deemed not commercially reasonable. Prior to receipt of such consent, TGTX shall make available to NOVIMMUNE all rights and other benefits of such contracts, on a subcontract or sublease basis or in some other appropriate manner to the fullest extent reasonably practicable, and NOVIMMUNE shall be considered an independent subcontractor or sublessee of TGTX, with respect to all matters concerning such contracts.

d. Remaining Inventories. NOVIMMUNE shall have the right to purchase from TGTX all of the inventory of ready-to-be-labelled and Finished Product held by TGTX for such terminated country(ies) as of the effective date of termination of this Agreement at a price equal to TGTX's cost to acquire or manufacture such inventory for such terminated country(ies). NOVIMMUNE shall notify TGTX within [2] (*) days after the date of termination of the Agreement whether NOVIMMUNE elects to exercise such right. If NOVIMMUNE does not exercise such right, then TGTX shall have the right to sell in such terminated country(ies) of the Territory any such remaining inventory over a period of no greater than * (*) months after the effective date of termination of this Agreement provided TGTX makes appropriate payment to NOVIMMUNE under similar terms of the prevailing P/L arrangements.

e. Termination of Licenses. For clarity, upon any termination of this Agreement under Section 13.2, the licenses granted to TGTX under this Agreement for such terminated country(ies) shall terminate.

f. Clinical Trials. In the event that any clinical trial of the Product being conducted by or on behalf of TGTX is on-going as of the effective date of any termination of this Agreement, then upon written request of NOVIMMUNE, TGTX shall cooperate to transfer responsibility for such clinical trial to NOVIMMUNE or its designee as expeditiously as possible in an orderly manner and in compliance with Law and common standards of industry practice, and cooperate to facilitate the transfer to NOVIMMUNE of, as applicable, regulatory filings, CRO contracts, site agreements and the like as expeditiously as possible, provided that the costs of conducting such clinical trial up to the effective date of termination of this Agreement shall be considered Development Costs. In the event that NOVIMMUNE does not request to transfer responsibility for the conduct of such on-going clinical trial, then TGTX shall wind down such on-going clinical trial as expeditiously as possible, consistent with TGTX's ethical and regulatory obligations and in compliance with Law and standards of industry practice, provided that all costs of TGTX in winding-down such clinical trial shall be considered Development Costs; provided, however, if the Agreement was terminated by NOVIMMUNE pursuant to Section 13.2(c)(i), Section 13.4, or Section 13.5, or upon termination by TGTX under Section 13.2(a), TGTX shall be responsible for such costs. However, if the Agreement was terminated by TGTX pursuant to Section 13.2(c)(ii) or Section 13.5, NOVIMMUNE shall be responsible for such costs.

13.6 Other Remedies. Other than as explicitly stated otherwise in this Article 13, termination or expiration of this Agreement for any reason shall not release any Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by NOVIMMUNE are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that TGTX, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against NOVIMMUNE, TGTX shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in TGTX's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon TGTX's written request therefor, unless NOVIMMUNE elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by or on behalf of NOVIMMUNE upon written request therefor by TGTX.

13.8 Survival. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified therein (or, if no such period is specified, indefinitely): Articles 1, 10, 11, 12, 14, and 15, and Sections 4.7, 9.1, 9.8 (to the extent that TGTX uses a Product Trademark after such expiration or termination), 13.4, 13.3, 13.6, 13.7, and 13.8.

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[*] Confidential material redacted and filed separately with the Commission.

[*] Confidential material redacted and filed separately with the Commission.

[*] Confidential material redacted and filed separately with the Commission.

[1] Confidential material redacted and filed separately with the Commission.

[2] Confidential material redacted and filed separately with the Commission.

ARTICLE XIV. ARTICLE 14

SECTION 14.01 DISPUTE RESOLUTION

14.1 English Language; Governing Law. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the Laws of the State of New York without giving effect to any choice of law principles that would require the application of the Laws of a different state.

14.2 Disputes.

(a) The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 14.2 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement. With respect to all disputes arising between the Parties (other than those matters delegated to the JSC, which shall be governed in accordance with Section 2.3(c)), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within sixty (60) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the senior executive officers for each Party for attempted resolution by good faith negotiations within [3] (*) days after such notice is received. If the senior executive officers designated by the Parties are not able to resolve such dispute within such * (*) day period, either Party may submit such dispute in accordance with Section 14.2(b).

(b) Arbitration. Any dispute arising out of or relating to this Agreement, including the breach, termination or validity thereof, which has not been resolved by the executives of the Parties as provided herein will be finally resolved by arbitration in accordance with the CPR Rules for Non-Administered Arbitration then currently in effect, by three arbitrators of whom each party will appoint one in accordance with the 'screened' appointment procedure provided in Rule 5.4, provided, however, that if one party fails to participate in either the negotiation or mediation as agreed herein, the other party can commence arbitration prior to the expiration of the time periods set forth above. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., and judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof. The place of arbitration will be New York, NY. The award may be made a judgment by any court of competent jurisdiction pursuant to the New York Convention, 9 U.S.C. § 201 et seq., and for this purpose the Party against whom the award is made will agree to the personal jurisdiction of the court in which recognition is sought and will not raise any argument of forum non conveniens.

(c) Notwithstanding anything to the contrary in this Article 14, either Party may seek injunctive relief in any court in any jurisdiction where appropriate.

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[3] Confidential material redacted and filed separately with the Commission.

ARTICLE XV. ARTICLE 15

SECTION 15.01 MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the Exhibits 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 agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. 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 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party, except in the case of a Financial Force Majeure. Nevertheless, any failure to make a payment as a result of a Financial Force Majeure will trigger a reduction in a Party's P/L Share Percentage in accordance with Sections 3.4 and 8.2 hereof.

15.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered sent by a reputable overnight delivery service, or by by e-mail, or (b) ^{4} (*) days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested.

If to NOVIMMUNE:

NOVIMMUNE, S.A.
14 ch. des Aulx,
1228 Plan-Les-Ouates,
Geneva,Switzerland
Attn: Eduard E. Holdener
-Email: Legal@novimmune.com

If to TGTX:

TG Therapeutics Inc.
2 Gansevoort Street | 9th Floor
New York, New York 10014
Attn: Michael S. Weiss

15.4 No Strict Construction; Headings. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.5 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 without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

15.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.7 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.9 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.10 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

15.11 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement shall be binding upon the delivery by each Party of an executed signature page to the other Party by PDF copy sent by email. If signature pages are so delivered each Party shall also immediately deliver an executed original counterpart of this Agreement to the other Party by courier delivery service.

15.12 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description preceding such term. References to "Article," "Section" or "Exhibit" are references to the numbered sections of this Agreement and the exhibits attached to this Agreement, unless expressly stated otherwise.

{Signature page follows.}

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[4] Confidential material redacted and filed separately with the Commission.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

TG THERAPEUTICS, INC.

By: _____

Name: Michael S. Weiss

Title: Chairman and CEO

NOVIMMUNE SA

By: _____

Name: Eduard E. Holdener

Title: Chairman and CEO

By: _____

Name:

Title:

Exhibits

Exhibit A: Press release of Joint Venture announcement

Novimmune SA

14 Chemin des Aulx
1228 Plan-Les-Ouates
Geneva, Switzerland

+41 22 839 71 41 Tel
+41 22 839 71 43 Fax

www.novimmune.com

[Missing Graphic Reference]

MEDIA INFORMATION

Novimmune SA and TG Therapeutics collaborate on novel treatment for hematological malignancies

Geneva, Switzerland – XXXXX, 2018 – Novimmune SA, a privately held Swiss biopharmaceutical company and TG Therapeutics (New York, USA), announced today that they have entered into an exclusive global agreement to collaborate on the development and commercialization of Novimmune's Anti-CD47/ Anti-CD19 bispecific antibody, NI-1701. The companies will jointly develop the product on a global basis to treat B cell malignancies.

NI-1701, a fully-human IgG1 bispecific antibody, is based on Novimmune's κλ body format and is designed to kill B cell tumors by engaging phagocytes. The novel compound is the first anti-CD47 bispecific antibody world wide that will go into clinical trials.

TG Therapeutics will make up-front licensing payments and milestone payments based on early clinical development. They will cover the costs of clinical development of the products through phase II. Both TG Therapeutics and Novimmune will then each have various options to continue the development of the molecule.

"We are delighted to see our first bispecific antibody move forward into the clinic with an experienced partner in the field of hematological malignancies, and to provide proof of principle for our completely novel approach", said Chairman and Chief Executive Eduard Holdener. We are excited about the potential benefit that this new approach could bring to B cell lymphoma patients.

About Novimmune

Novimmune SA is a privately held, Swiss biopharmaceutical company focused on the discovery and development of antibody-based drugs for the targeted treatment of inflammatory diseases, immune-related disorders, and cancer. The company is headquartered in Geneva and runs a Clinical and Commercial Development Center in Basel. The company currently employs 130 people. More information is available on the company website at www.novimmune.com.

Contact:

Eduard Holdener

+41 22 839 71 41

eholdener@novimmune.com

About TG Therapeutics

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing umbralisib (TGR-1202), an orally available PI3K delta inhibitor for various hematologic malignancies (www.tgtxinc.com)

Contact:

xxxxxxxxxxx

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Exhibit B: Novimmune Patents

B(1) Product Patents

CD47 mAbs & CD47 x CD19 bispecifics (NI-1701):

(*[5] **Ref. No. * // NovImmune Ref. No. *)** is directed to fully human antibodies that recognize CD47. This family discloses the nucleic acid and amino acid sequences for a variety of fully human anti-CD47 monoclonal antibodies and bispecifics that bind CD47 and a second antigen developed by NovImmune. Specific CD19 sequences are disclosed in this application. The earliest cases in this family include:

- U.S. Nonprovisional Application No. * , filed * , * and claiming priority to a provisional application filed * , *;
- National Stage Applications based on PCT Application No. * , filed * , * and claiming priority to a provisional application filed * , *
  - This family is filed in * , * , * , * , *

B(2) Platform Patents

(* Ref. No. * // NovImmune Ref. No. *) * . The cases in this family include:

- U.S. Nonprovisional Application No. * , filed * , * and claiming priority to a provisional application filed * , * ; and
- National Stage Applications based on PCT Application No. * , filed * , * and claiming priority to a provisional application filed * , *
  - Pending in the * ; Granted in * , * , * , * , * , * , and *

(* Ref. No. * // * **Ref. No.** * **)** * . The cases in this family include:

- U.S. Nonprovisional Application No. * filed * , * and a provisional application filed * , * ; and
- National Stage Applications based on National Stage Applications based on PCT Application No. * , filed * , * and a provisional application filed * , *
  - Pending in * , * , * , * , * (all cases in substantive examination)

(* Ref. No. * // * **Ref. No.** * **)** * . This family includes:

- U.S. Application No. * and * , claiming priority to a provisional filed * , *

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[5] Confidential material redacted and filed separately with the Commission.

Exhibit C:[6] **NI-1701 Sequence**[7]

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[6] Confidential material redacted and filed separately with the Commission.

[7] Includes Confidential Material redacted in the publicly-filed copy of the Agreement.

Exhibit D: Phase 1 clinical trial Plan

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CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Exhibit E: Licensing Agreement

LICENSING AGREEMENT

BY AND BETWEEN

TG THERAPEUTICS, INC.

AND

NOVIMMUNE S A

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

This Licensing Agreement is made and entered into on [ ] (the ***"Effective Date"***) by and between

Novimmune S.A., a Swiss corporation having its principal place of business at 14 ch. des Aulx, 1228 Plan-Les-Ouates, Geneva, Switzerland ("NOVIMMUNE").

On the one hand,

And

TG Therapeutics, Inc., a Delaware corporation, with a place of business at 2 Gansevoort Street | 9th Floor, New York, NY (**"TGTX"**).

On the other hand;

WITNESSETH:

WHEREAS, Novimmune is a pharmaceutical company focused on the development of novel CD47/CD19 bi-specific antibodies for the treatment of various B-cell proliferative diseases;

WHEREAS, TGTX is a biopharmaceutical company engaged in the development, manufacturing and marketing of pharmaceutical products directed toward the treatment of B-cell proliferative diseases;

WHEREAS, Novimmune and TGTX are parties to that certain Joint Venture and License Option Agreement, dated [ ] May, 2018 (the "JV Agreement").

WHEREAS, The development of the Product has, to date, progressed satisfactorily to each Party to the JV Agreement, and each Party has upheld the responsibilities delegated to such Party dictated in the JV Agreement;

WHEREAS, The JV Agreement affords [TGTX/Novimmune] the option to convert the JV into an exclusive license to the Product under the terms of Article 6.2 and Exhibit F of such JV Agreement;

WHEREAS, [TGTX/Novimmune] pursuant to the JV Agreement wishes to exercise its option to in license to TGTX all the proprietary rights in and to the compound known as "NI-1701"and Novimmune agrees to out license "NI-1701" to TGTX in order to develop, manufacture and commercialize Products (as hereinafter defined); and

WHEREAS, both TGTX and Novimmune, pursuant to the **JV Agreement** wish to enter into this definitive Agreement, which provides TGTX with an exclusive license to develop, manufacture and commercialize Products (as hereinafter defined) in the Field of Use (as hereinafter defined) and in the Territory (as hereinafter defined), under the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the foregoing and the covenants and obligations set forth herein, including the exhibits or appendices hereto, and intending to be legally bound, TGTX and Novimmune hereby agree as follows:

1 DEFINITIONS AND INTERPRETATIONS

Terms, when used with initial capital letters, shall have the meanings set forth below or at their first use when used in this Agreement:

1.1 "Agreement": shall mean this License Agreement

1.2 "API": shall mean an active pharmaceutical ingredient.

1.3 "BLA": shall mean a "Biologics License Application" (as more fully defined in 21 C.F.R. 601 *et seq.*) filed with the FDA or the equivalent application filed with any other Regulatory Authority to obtain marketing approval for a Product in a country or jurisdiction in the Territory.

1.4 "Biosimilar Product" means a biologic product that (i) is highly similar to the active ingredient in the Product where the Product is the reference-listed biologic, and (ii) is approved by a Governmental Authority pursuant to a Biosimilar License Application, an application under 42 U.S.C. §262(k), or similar application.

1.5 "Change of Control": means (i) the acquisition, directly or indirectly, by any person, entity or "group" (within meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) by means of a transaction or series of related transactions, of (a) beneficial ownership of fifty percent (50%) or more of the outstanding voting securities of a Party (or the surviving entity, as applicable, whether by merger, consolidation, reorganization, tender offer or other similar means), or (b) all, or substantially all, of the assets of a Party; or (ii) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of the Party immediately prior to such consolidation, merger or reorganization (or prior to any series of related transactions leading up to such event) own fifty (50%) or less of the surviving entity's voting power immediately after such consolidation, merger or reorganization.

1.6 "Change of Control Transaction": shall have the meaning ascribed to this term in Article 16.

1.7 "**Cause**" means, for purposes of Section 11.1, any unfavorable result from a pre-clinical or clinical trial that, as reasonably determined by TGTX, causes material concerns regarding the tolerability, safety or effectiveness of the Product.

1.8 "Combination" shall mean a co-administration of Product together with any other product.

1.9 "Commercialization", with a correlative meaning for **"Commercialize"**: means all activities undertaken before and after obtaining Regulatory Approval relating specifically to the pre-marketing, launch, promotion, marketing, sale, and distribution of a pharmaceutical product, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and product support; and (b) any Phase IV Clinical Trials, and (c) all customer support and Product distribution, invoicing and sales activities.

1.10 "Compound": shall mean NI-1701 as described herein and as used in Product.

1.11 "Confidential Information": means, with respect to a Party, all confidential information of such Party that is disclosed to the other Party under this Agreement, which may include specifications, know-how, trade secrets, legal information, technical information, drawings, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, in each case whether disclosed in oral, written, graphic, or electronic form. All Confidential Information disclosed by either Party pursuant to the Mutual Confidential Disclosure Agreement between the Parties dated 15th February 2018 shall be deemed to be such Party's Confidential Information disclosed hereunder.

1.12 "Control" shall mean, with respect to any material, Information, or intellectual property right, that a Party owns or has a license to such material, Information, or intellectual property right and has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be first required hereunder to grant to the other Party such access, license, or sublicense.

1.13 "Data": shall mean any and all scientific and research data, technical data, test and development data, pre-clinical and clinical data (including pharmacological, biological, chemical, biochemical, toxicological, pre-clinical and clinical test data, analytical and quality control data, stability data, results of studies and patient lists), formulations, processes, protocols, regulatory files and the like which are developed by either Party in connection with the Compound or the Product.

1.14 "Develop or Development": shall mean all activities relating to preparing and conducting preclinical testing, toxicology testing, human clinical studies, regulatory affairs for obtaining the Regulatory Approvals, formulation development, process development for manufacture and associated validation, quality assurance and quality control activities (including qualification lots). Development shall exclude all Phase IV Clinical Trials.

1.15 "Development Plan": shall mean plans for development of the Product as outlined in Exhibit D which shall be provided by TGTX and updated and amended pursuant to Section 3.

1.16 "Diligent Efforts": means, with respect to a Party's obligation under this Agreement to Develop or Commercialize a Product, the level of efforts and resources required to carry out such obligation in a sustained manner consistent with the efforts and resources a similarly situated biopharmaceutical company devotes to a product of similar market potential, profit potential or strategic value within its portfolio, based on conditions then prevailing i.e. it shall mean the efforts required in order to carry out a task or objective in a diligent and sustained manner without undue interruption, pause or delay, which level is at least commensurate with the level of efforts that a pharmaceutical company would devote to a product of similar potential and having similar commercial and scientific advantages and disadvantages as compared to the Product hereunder. Diligent Efforts requires (without limitation) that the Party exerting such efforts (i) promptly assign responsibility for its obligations to specific employee(s) or contractor(s) who are held accountable for progress and monitor such progress, on an ongoing basis, (ii) set and continue to seek to achieve specific and meaningful objectives for carrying out such obligations, and (iii) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives, in each case in a diligent manner.

1.17 "Diligence Failure": shall mean TGTX does not correct a failure to use Diligent Efforts within the applicable period specified in, or determined in accordance with Section 3.2.5(b).

1.18 "EMA": shall mean the European Medicines Agency or any successor agency thereto.

1.19 "FDA": shall mean the United States Food and Drug Administration, or a successor federal agency thereto.

1.20 "Field" means the prevention, diagnosis, treatment or amelioration of any disease or condition in humans or animals.

1.21 **"Field of Use":** shall mean the use of Compound or Products in the Field as defined herein.

1.22 **"Finished Product"** shall mean a Product that has been filled into vials, syringes or capsules or manufactured into other pharmaceutical presentations for administration, such as tablets or pills; finished and labeled for use in clinical trials or for commercial purposes in accordance with the applicable specifications and legal requirements.

1.23 **"First Commercial Sale":** shall mean the first commercial sale by TGTX, its Affiliates and/or Sublicensees to a Third Party of a Product for value in any country in the Territory following receipt of approval to market such Product from the relevant Regulatory Authority in the applicable country.

1.24 **"Governmental Authority":** means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.25 **"Good Clinical Practices"** or **"GCP"** means the then-current good clinical practice standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA, and comparable regulatory standards, practices and procedures in jurisdictions outside the U.S., in each case as they may be updated from time to time.

1.26 **"Good Laboratory Practices"** or **"GLP"** means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards in jurisdictions outside the U.S., in each case as they may be updated from time to time.

1.27 **"Good Manufacturing Practices"** or **"GMP"** means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical and biological materials, and comparable Laws applicable to the manufacture and testing of pharmaceutical and biological materials in jurisdictions outside the U.S., including without limitation 21 CFR 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals) and the guideline promulgated by the International Conference on Harmonization designated ICH Q7A, entitled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and associated guidelines and regulations, in each case as they may be updated from time to time.

1.28 **"IND":** shall mean (a) an Investigational New Drug application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA or any successor application or procedure required to initiate clinical testing of a Product in humans in the Territory; and (b) all supplements and amendments to the foregoing.

1.29 **"Indication":** means any indication for which (a) a Product is developed pursuant to an IND or CTA (or if no such filing is required, pursuant to the applicable clinical trial protocol), (b) a BLA for a Product is submitted, or (c) a BLA for a Product is approved by a Regulatory Authority.

1.30 **"Information"** means any data, results, technology, business information, and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

1.31 **"Joint Inventions":** Any new invention pertaining to the Compound, Product, or their uses made jointly by the Parties.

1.32 "Joint Know-How": shall mean all Know-How developed or acquired by either Party in performing its obligations pursuant to the JV Agreement that is necessary or useful for the Development, manufacture or Commercialization of the Compound or the Product.

1.33 "Joint Patents": shall mean any and all patents and patent applications claiming any Joint Invention, together with any and all patents issued on any such applications as well as any divisional, continuation, continuation-in-part, substitution applications, re-issue, re-examination, renewal and extended patents (including supplementary protection certificates (SPC)) of any of the foregoing.

1.34 "Know-How": shall mean any and all technical information, test and development data and results, formulations, processes, ideas, protocols, regulatory files, preclinical and clinical data (including, without limitation, Data) and the like relating to the use, manufacture, Development, or Commercialization of the Compound or the Product.

1.35 "Launch": shall mean the First Commercial Sale in a country.

1.36 "Major Market(s)": shall mean any of the following countries or groups of countries: (i) [8] ; (ii) * ; (iii) * , * , * , * , and the * (each, a " * "); (iv) * ; and (v) * , * or * (each, a " * ").

1.37 "Net Sales": shall mean, with respect to a particular time period, the total amounts received or invoiced by TGTX, its Affiliates, and sublicensees (subject to the provisions set forth in Section 6) for sales of Product made during such time period to unaffiliated Third Parties, less the following deductions to the extent actually allowed or incurred with respect to such sales:

discounts, including cash, trade, and quantity discounts, retroactive price reductions, charge-back payments, and rebates actually granted or administrative fees actually paid to trade customers, patients (including those in the form of a coupon or voucher), managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, federal, state, or local government and the agencies, purchasers and reimbursers of managed health organizations, pharmaceutical benefit managers, group purchasing organizations, or federal, state or local government;

credits or allowances actually granted upon prompt payment, or losses, actually incurred as a result of damaged goods, rejections or returns of such Product, including in connection with recalls, and all other reasonable and customary allowances and adjustments actually credited to customers;

packaging, freight, postage, shipping, transportation, warehousing, handling and insurance charges, credit card processing fees and any customary payments with respect to the Products actually made to wholesalers or other distributors, in each case actually allowed or paid for distribution and delivery of Product, to the extent billed or recognized; and

taxes, including sales taxes, excise taxes, value-added taxes, and other taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of such Product, including, without limitation, value-added and sales taxes.

Notwithstanding the foregoing, amounts received or invoiced by TGTX, its Affiliates and sublicencees for the sale of Product among TGTX, its Affiliates and sublicencees shall not be included in the computation of Net Sales hereunder. In any event, any amounts received or invoiced by TGTX and its Affiliates or sublicensees shall be accounted for only once. Net Sales shall be accounted for in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") consistently applied. Net Sales shall exclude any samples of Product transferred or disposed of at no cost for promotional or educational purposes, and the cost for such samples transferred or disposed of shall be deemed to be included in the Commercial Expenses.

For the purposes of determining royalty rates and the royalties payable on Combinations, Net Sales of Product shall be calculated [9] , * , * , * , and * , * , * (*) * (*) * . In the event that such average selling price cannot be determined for both Product and all other active ingredient(s) and component(s) included in the Combination Product, Net Sales for purposes of determining payments under this Agreement shall be calculated by * , and * (s) * (s) * , as determined by TGTX using its standard accounting procedures consistently applied. In the event that the standard fully-absorbed cost of the Product and/or the other active ingredient(s) or component(s) included in such Combination cannot be determined, for the purposes of determining royalties payable hereunder, the Parties shall negotiate in good faith to determine an appropriate commercial value for all the components in the Combination and calculate Net Sales of such Combination accordingly.

Further, the Parties agree to negotiate in good faith for an equitable determination of the Net Sales of the Product in the event TGTX and its Affiliates sells the Product in such a manner that gross sales of the Product are not readily identifiable. In addition, for purposes of this Agreement, "sale" shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of Product at no charge for academic research, preclinical, clinical, or regulatory purposes (including the use of a Product in Clinical Trials) or in connection with patient assistance programs or other charitable purposes or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry and/or which is reasonably proportional to the market for such Product).

1.38 "Novimmune Know-How": shall mean (i) all Know-How that is Controlled by Novimmune or its Affiliates on the Effective Date and during the Term, and (ii) Novimmune's interest in any Joint Know-How, in each case that is necessary or useful for the Development, manufacture or Commercialization of the Compound or the Product. For clarity, Novimmune Know-How excludes the Novimmune Product and Platform Patents.

1.39 "Novimmune Platform Patent(s)": shall mean any Patent, including Novimmune's interest in any Joint Patent, that (a) is Controlled by Novimmune or its Affiliates on the Effective Date and during the Term, and (b) generically claims the Compound or the Product or its manufacture or its use, or any other invention that is otherwise necessary for the Development, manufacture, use or Commercialization of the Compound or the Product in the Field of Use including the patents listed in Exhibit B which shall be from time to time amended and updated during the Term to incorporate the then-current Novimmune Patents.

1.40 "Novimmune Product Patent(s)": shall mean any Patent, including Novimmune's interest in any Joint Patent, that (a) is Controlled by Novimmune or its Affiliates on the Effective Date and during the Term, and (b) specifically claims the Compound or the Product or its specific manufacture or its specific use, including the patents listed in Exhibit B which shall be from time to time amended and updated during the Term to incorporate the then-current Novimmune Patents.

1.41 "Party": shall mean either TGTX or Novimmune, as the context requires, or both TGTX and Novimmune when used in the plural form

1.42 "Patent(s)": shall mean (a) pending patent applications, including provisional patents, issued patents, utility models and designs; and (b) extensions, reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, requests for continued examination, continuations-in-part, or divisions of or to any patents, patent applications, utility models or designs.

1.43 "Phase I Clinical Trial": means a small scale trial of a pharmaceutical product on subjects that generally provides for the first introduction into humans of such product with the primary purpose of determining safety, metabolism and pharmacokinetic properties, clinical pharmacology and any other properties of such product as per the study protocol design, as required by 21 C.F.R. 312(a) or a similar study in other countries.

1.44 "Phase II Clinical Trial": means a small scale clinical trial of a pharmaceutical product on patients, including possibly pharmacokinetic studies, the principal purposes of which are to make a preliminary determination that such product is safe for its intended use and to obtain sufficient information about such product's efficacy to permit the design of further clinical trials, as required by 21 C.F.R. 312(b) or a similar study in other countries.

1.45 "Phase III Clinical Trial": means one or more clinical trials on sufficient numbers of patients, which trial(s) are designed to (a) establish that a drug is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the drug in the dosage range to be prescribed; and (c) support Regulatory Approval of such drug, as required by 21 C.F.R. 312(c) or a similar study in other countries.

1.46 "Product(s)": shall have the meaning set forth in Section 1.71 of the JV Agreement.

1.47 "Regulatory Approvals" means all approvals (including without limitation supplements, amendments, and pricing approvals), licenses, registrations or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the manufacture, storage, import, transport, distribution, marketing, use or sale of a pharmaceutical product in a given regulatory jurisdiction.

1.48 "Regulatory Authority": means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including without limitation, in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over the Product, and, in the European Union, the EMEA and any other applicable Governmental Authority having jurisdiction over the Product..

1.49 "Royalties": shall mean the royalties to be paid by TGTX to Novimmune on the basis of Net Sales pursuant to Section 4.3.3 hereof

1.50 "Royalty Term": shall mean, on a country-by-country basis, the period beginning upon the First Commercial Sale of a Product in a country and ending on the later of (i) on the expiration of the[10] within the Licensed Patents covering the sale of the Product in such country, or (ii) expiry of any other * with respect to the Product in a country, including patent term extensions, marketing exclusivity or any other non-patent exclusivity.

1.51 "Sole Inventions": Any new invention pertaining to the Compound, Product, or their uses made solely by one of the Parties.

1.52 "Subcontractor": means a Third Party service provider engaged by TGTX to perform contract services on behalf of TGTX or its Affiliates, where TGTX retains a meaningful participatory role in the overall development and commercialization of the Product (*e.g.*, contract research or development organizations, clinical sites performing clinical trials, universities and scientific institutes, distributors in certain countries in the Territory, or contract manufacturing organizations).

1.53 "Sublicensee(s)": shall mean any Third Party to whom TGTX, or any of its Affiliates, has sublicensed any of TGTX's rights under the license granted to TGTX pursuant to Section 2.1

1.54 "Technology Transfer Plan": shall have the meaning ascribed to this term in Section 3.1.1.

1.55 "Territory": shall mean the entire world.

1.56 "TGTX Exercise Fee": shall have the meaning ascribed to this term in Section 6.2.

1.57 "TGTX Intellectual Property Rights": shall mean all TGTX Patents and TGTX Know-How.

1.58 "TGTX Know-How": shall mean (i) all Know-How that is Controlled by TGTX or its Affiliates on the Effective Date and during the Term, and (ii) TGTX's interest in the Joint Know-How, in each case that is necessary or useful for the Development, manufacture or Commercialization of the Compound or the Product. For clarity, TGTX Know-How excludes TGTX Patents.

1.59 "TGTX Patent(s)": shall mean any Patent, including TGTX's interest in any Joint Patent, that (a) is Controlled by TGTX or its Affiliates on the Effective Date and during the Term, and (b) claims the Product or its manufacture or its use, or any other invention that is otherwise necessary or useful for the Development, manufacture, use or Commercialization of the Compound or the Product in the Field of Use, including the patents listed in Exhibit [ ], which shall be from time to time amended and updated during the Term to incorporate the then-current TGTX Patents.

1.60 **"Third Party":** shall mean any entity other than TGTX or Novimmune or an Affiliate of TGTX or Novimmune.

1.61 **"Valid Claim"** shall mean (a) any claim of an issued unexpired patent that (i) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, and (ii) is not lost through an interference proceeding that is unappealable or unappealed within the time allowed for appeal; or (b) provided there is no Biosimilar Product available in the market, a claim of a patent application, which claim has not been abandoned or finally disallowed without the possibility of appeal and provided that such patent application has not been pending before an examining authority for more than [11] (*) years from its filing date.

2 LICENSE

2.1 Subject to the terms and conditions of this Agreement, Novimmune grants to TGTX an exclusive license under the Novimmune Product Patents and a non-exclusive license under the Novimmune Platform Patents and Novimmune Know-How, to develop, have developed, make, have made, use, have used, sell, have sold, offer for sale, register, have registered, Commercialize, and have Commercialized and import the Compound or the Product for any Indication in the Field of Use in the Territory. For avoidance of doubt, Novimmune does not grant to TGTX any right or license with respect to any API other than the Compound, as defined herein above.

2.2 The license granted to TGTX by Novimmune under Section 2.1 includes the right for TGTX to grant sublicenses (across multiple tiers) to its Affiliates and to Third Parties for the development, manufacture, sale and/or commercialization of the Compound or the Product. All sublicenses granted by TGTX shall be subject to the terms and conditions of this Agreement and TGTX shall enter into a written sublicense agreement with each Sublicensee which will contain terms and conditions fully consistent with the terms and conditions contained in this Agreement. TGTX shall use Diligent Efforts to include in any Commercial Sublicense Agreement express permission to assign all of the rights and obligations under such agreement to Novimmune without consent from the Sublicensee. TGTX shall provide to Novimmune a true and complete copy of each Commercial Sublicense Agreement entered into by TGTX or any of its Affiliates and any Sublicensee, and of each amendment to any such Commercial Sublicense Agreement, in each case, within * (*) days after execution of such Commercial Sublicense Agreement or amendment. For the purpose of this Section 2.2, the term **"Commercial Sublicense Agreement"** shall mean any agreement executed by TGTX or any of its Affiliates under which any of TGTX's rights under the license granted to TGTX pursuant to Section 2.1 are sublicensed; *provided*, *however*, that the term Commercial Sublicense Agreement shall exclude any agreement between TGTX or its Affiliate and a Subcontractor. In addition, TGTX shall notify Novimmune in writing of the termination of any Commercial Sublicense Agreement within * (*) days after such termination. If TGTX determines that there is a reasonable likelihood of its execution of a Commercial Sublicense Agreement or an amendment to, or termination of, an existing Commercial Sublicense Agreement, TGTX shall use reasonable efforts to provide notice thereof to Novimmune, which notice shall be provided solely for Novimmune' information and planning purposes. No sublicense hereunder shall limit or affect the obligations of TGTX under this Agreement, and TGTX shall remain fully responsible for each Affiliate's or Sublicensee's compliance with the applicable terms and conditions of this Agreement. TGTX agrees to take Diligent Efforts to enforce the terms of each Commercial Sublicense Agreement against the relevant Sublicensee in the event of a material breach thereof. Notwithstanding anything else to the contrary contained in this Agreement, all Commercial Sublicense Agreements shall survive any termination of this Agreement by Novimmune, so long as such Sublicensee is not in breach of the Commercial Sublicense Agreement.

2.3 TGTX may subcontract certain activities to Subcontractors who will conduct such activities, or a portion thereof, on behalf of TGTX. TGTX's execution of a subcontracting agreement with any Subcontractor shall not relieve TGTX of any of its obligations under this Agreement. TGTX shall remain directly liable to Novimmune for any performance or non-performance of a Subcontractor that would be a breach of this Agreement if performed or omitted by TGTX, and TGTX shall be deemed to be in breach of this Agreement as a result of such performance or non-performance of such Subcontractor. TGTX shall use reasonable efforts to include in any agreement with a Subcontractor express permission to assign all of the rights and obligations under such agreement to Novimmune without consent from the Subcontractor.

2.4 Except as expressly provided in this Agreement, no license or other right is or shall be created or granted hereunder by implication, estoppel or otherwise.

3 DEVELOPMENT PLAN

3.1. **Obligations of Novimmune**

3.1.1 As soon as possible after the Effective Date, Novimmune shall transfer to TGTX, all Novimmune Know-How that is necessary for TGTX to continue the development and manufacture of the Compound and the Products in accordance with the Development Plan and transfer the relevant information and materials.

3.1.2 At no cost to TGTX, Novimmune shall provide a reasonable amount of technical, scientific and intellectual property support to the Development Plan, as requested by TGTX, during the first [12] (*) month period beginning on the Effective Date unless the costs associated with such support has been already shared by both Parties pursuant to the JV Agreement.

3.2 Obligations of *

3.2.1 TGTX shall undertake Diligent Efforts to Develop, register and Commercialize the Product in the Field of Use in at least one Major Market and in such other markets as TGTX deems commercially reasonable. TGTX shall use Diligent Efforts to maximize Net Sales and shall not take any action with the intent of reducing or avoiding the milestone payments or any royalties hereunder. From and after the Effective Date, [13] shall be solely responsible for all the costs relating to the Development, registration and Commercialization of the Product in the Field of Use. * shall solely assume the managing and the financing of the Development Plan, with the objective of verifying the safety, potency and efficacy of the Product and, if the results of clinical development are positive, filing applications for BLA approval in an expeditious manner, within the limits of the demands of the Regulatory Authorities and consistent with Diligent Efforts, as more fully described below in this Section **3.2.2** TGTX shall retain final decision making authority on all Development, Commercialization, marketing, manufacturing and regulatory matters relating to the Product.

3.2.3 TGTX shall conduct the activities set forth in the Development Plan in accordance with all applicable Laws and current good manufacturing practice (cGMP), current good laboratory practice (cGLP) and current good clinical practice (cGCP), where applicable.

3.2.4 The Development Plan will be updated from time to time in accordance herewith and such updates shall be attached hereto as Exhibit D. The Development Plan indicates in reasonable details TGTX's plans for the Development of Product in the Field of Use, including regulatory and registration strategy consistent with Diligent Efforts. Without limiting the generality of any of the foregoing obligations in this Section 3.2.3, TGTX shall use Diligent Efforts to Develop the Product. TGTX may reasonably revise and amend the Development Plan from time to time upon as much advance notice to Novimmune as is practicable under the circumstances, so long as such amended Development Plan meets the criteria described above.

3.2.5 If at any time TGTX definitively and formally suspends its research or development efforts for the Product, TGTX shall provide Novimmune notification of such suspension, giving reasons and a statement of its intended actions.

3.2.6 TGTX shall be obligated to make Diligent Efforts to Develop, itself or through Affiliates, subcontractors and/or Sublicensees, at least * (*) Product in one Major Market. If Novimmune considers that TGTX has failed to exercise Diligent Efforts, then Novimmune shall notify TGTX in writing within * (*) days of appearance of such potential failure thereof stating in reasonable detail the particular alleged failure.

(a) If TGTX disagrees with Novimmune's claim that TGTX has failed to exercise Diligent Efforts, TGTX shall so notify Novimmune in writing within * (*) days after receipt of Novimmune's notice, in which event the Parties shall promptly refer the matter to a Third Party expert in drug development, completely unaffiliated and independent of the Parties and jointly selected by the Parties, to determine whether a failure by TGTX to use Diligent Efforts occurred, or if the related problem was due to some other cause. Neither Party shall unreasonably withhold or delay its approval of such expert. The Parties shall initially share equally the fees and costs of such expert, but promptly after such expert makes a determination regarding the matter, the non-prevailing Party shall reimburse the prevailing Party for the share of such fees and costs borne by the prevailing Party. Should it be determined by the expert that such failure resulted from TGTX's failure to use Diligent Efforts to Develop the Product, then the expert shall determine what corrective action by TGTX would best meet the standard of Diligent Efforts and a timeframe for the completion of such corrective action by TGTX. The determination of such expert shall be final and binding on the Parties.

(b) If TGTX does not correct such alleged failure either: (i) within [14] (*) days after notice of such alleged failure from Novimmune; or (ii) if TGTX disputes Novimmune's allegation of failure to use Diligent Efforts in accordance with the preceding paragraph (a), within the period specified by the expert; then, in each case, Novimmune shall have the right to terminate this Agreement in accordance with Section 12.3.

3.2.7 TGTX shall maintain reasonable records of its work, including research, development, clinical, manufacturing and commercialization activities with respect to the Product conducted by TGTX under this Agreement, together with all results, data and developments made or generated in connection with any of the foregoing. Such records shall fully and properly reflect all work done and results achieved in the performance of this Agreement in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

3.2.8 During the Term, TGTX shall use commercially reasonable efforts to keep Novimmune regularly informed of TGTX's worldwide Product development through periodic reports, including through the issuance of annual and quarterly reports pursuant to the Securites and Exchange Act of 1934. In addition, throughout the Term, TGTX shall notify Novimmune promptly of the occurrence of the following with respect to a Product: (i) initiation of any material Phase II Clinical Trial in a Major Market; (ii) initiation of any Phase III Clinical Trial in a Major Market; (iii) BLA filing and acceptance in any Major Market; (iv) BLA approval in any Major Market; and (v) First Commercial Sale in any Major Market. TGTX shall also respond to reasonable (*i.e.*, not unduly frequent or burdensome) informal requests from Novimmune for additional information regarding the development of the Product from time to time; provided however, to the extent, TGTX makes a public announcement with respect to the foregoing (i) – (v), such public announcement shall serve as notice.

3.2.9 Novimmune agrees that the results of the Development Plan cannot be accurately predicted, that TGTX's obligation with respect to the Development Plan is not an obligation to obtain a particular result and that TGTX does not warrant or guarantee that the Development Plan will yield any useful or anticipated results.

4 CONSIDERATION

4.1 As consideration for the exclusive license rights provided in Section 2.1, TGTX shall pay to Novimmune the amounts set forth in this Article 4.

4.2 Exercise Fee

Upon the Effective Date of this Agreement, TGTX shall pay to Novimmune a fully earned, non-refundable, one-time, up-front license fee equal to the sum of [15] ($ *) [or * ($ *), if Novimmune exercises their put option under the provisions of the JV Agreement] (the "**Exercise Fee**"), which shall be payable in cash and/or shares of TGTX Common Stock (the "**TGTX Shares**") at the discretion of TGTX.

Upon signature of this Agreement, Novimmune shall provide an original invoice for the TGTX Exercise Fee to TGTX, who shall pay the cash portion of the Exercise Fee within * (*) days of receipt of such invoice.

For payments made in TGTX Shares pursuant to this Section 4, such portion of the Exercise Fee shall be made through the issuance of that number of shares of Common Stock of TGTX as shall equal a fraction where the numerator is * and the denominator is the * . For purposes of this Section 4, the " * " means the * (or, * , *) for the * (*) trading days prior to the Effective Date; provided, however, that in the event that TGTX effects a stock split, combination or stock dividend at any time during such * trading days or subsequent thereto and prior to the issuance of the TGTX Shares, the number of shares of TGTX Common Stock issuable shall be appropriately adjusted to give effect to such action. Within * (*) business days of the Effective Date, TGTX shall issue to Novimmune certificates representing the TGTX Shares and within * (*) business days of the issuance of such certificates for the TGTX shares, TGTX shall file a resale registration statement covering such shares and shall use Diligent Efforts to make such resale registration statement effective as quickly as possible. TGTX covenants to use Diligent Efforts to keep such registration statement continuously effective until such time as such shares can be sold without restriction under Rule 144.

4.3 Milestones and Royalties

4.3.1 BLA Acceptance Payment

(a) BLA acceptance payment: Whether such event is achieved by TGTX, its Affiliates, its Sublicensees or any Third Party acting on behalf of TGTX, its Affiliates or its Sublicensees, TGTX shall pay Novimmune a fully earned, non-refundable, one-time, payment in each of the territories listed below upon the acceptance of the first BLA in each such territory:

*	$*
*	$*
*	$*

4.3.2 Approval and Sales Milestone:

(a) Sales Milestones. TGTX shall pay the sales milestone payments set forth below (which, when paid, shall be considered fully earned and non-refundable) based on cumulative net sales of Product (each, a "**Sales Milestone Payment**"). The Sales Milestone Payments shall be paid only once for each of the events set forth in this Section 4.3.2(a), whether such milestone event is achieved by TGTX, its Affiliates, its Sublicensees, or any Third Party acting on behalf of TGTX, its Affiliates, or its Sublicensees. No payment shall be due for any milestone event which is not achieved.

Sales Milestones:	$*
	$*
	$*

(b) Approval Milestones. Whether such event is achieved by TGTX, its Affiliates, its Sublicensees or any Third Party acting on behalf of TGTX, its Affiliates or its Sublicensees, TGTX shall pay Novimmune a fully earned, non-refundable, one-time, milestone payment in each of the territories listed below upon the approval of the first BLA in each such territory:

Approval Milestone:	$*
	$*
	$*

Any milestone payments owed under Sections 4.3.1 and 4.3.2 may be paid on cash and/or TGTX Shares, or a combination of both, at the discretion of TGTX. TGTX shall provide Novimmune with written notice within [17] (*) working days of the occurrence of any of the foregoing milestone events and the relevant milestone payment is payable by TGTX to Novimmune within * (*) days of receipt of a corresponding invoice issued by Novimmune. If TGTX determines that there is a reasonable likelihood of a particular milestone event being achieved on or about a particular date, TGTX shall use reasonable efforts to provide advance notice thereof to Novimmune, which notice shall be provided solely for Novimmune' planning purposes and shall not be construed as a representation, warranty or covenant by TGTX that such milestone event will occur when anticipated or at all.

4.3.3 Royalties on Net Sales. TGTX shall pay to Novimmune royalties based on the aggregate annual Net Sales of each Product(s) sold in the Territory at the rate shown in the table below during the Royalty Term for each country.

Sales Royalties	*	*** %**
	*	*** %**
	*	*** %**

4.3.4 Royalty Stacking:

(a) Required Third Party License(s). Subject to the limitation set forth in clause (b) below, if one or more licenses to patent rights owned or controlled by one or more Third Parties are necessary, as reasonably determined by TGTX and Novimmune jointly, for TGTX to have freedom to operate under the Novimmune Product Patents to Commercialize the Product in the Field and in the Territory, TGTX may obtain such one or more Third Party licenses under such patent rights and to deduct from any royalty payments due to NOVIMMUNE hereunder an amount equal to * percent (* %) of any royalties paid by TGTX to such one or more Third Parties.

(b) Royalty Floor. The deductions in the foregoing clause (a) shall be limited in their cumulative application so that no royalty payments due to NOVIMMUNE hereunder shall be reduced by more than * percent (* %).

4.3.5 Additional Royalty Payments:

At TGTX's discretion, TGTX shall negotiate a license with * to manufacture the Product. It is acknowledged that TGTX may be required to pay * for the use of their [18] cell line, media and feeds and manufacturing process, and also a technology transfer fee (to be directly negotiated with *) if the * cell line and process is transferred to a third party CMO.

TGTX shall pay Novimmune for the use of their * cell line, if available, and if required, an additional Royalty payment of * %.

4.4 Payments

4.4.1 Timing of Royalty Payments:

(a) Royalties on Net Sales pursuant to Section 4.3.3 shall be paid by TGTX to Novimmune * within * (*) days after the end of calendar * in which such Net Sales are made (as determined by the date of invoice or billing). Simultaneously with such payment, TGTX shall provide a report to Novimmune of its calculation of such Royalties, in sufficient detail, including the amounts of gross revenues and applicable deductions (the " * Royalty Report"). Such Royalties shall be subject to a true-up adjustment to take into account deductions under the definition of Net Sales either (A) allowed during a calendar * that were not accrued during such calendar * , or (B) accrued during a calendar * but not taken or later subject to a reversal following the end of such calendar * (each of (A) and (B), a "True-up Adjustment"). Each * Royalty Report provided by TGTX shall set forth the amount of any True-up Adjustment applicable to any prior calendar * .

4.4.2 All payments to Novimmune hereunder shall be made using the bank details provided by Novimmune. All payments to Novimmune shall be made in US dollars. If Net Sales are made in another currency other than US dollars, TGTX shall convert them into US dollars for the purpose of the calculation of Royalties by applying the average interbank exchange rate as published by (OANDA/US treasury) for the last day of each month within the calendar * for which payment to Novimmune is due. All costs associated with making payments to Novimmune, including the cost of wire transfers, shall be paid by * .

4.4.3 TGTX shall (and shall require its Affiliates to) prepare and maintain complete and accurate books and records regarding Net Sales (including gross sales and applicable deductions from gross sales), Royalties due hereunder. Novimmune shall have the right to have such books and records reasonably inspected by an independent certified auditor selected by Novimmune and accepted by TGTX, whose acceptance shall not be unreasonably withheld, to confirm Net Sales (including gross sales and applicable deductions from gross sales), Royalties due hereunder. Such auditor will execute a written confidentiality agreement with TGTX and will disclose to Novimmune only such information as is reasonably necessary to provide Novimmune with information regarding any actual discrepancies between the amounts reported or paid and the amounts payable under this Agreement. Such auditor will send a copy of its report to TGTX within [19] (*) days of delivery of such report to Novimmune. Such report will include the methodology and calculations used to determine the results. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Records to be available under an inspection shall include all relevant documents pertaining to payments specified above. Novimmune shall bear the fees and expenses of such inspection, provided that, if an underpayment of more than * percent (* %) of the payments due for any calendar year is discovered in any inspection, then TGTX and or its affiliates shall bear all fees and expenses of that inspection within * (*) days after receipt of invoice from Novimmune.

4.4.4 Without limiting any other rights or remedies available to Novimmune, TGTX shall pay Novimmune interest on any payments that are not paid on or before * days from the due date at the British Bankers Association's one month LIBOR Rate for United States Dollar deposits calculated from the due date to the date paid in full.

4.4.5 In the event TGTX fails to pay overdue amounts to Novimmune within the due date under this Section 4.4, Novimmune shall have the right to terminate this Agreement upon * (*) days' prior written notice to TGTX pursuant to Section 8.4, unless TGTX has cured such failure to pay by the end of such * (*) day period.

4.4.6 TGTX shall make payments to Novimmune under this Agreement withholding any taxes that may be due with respect to such payments to the extent that such withholding is required by applicable law. If any taxes are required to be withheld by TGTX, then TGTX shall (a) deduct such taxes from the payment made to Novimmune, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of such tax payments to Novimmune and certify receipt of such payment by the applicable tax authority within * (*) days following such tax payment

5 INTELLECTUAL PROPERTY

5.1 Ownership of Intellectual Property Rights and Inventions

5.1.1 Ownership of Inventions.

The Novimmune Product Patents and Novimmune Platform Patents shall at all times be and remain the sole property of Novimmune, subject to any limitation on the transfer of such rights contained herein.

Inventorship shall be determined in accordance with U.S. patent laws. Sole Inventions owned by TGTX and TGTX's interest in all Joint Inventions shall be included in the TGTX Intellectual Property Rights. Sole Inventions owned by Novimmune and Novimmune's interest in all Joint Inventions shall be included in the Novimmune Product Patents or Novimmune Platform Patents, as determined by the claimed subject matter; provided that if the claimed subject matter includes a claim specifically directed to the Product, NOVIMMUNE's interest in all Joint Inventions shall be included in the NOVIMMUNE Product Patent regardless of the existence the same patent or application of claimed subject matter providing generic Product coverage.

5.1.2 Disclosure of Inventions. Each Party shall promptly disclose to the other any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing inventions that may be either Sole Inventions or Joint Inventions, and all Information relating to such inventions. Either Party's Sole Inventions and Joint Inventions required for the development or commercialization of the Product, shall automatically be included in this Agreement and available for use by the Commercializing Party.

5.1.3 Prosecution of Patents.

a. Novimmune Patents Other than Joint Patents. Except as otherwise provided in this Section 5.1.3(a), Novimmune shall have the sole right, authority and obligation to file, prosecute and maintain the Novimmune Product Patents and Novimmune Platform Patents (other than Joint Patents which shall be prosecuted and maintained in accordance with Section 5.1.3(b)) in the Territory and on a worldwide basis. Novimmune shall provide TGTX reasonable opportunity to review and comment on such prosecution efforts regarding such Novimmune Product Patents in the Territory. Novimmune shall provide TGTX with a copy of material communications from any patent authority in the Territory regarding such Novimmune Product Patents, and shall provide TGTX with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. Notwithstanding the foregoing, if Novimmune desires to abandon or not maintain any Patent within such Novimmune Product Patents in the Territory, then Novimmune shall provide TGTX with [20] (*) days prior written notice of such desire (or such longer period of time as reasonably necessary to allow TGTX to assume such responsibilities) and, if TGTX so requests, shall provide TGTX with the opportunity to prosecute and maintain such Patent in the Territory in place of Novimmune. If TGTX desires Novimmune to file, in the Territory, a patent application that claims priority from a Patent within the Novimmune Product Patents, other than a Joint Patent, in the Territory, TGTX shall provide written notice to Novimmune requesting that Novimmune file such patent application in the Territory. If TGTX provides such written notice to Novimmune, Novimmune shall either (i) file and prosecute such patent application and maintain any patent issuing thereon in the Territory or (ii) notify TGTX that Novimmune does not desire to file such patent application and provide TGTX with the opportunity to file and prosecute such patent application and maintain any patent issuing thereon in the Territory in place of Novimmune. Any patent controlled by or taken over by TGTX under this Section 5.1.3(a) shall henceforth be automatically assigned by NOVIMMUNE in favor of TGTX.

c. Joint Patents. Except as otherwise provided in this Section 5.1.3 (b), TGTX shall be entrusted with the right and authority, to prosecute and maintain the Joint Patents on a worldwide basis at its sole discretion herein referred to as an "Entrusted Party" (subject to this Section 5.1.3 (b)). The Entrusted Party shall provide the other party reasonable opportunity to review and comment on such prosecution efforts regarding such Joint Patents. The Entrusted Party shall provide the other party with a copy of material communications from any patent authority regarding such Joint Patents, and shall provide the other party with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. If one Party determines in its sole discretion to abandon or not maintain any Patent within the Joint Patents anywhere in the world, then such Party shall provide the other Party with [21] (*) days' prior written notice of such determination (or such longer period of time reasonably necessary to allow the other party to assume such responsibilities) and shall provide the other Party with the opportunity to prosecute and maintain such Patent at the other Party's sole expense, and if the other Party so requests, the one Party shall assign such Patent to the other Party (if the other Party is Novimmune, such Patent shall be included in the Novimmune Product Patents or if the other Party is TGTX, in which case such patent will be included in the TGTX Patents). If the other Party desires to file, in a particular jurisdiction, a patent application that claims priority from a Patent within the Joint Patents, the other Party shall provide written notice to the Entrusted Party of such desire. Within * (*) days of such written notice, the Entrusted Party shall provide written notice to the First Party as to whether the Entrusted Party agrees to file a patent application in such jurisdiction or not. In the event the Entrusted Party agrees to such a filing, the Entrusted Party shall file such patent application in such jurisdiction. In the event the Entrusted Party does not desire to file in such jurisdiction, the Entrusted Party shall (i) provide the other Party with the opportunity to file and prosecute such patent application and maintain any patent issuing therefrom, and (ii) assign such patent application or a right to file such patent application to the other Party; and the other Party may file such patent application in such jurisdiction at its sole expense (in which case such Patent shall be included in the respective Party's Patents).

d. Cooperation in Prosecution. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 5.1.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

e. Costs of Prosecution. The costs to prosecute and maintain the Novimmune Product Patents related to the Product shall be borne by Novimmune. The costs to prosecute and maintain the Joint Patents related to the Product shall be borne equally by Novimmune and TGTX. The costs to prosecute and maintain the TGTX Patents related to the Product shall be borne by TGTX. A Party taking over responsibility for a particular patent or patent application under this Section 5 shall be responsible for costs associated with same.

5.1.4 Infringement of Patents by Third Parties.

(a) Notification. Each Party shall promptly notify the other Party in writing of any existing or threatened infringement of the Novimmune Product Patents, Joint Patents or TGTX Patents of which it becomes aware, and shall provide evidence in such Party's possession demonstrating such infringement**.** The Party that is commercializing the Product shall be deemed the "Commercializing Party."

(b) Infringement of Patents in the Territory.

i. If a Party becomes aware that a Third Party infringes any Novimmune Product Patent, TGTX Patent, or Joint Patent in the Territory by making, using, importing, offering for sale or selling the Product or any similar CD47/CD19 bi-specific antibody covered by any of such Patents (such activities, **"Product Infringement"**), then such Party shall so notify the other Party as provided in Section 5.1.4 (a), which such notice shall include all information available to the notifying Party regarding such alleged infringement.

.In the Territory, TGTX shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement, subject to Section 5.1.4 (b)(iii) below, the cost and expense will be borne by TGTX. TGTX shall have a period of [22] (*) days (or shorter period, if required by the nature of possible proceeding) after notification by Novimmune or providing notification to Novimmune pursuant to Section 5.1.4 (a), to elect to so enforce such Patent. In the event TGTX does not so elect, it shall so notify Novimmune in writing during such [23] (*) day time period (or the above-mentioned shorter period), and Novimmune shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such Product Infringement at its sole cost and expense (except as otherwise expressly provided in this Section 5.1.4 (b)(ii)). Each Party shall provide to the Party enforcing any such rights under this Section 5.1.4 (b)(ii) reasonable assistance in such enforcement, at such enforcing Party's request, including joining such action as a party plaintiff if required by applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider the other Party's comments on any such efforts. Any recoveries obtained from a suit or an action commenced by TGTX hereunder shall first be applied to the recovery of expenses incurred by TGTX or Novimmune (if any) in bringing the suit or action and the remaining amounts, if any, shall be deemed additional Net Sales; provided, further, however, if Novimmune proceeds with the enforcement after TGTX decides not to move forward, then any amounts recovered shall belong solely to Novimmune.

.The Party not bringing an action with respect to Product Infringement in the Territory under Section 5.1.4 (b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action. Additionally, the Party not bringing an action under this Section 5.1.4 (b) may have an opportunity to participate in such action to the extent that the Parties may mutually agree at the time the other Party elects to bring an action hereunder.

(c) Settlement. TGTX shall not settle any claim, suit or action that it brings under this Section 5.1.4 involving Novimmune Product Patents (excluding Joint Patents) in any manner that would have a materially adverse impact on Novimmune Patents anywhere in the world, or that would materially limit or restrict the ability of either Party to manufacture, use, sell, offer for sale or import the Product anywhere in the world, without the prior written consent of Novimmune. Novimmune shall not settle any claim, suit or action that it brings under this Section 5.1.4 involving TGTX Patents (excluding Joint Patents) in any manner that would negatively impact the TGTX Patents or that would limit or restrict the ability of either Party to manufacture, use, sell, offer for sale or import the Product anywhere in the world, without the prior written consent of TGTX. Neither Party shall settle any claim, suit or action that it brings under this Section 5.1.4 involving Joint Patents in any manner that would negatively impact the Joint Patents or that would limit or restrict the ability of either Party to manufacture, use, sell, offer for sale or import the Product anywhere in the world, without the prior written consent of such other Party.

(d) Reserved

6 REPRESENTATIONS, WARRANTIES AND CERTAIN COVENANTS

6.1 Each Party represents, warrants and covenants to the other that:

(i) It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder;

(ii) As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement or instrument, oral or written, to which it is a party or by which it may be bound;

(iii) It has not granted, and shall not grant, any right to any Third Party which would conflict with the rights granted to the other Party hereunder; and

(iv) It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement. The execution, delivery and performance of this Agreement shall not violate, conflict with or constitute a default under any agreement (including its corporate charter or other organizational documents) to which it is a party or to which it may be bound, or to its best knowledge, any applicable Laws or order of any court or other tribunal.

6.2 Novimmune represents and warrants and covenants to TGTX that as of the Effective Date:

(i) All rights pertaining to the Novimmune Product Patents and Novimmune Platform Patents are owned by Novimmune;

(ii) The Novimmune Product Patents and Novimmune Platform Patents are not subject to any encumbrance, lien or claim or ownership by any Third Party that is inconsistent with the rights and licenses granted to TGTX hereunder;

(iii) Novimmune owns or possesses adequate right, title and interest in the Novimmune Product Patents and Novimmune Platform Patents to grant the license thereto to TGTX as provided in this Agreement;

(iv) No claim or litigation has been brought, or is threatened to be brought, by any person or entity (A) alleging that any of the Novimmune Product Patents or Novimmune Platform Patents in the Territory is invalid or unenforceable, or (B) alleging that use of the Novimmune Product Patents or Novimmune Platform Patents in the Territory infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party;

(v) No Third Party has infringed or misappropriated any Novimmune Product Patents by making, using, importing, offering for sale or selling the Compound or the Product and, as of the Effective Date, there is no actual or threatened infringement or misappropriation of the Novimmune Know How by any Third Party by making, using, importing, offering for sale or selling the Compound or the Product;

(vi) To Novimmune's knowledge, neither A) TGTX's exercise of its rights hereunder with respect to the Novimmune Product Patents or Novimmune Platform Patents, nor (B) TGTX's Development or Commercialization of the Product in the Territory, shall infringe any valid and enforceable Patent of any Third Party;

(vii) This Agreement is consistent with all Novimmune's Third Party license agreements in all respects and does not conflict with, violate, breach or otherwise give rise to a default by Novimmune under, any term of any Novimmune Third Party license agreement;

(viii) Novimmune has obtained any and all consents, if any, required from Third Parties for Novimmune to enter into this Agreement and to grant to TGTX the licenses and other rights provided herein and has provided a copy of such consents to TGTX;

(ix) Novimmune has not received any written notice from any Third Party claiming that the manufacture, use, sale, or importation of the Compound or Product by Novimmune prior to the Effective Date infringed any patent owned or controlled by any Third Party;

(x) Novimmune has not granted any license or other right to any Third Party regarding the Compound or the Product and/or the Novimmune Product Patents; and

(xi) Novimmune has not received any grant from or entered into any agreement with any government and/or any of its subdivisions or federal governmental bodies, or any other governmental bodies, regarding the Compound or the Product and/or the Novimmune Product Patents.

(xii) Novimmune has ended its CD47/CD19 bispecific antibody program and will not engage in a future program that will produce bispecific antibodies that target CD47/CD19.

6.3 Representations, Warranties, and Covenants of TGTX.

6.3.1 TGTX agrees that all of its activities, and the activities of its Affiliates related to its use of the Novimmune Product and Platform Patents and Novimmune Know-How and all Development and Commercialization of the Product including the transport, storage, sale and promotion thereof, pursuant to this Agreement shall comply with all applicable legal and regulatory requirements. TGTX and its Affiliates shall not engage in any activities that use the Novimmune Product and Platform Patents and/or Novimmune Know-How in a manner that is outside the scope of the license rights granted to TGTX hereunder. TGTX represents and warrants that it will comply with the U.K. Bribery Act, the United States Foreign Corrupt Practices Act and any and all other applicable Laws prohibiting corruption or bribery (collectively referred to as the "**Anti-Corruption Laws**").

6.3.2 TGTX represents, warrants, and covenants that (i) the issuance of the Shares has been duly authorized by all necessary corporate action; (ii) upon issuance, the Shares will be validly issued, fully paid and nonassessable, free and clear of all liens, encumbrances, restrictions (including under the Securities Act), charges, security interests, rights of first refusal and preemptive rights; and (iii) TGTX shall reserve from its authorized and unissued shares of Common Stock, a sufficient number of shares of Common Stock to issue Novimmune the shares in accordance with Article 6 hereof.

6.4 No Other Representations or Warranties: Except as expressly set forth in this Agreement, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES

7 INDEMNIFICATION AND INSURANCE

7.1 TGTX shall indemnify, defend, and hold harmless Novimmune and its Affiliates and their respective directors, officers, employees and agents (each, a **"Novimmune Indemnitee"**) from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, **"Losses"**), to which any Novimmune Indemnitee may become subject as a result of any claim, demand, action or other proceeding (each, a **"Claim"**) by any Third Party to the extent such Losses arise out of or result from (a) any breach by TGTX of its representations, warranties, covenants or obligations in this Agreement or (b) the gross negligence or willful misconduct of TGTX and its Affiliates or Sublicensees; except, in each case, to the extent such claim is caused by a breach of this Agreement by Novimmune or the gross negligence or willful misconduct of Novimmune.

7.2 Novimmune shall indemnify, defend, and hold harmless TGTX and its Affiliates and their respective directors, officers, employees and agents (each, a **"TGTX Indemnitee"**) from and against any and all Losses to which any TGTX Indemnitee may become subject as a result of any Claim by a Third Party to the extent such Losses arise out of or result from (a) any breach by Novimmune of its representations, warranties, covenants or obligations in this Agreement, or (b) the gross negligence or willful misconduct of Novimmune or its Affiliates; except, in each case, to the extent such claim is caused by a breach of this Agreement by TGTX or the gross negligence or willful misconduct of TGTX.

7.3 For purposes of Sections 7.1 and 7.2, the Novimmune Indemnitee or TGTX Indemnitee (the **"Indemnified Party"**) shall give prompt written notice to the other Party (the **"Indemnifying Party"**) of any claims, suits or proceedings by Third Parties which may give rise to any claim for which indemnification may be required under Section 7.1 or 7.2; *provided, however,* that failure to give such notice shall not relieve the Indemnifying Party of its obligation to provide indemnification hereunder except, if and to the extent that such failure materially and adversely affects the ability of the Indemnifying Party to defend the applicable claim, suit or proceeding. The Indemnifying Party shall be entitled to assume the defence and control of any such claim at its own cost and expense; provided, however, that the Indemnified Party shall have the right to be represented by its own counsel at its own cost in such matters. Neither the Indemnifying Party nor the Indemnified Party shall settle or dispose of any such matter in any manner which would adversely affect the rights or interests of the other Party (including the obligation to indemnify hereunder) without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defence of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses.

7.4 At and during such time as TGTX, its Affiliates, or its Sublicensees, begins clinical testing, sale or distribution of Products, TGTX shall (and shall require its Affiliates and Sublicensees to) at its sole expense, procure and maintain commercially reasonable insurance policies as would be maintained by similarly situated pharmaceutical companies consistent with the current industry standards for similar products, and compliant with any applicable law or regulation.

7.5 EXCEPT WITH RESPECT TO A BREACH OF SECTION 10 HEREOF, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR INCIDENTAL, CONSEQUENTIAL, INDIRECT, PUNITIVE OR SPECIAL DAMAGES OF THE OTHER PARTY ARISING OUT OF OR RELATED TO THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

8 CONFIDENTIALITY

8.1 Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and until the later of (i) the [24] (*) anniversary of the Effective Date, or (ii) * (*) years after the expiration or termination of the Term, it shall keep confidential and shall not publish or otherwise disclose, and shall not use for any purpose other than as provided for in this Agreement~~,~~ any Confidential Information furnished to it by the other Party pursuant to this Agreement except for that portion of such information or materials that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality to the disclosing Party, at the time of disclosure by the other Party, as evidenced by written documentation;
(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
(c) became generally available to the public or otherwise part of the public domain after it disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
(d) was disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto; or
(e) was independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information of the other Party, as evidenced by written documentation; provided, however, that this exception shall not apply to information or materials consisting of data and results generated or resulting from Development activities with respect to the Product, which information and materials shall be deemed Confidential Information of the Party who has developed such information or materials regardless of whether such information and materials were independently discovered or developed by the receiving Party or its Affiliate.

8.2 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting Patents as permitted in this Agreement;
(b) regulatory submissions and other filings with Governmental Authorities, including filings with the Securities and Exchange Commission;
(c) prosecuting or defending litigation or other proceedings or regulatory actions;
(d) complying with applicable Laws;
(e) disclosure to its employees, agents, and consultants, and any Third Parties (and potential licensees and) with which a Party is Developing or Commercializing the Product) only on a need-to-know basis and solely as necessary in connection with the performance of this Agreement, provided that in each case the recipient of such Confidential Information must agree to be bound by similar obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Article 10 prior to any such disclosure; and
(f) disclosure of the material financial terms of this Agreement to any bona fide potential investor, investment banker, acquiror, merger partner, or other potential financial partner; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each recipient of the confidential nature of such Confidential Information and shall cause each recipient of such Confidential Information to treat such Confidential Information as confidential.

8.3 The Parties agree that the terms of this Agreement shall be treated as Confidential Information by both Parties.

8.4 The Parties acknowledge that each Party may desire or be required to issue press releases or to make other public disclosures relating to this Agreement or its terms. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases or other public disclosures prior to the issuance thereof, provided that a Party may not unreasonably withhold consent to such releases, and that either Party may issue such press releases as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations. In addition, following an initial press release announcing this Agreement, each Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of this Agreement which have already been publicly disclosed in accordance herewith.

8.5 Subject to Section 8.4, TGTX shall not use the name "Novimmune" nor any variation or adaptation thereof, nor any trademark, tradename or other designation owned by Novimmune or its Affiliates, nor the names of any of its officers, employees or agents, for any purpose without the prior written consent of the other Party in each instance, except that TGTX may state that it has licensed from Novimmune one or more of the patents and/or applications within the Novimmune Patents, and TGTX may use Novimmune's logo on TGTX's corporate website and corporate presentation materials for such purpose, subject to Novimmune's prior review and approval (not to be unreasonably withheld) of TGTX's proposed use thereof.

8.6 Subject to Section 8.4, Novimmune shall not use the name of "TGTX" or its Affiliates nor any variation or adaptation thereof, nor any trademark, tradename or other designation owned by TGTX or its Affiliates, nor the names of any of its officers, employees or agents, for any purpose without the prior written consent of the other Party in each instance, except that Novimmune may state that it has licensed to TGTX one or more of the patents and/or applications within the Novimmune Patents, and Novimmune may use TGTX's logo on Novimmune's corporate website and corporate presentation materials for such purpose, subject to TGTX's prior review and approval (not to be unreasonably withheld) of Novimmune's proposed use thereof.

8.7 Each Party recognizes that the publication by TGTX of Data and other information regarding Compounds and Products, such as by public oral presentation, manuscript or abstract, may be beneficial to both Parties provided such publications are subject to reasonable controls to protect Confidential Information. Accordingly, Novimmune shall have the right to review and comment on any material proposed for public oral presentation or publication by TGTX that includes Data or other results of preclinical or clinical development of the Compound or any Product and/or includes Confidential Information of Novimmune. Before any such material is submitted for publication, TGTX shall use reasonable efforts to deliver a complete copy to Novimmune at least [25] (*) days prior to submitting the material to a publisher or initiating any other disclosure. Novimmune shall review any such material and give its comments to TGTX within ten (*) * of the delivery of such material to Novimmune. With respect to public oral presentation materials and abstracts, Novimmune shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to TGTX with appropriate comments, if any, but in no event later than ten (*) * from the date of delivery to Novimmune. TGTX shall comply with Novimmune's request to delete references to Novimmune's Confidential Information in any such material. In addition, if any such publication contains patentable subject matter, then at Novimmune's request, TGTX shall either delete the patentable subject matter from such publication or delay any submission for publication or other public disclosure for a period of up to an additional * (*) days so that appropriate patent applications may be prepared and filed.

8.8 Subject to Section 8.7, TGTX and its contractors, including without limitation clinical research organizations, shall have the right to publish results of all clinical trials of the Compound or any Product on TGTX's clinical trial register, and such publication will not be a breach of the confidentiality obligations provided in this Article 8.

8.9 All obligations of confidentiality and non-use imposed under this Article 8 shall expire [26] (*) years after the date of termination or expiration of this Agreement.

9 EXPIRY OF THE AGREEMENT; CONSEQUENCES OF EXPIRY

9.1 Unless terminated earlier pursuant to Article 10 or other mutual written agreement, this Agreement shall commence upon the Effective Date and shall expire, on a country-by-country basis on the expiration of the Royalty Term (the "**Royalty Term**").

10 TERMINATION

10.1 TGTX Termination with Cause: TGTX may terminate this Agreement at any time for Cause upon * (*) days' prior written notice to Novimmune.

10.2 TGTX Termination: TGTX may terminate this Agreement at any time for any reason upon * (*) days' prior written notice to Novimmune.

10.3 Novimmune Termination for TGTX Diligence Failure: If TGTX does not correct a failure to use Diligent Efforts within the applicable period specified in, or determined in accordance with, Section 3.2.5 (b) (a ***"Diligence Failure"***), Novimmune shall have the right to terminate this Agreement on * (*) days' written notice to TGTX unless TGTX cures such Diligence Failure before the end of such * (*) day period.

10.4 Termination for Material Breach: Each Party shall have the right to terminate this Agreement upon * (*) days' (or * (*) days' in the case of failure to make payment of amounts due hereunder) prior written notice to the other Party in the event of the material breach of any term or condition of this Agreement by the other Party, unless the breaching Party has cured such breach by the end of the applicable cure period; *provided, however,* that:

(a) this Section 10.4 shall not apply to any Diligence Failure by TGTX (in which case, Novimmune's termination right shall be as set forth in Section 10.3); and

(b) any right to terminate under this Section 10.4 shall be stayed and the cure period shall be stopped in the event that, during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 19 with respect to the alleged breach, which stay and stopping shall last so long as the dispute resolution proceedings are ongoing.

11 CONSEQUENCES OF TERMINATION

11.1 In the event of

(A) termination of this Agreement by TGTX pursuant to Section 10.1 or 10.2:

(a) The license granted by Novimmune to TGTX under Section 2.1 shall terminate and revert to Novimmune on the effective date of termination.

(b) Novimmune shall have the right, exercisable upon written notice by Novimmune to TGTX given within [27] (*) days after the effective date of such termination, to obtain, and effective upon such notice, TGTX shall, and it hereby does, grant to Novimmune, a perpetual, non-exclusive, worldwide, royalty-bearing license, with the right to sublicense, under TGTX Intellectual Property Rights (which, for purposes of this Section 11.1(A)(b) shall not include the Joint Patents or the Joint Know-How) solely to develop, make, have made, use, sell, offer for sale, have sold and import the Compound and Products in the Field of Use, subject to the terms and conditions set forth below in subparagraph (c). In consideration for such exclusive license, Novimmune shall pay to TGTX a royalty that is * % of the royalty amounts set forth in section 4.3.3 herein.

TGTX shall provide to Novimmune when enforcing any such rights under this Section 11.1(A)(b) reasonable assistance in such enforcement, at Novimmune's request and cost, including joining such action as a party plaintiff if required by applicable Law to pursue such action.

In addition, TGTX shall, and it hereby does, upon such Termination grant to Novimmune, (i) a perpetual, exclusive, worldwide, royalty-free license, with the right to sublicense, under the Joint Patents; and (ii) a perpetual, exclusive, royalty-free license to the Joint Know-How, in each case solely to develop, make, have made, use, sell, offer for sale, have sold and import the Compound and Products in the Field of Use, subject to the terms and conditions set forth below in subparagraph (c). TGTX shall provide to Novimmune when enforcing any such rights under this Section 11.1(A)(b) reasonable assistance in such enforcement, at Novimmune's request and cost, including joining such action as a party plaintiff if required by applicable Law to pursue such action.

(c) TGTX shall:

(i) at no cost to Novimmune transfer to Novimmune as soon as reasonably practicable all Data and information in TGTX's or its Affiliates' Control and possession relating to the Compound or Products as may be necessary to enable Novimmune to practice such license,

(ii) at no cost to Novimmune transfer and assign to Novimmune all of its right, title and interest in and to all INDs, BLAs, drug dossiers and master files with respect to any and all Products and all regulatory approvals with respect to any and all Products, and

(iii) Take such other commercially reasonable actions and shall execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under this subparagraph (c) to Novimmune, including without limitation assignments of any contracts, including sublicensing agreements, related to the Development and Commercialization of any Product or New Product, unless such assignment is prohibited by a contract and the applicable consent cannot be reasonably procured at reasonable cost. TGTX will use reasonable commercial efforts to obtain the consent of any third-party to any contract or agreement related to the Development or Commercialization of the Product or a New Product, which consent is required for the assignment of any such contract or agreement from TGTX to Novimmune, provided, however, that any cash payment required by TGTX in order to procure any such consent shall be deemed not commercially reasonable. Prior to receipt of such consent, TGTX shall make available to Novimmune all rights and other benefits of such contracts, on a subcontract or sublease basis or in some other appropriate manner to the fullest extent reasonably practicable and permitted by the terms of the contract or otherwise consented to by the other party to such contract, and Novimmune shall be considered an independent subcontractor or sublessee of TGTX, with respect to all matters concerning such contracts.

(B) termination of this Agreement by TGTX pursuant to Section 10.4:

(a) the license granted by Novimmune to TGTX pursuant to Section 2.1 remains in full force and effect in accordance with its terms and until such time on a country-by-country basis (i.e. partial) as the expiration of the Royalty Term or Entire territory , subject to TGTX's compliance with Article 4;

(b) all notification and reporting rights of Novimmune shall terminate and be of no further force or effect;

(c) pending the outcome of arbitration proceedings pursuant to Article 17, TGTX shall have the right to pay all amounts that become due under Article 4 after such termination into an escrow account with a reputable bank, and to the extent the arbitrators award damages to TGTX, the arbitrators shall be authorized, in their discretion, (i) to cause the release to TGTX of all or any part of the escrowed funds in partial or full satisfaction of such award, and/or (ii) to adjust the amounts payable by TGTX to Novimmune under this Agreement to compensate TGTX for damages suffered by TGTX as a result of Novimmune' material breach.

(C) termination of this Agreement by Novimmune pursuant to Section 10.3, or termination of this Agreement by Novimmune pursuant to Section 10.4 (subject to paragraph (b) thereof):

(a) The license granted by Novimmune to TGTX under Section 2.1 shall terminate and revert to Novimmune on the effective date of termination.

(b) Novimmune shall have the right, exercisable upon written notice by Novimmune to TGTX given within [28] (*) days after the effective date of such termination, to obtain, and effective upon such notice, TGTX shall, and it hereby does, grant to Novimmune, a perpetual, non-exclusive, worldwide, royalty-bearing license, with the right to sublicense, under TGTX Intellectual Property Rights (which, for purposes of this Section 11.1(C)(b) shall not include the Joint Patents or the Joint Know-How) solely to develop, make, have made, use, sell, offer for sale, have sold and import the Compound and Products in the Field of Use, subject to the terms and conditions set forth below in subparagraph (c). TGTX shall provide to Novimmune when enforcing any such rights under this Section 11.1(C)(b) reasonable assistance in such enforcement, at Novimmune's request and cost, including joining such action as a party plaintiff if required by applicable Law to pursue such action. In consideration for such license, Novimmune shall pay to TGTX a royalty based on the fair market value of such license. The royalty will be negotiated in good faith by the Parties within * (*) days following the effective date of the termination. If the Parties cannot agree on the terms of the royalty, the parties will select a disinterested Third Party to determine the fair market value of the license (the "Appraiser"). Once the Appraiser is selected, the Appraiser shall be instructed to furnish a written appraisal within * (*) days of it selection. TGTX shall bear the Appraiser's reasonable costs and expenses. The fair market value royalty will be paid out of Novimmune's gross profits following the first commercial sale of the Product, and which gross profits will be based on all amounts paid to Novimmune from its sublicensing or from sales directly or indirectly in the particular country or Territory. The term of such royalty will expire on the expiration of the * .

TGTX shall, and it hereby does, upon such Termination grant to Novimmune, (i) a perpetual, exclusive, worldwide, royalty-free license, with the right to sublicense, under the Joint Patents; and (ii) a perpetual, exclusive, royalty-free license to the Joint Know-How, in each case solely to develop, make, have made, use, sell, offer for sale, have sold and import the Compound and Products in the Field of Use, subject to the terms and conditions set forth below in subparagraph (c). TGTX shall provide to Novimmune when enforcing any such rights under this Section 11.1(C)(b) reasonable assistance in such enforcement, at Novimmune's request and cost, including joining such action as a party plaintiff if required by applicable Law to pursue such action.

(c) TGTX shall:

(i) at no cost to Novimmune , transfer to Novimmune as soon as reasonably practicable all Data and information in TGTX's or its Affiliates' Control and possession relating to the Compound or Products as may be necessary to enable Novimmune to practice such license; (ii) at no cost to Novimmune, transfer and assign to Novimmune all of its right, title and interest in and to all INDs, BLAs, drug dossiers and master files with respect to any and all Products and all regulatory approvals with respect to any and all Products; and (iii) Take such other commercially reasonable actions and shall execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under this subparagraph (c) to Novimmune, including without limitation assignments of any contracts, including sublicensing agreements, related to the Development and Commercialization of any Product or New Product, unless such assignment is prohibited by a contract and the applicable consent cannot be reasonably procured at reasonable cost. TGTX shall use reasonable commercial efforts to obtain the consent of any third-party to any contract or agreement related to the Development or Commercialization of the Product or a New Product, which consent is required for the assignment of any such contract or agreement from TGTX to Novimmune, provided, however, that any cash payment required by TGTX in order to procure any such consent shall be deemed not commercially reasonable. Prior to receipt of such consent, TGTX shall make available to Novimmune all rights and other benefits of such contracts, on a subcontract or sublease basis or in some other appropriate manner to the fullest extent reasonably practicable and permitted by the terms of the contract or as consented to by the other party to the contract, and Novimmune shall be considered an independent subcontractor or sublicensee of TGTX, with respect to all matters concerning such contracts.

(d) pending the outcome of arbitration proceedings pursuant to Article 19, TGTX shall pay all amounts that become due under Article 6 after such termination into an escrow account with a reputable bank, and to the extent the arbitrators award damages to Novimmune, the arbitrators shall be authorized, in their discretion, (i) to cause the release to Novimmune of all or any part of the escrowed funds in partial or full satisfaction of such award, and/or (ii) to adjust the amounts payable to Novimmune under this Agreement to compensate Novimmune for damages suffered by Novimmune as a result of TGTX's material breach.

11.2 Any termination of this Agreement shall be without prejudice to any rights or obligations which have accrued to any Party prior to such termination. Without limiting the generality of the foregoing, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to hereunder.

12 SURVIVING PROVISIONS

Sections 4.4 and Articles 1, 8, 9, 10, 13, 14, 15, 17, 18, 19 and 21 shall survive termination or expiration of this Agreement.

13 NOTICES

Notices required or permitted to be made or given to either Party hereto pursuant to this Agreement shall be sufficiently made or given on the date of mailing if sent to such Party by certified or registered mail, postage prepaid, addressed to it at its address set forth or to such other address as it shall designate in the course of this Agreement by written notice to the other Party as follows:

If to Novimmune:	**If to TGTX:**
Novimmune Attention: Novimmune 14 ch. des Aulx, 1228 Plan-Les-Ouates, Geneva,Switzerland Email- Legal@Novimmune.com	TGTX Attention: Hari Miskin TG Therapeutics, Inc. 2 Gansevoort Street | 9th Floor New York, NY 10014 U.S.A. Email – hm@tgtxinc.com

14 INDEPENDENT CONTRACTOR

The relationship of TGTX and Novimmune under this Agreement is intended to be that of an independent contractor. Nothing contained in this Agreement is intended or is to be construed so as to constitute the Parties as partners or joint ventures or either Party as an agent or employee of the other. Neither Party has any express or implied right or authority under this Agreement to assume or create any obligations on behalf of or in the name of the other, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

15 COMPLETE AGREEMENT

The Parties hereto acknowledge that this Agreement sets forth the entire agreement and understanding of the Parties, and supersedes all prior written or oral agreements or understandings with respect to the subject matter hereof, including JV Agreement, but *excluding*:

(a) that certain Confidentiality Agreement between the Parties dated 15th February 2018 (the ***"Original Confidentiality Agreement"***), which shall remain in full force and effect in accordance with its terms; *provided, however,* that all "Confidential Information" (as defined by the Original Confidentiality Agreement) of Novimmune relating to its CD47/CD19 bi-specific antibody programs, shall be deemed Confidential Information for purposes of this Agreement; and

(b) In the event of any conflict between the provisions of this Agreement and the provisions of the Original Confidentiality Agreement, this Agreement shall control. No modification of this Agreement shall be deemed to be valid unless in writing and signed by both Parties

16 ASSIGNMENT

Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided*, *however*, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent: (a) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise (each, a ***"Change of Control Transaction"***), provided that in the event of a Change of Control Transaction in which the acquiring party is a Third Party, intellectual property rights of the acquiring party to such Change of Control Transaction that exist prior to the effective time of such Change of Control Transaction shall not be included in the technology licensed hereunder or otherwise subject to this Agreement; or (b) to an Affiliate, provided that no such assignment to an Affiliate shall relieve the assigning Party of its obligations hereunder. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

17 GOVERNING LAW AND DISPUTE RESOLUTION

17.1 English Language; Governing Law. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the Laws of the State of New York without giving effect to any choice of law principles that would require the application of the Laws of a different state.

17.2 Disputes.

(a) The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 17.2 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement. With respect to all disputes arising between the Parties, including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [29] (*) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the senior executive officers for each Party for attempted resolution by good faith negotiations within * (*) days after such notice is received. If the senior executive officers designated by the Parties are not able to resolve such dispute within such * (*) day period, either Party may submit such dispute in accordance with Section 17.2(b).

(b) Arbitration. Any dispute arising out of or relating to this Agreement, including the breach, termination or validity thereof, which has not been resolved by the executives of the Parties as provided herein will be finally resolved by arbitration in accordance with the CPR Rules for Non-Administered Arbitration then currently in effect, by three arbitrators of whom each party will appoint one in accordance with the 'screened' appointment procedure provided in Rule 5.4, provided, however, that if one party fails to participate in either the negotiation or mediation as agreed herein, the other party can commence arbitration prior to the expiration of the time periods set forth above. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., and judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof. The place of arbitration will be New York, NY. The award may be made a judgment by any court of competent jurisdiction pursuant to the New York Convention, 9 U.S.C. § 201 et seq., and for this purpose the Party against whom the award is made will agree to the personal jurisdiction of the court in which recognition is sought and will not raise any argument of forum non conveniens.

(c) Notwithstanding anything to the contrary in this Article 19, either Party may seek injunctive relief in any court in any jurisdiction where appropriate.

18 FORCE MAJEURE

18.1 Neither Party shall be liable for a failure to comply with a provision herein, if it is prevented from performing the said provision because of force majeure, this notion being defined as an event beyond the control of the Parties and independent from their will including, but not limited to, strikes or other labor trouble, war, insurrection, fire, flood, explosion, extreme weather and storms, discontinuity in supply of power, court order or governmental interference

18.2 Despite the event of force majeure, either Party hereto shall undertake reasonable efforts to comply to the extent possible with its obligations towards the other Party, pursuant to this Agreement.

18.3 The Party invoking an event of force majeure shall notify it forthwith to the other Party, and must specify which one or ones of its obligations it is being prevented from complying with, and the nature of force majeure, and must give an estimate of the period during which it is likely that it shall be prevented from complying with the said obligation or obligations

19 MISCELLANEOUS

19.1 If any provision of this Agreement should be or become fully or partly invalid or unenforceable for any reason whatsoever or should violate any applicable law, this Agreement is to be considered divisible as to such provision and such provision is to be deemed deleted from this Agreement, and the remainder of this Agreement shall be valid and binding as if such provision were not included therein. There shall be substituted for any such provision deemed to be deleted a suitable provision which, as far as is legally possible, comes nearest to the sense and purpose of the stricken provision

19.2 Failure by any Party to enforce any term or provision of this Agreement in any specific instance or instances hereunder shall not constitute a waiver by such Party of any such term or provision, and such Party may enforce such term or provision in any subsequent instance without any limitation or penalty whatsoever.

19.3 This Agreement is neither expressly nor impliedly made for the benefit of any entity other than the Parties.

19.4 The headings set forth in this Agreement are for convenience only and do not qualify or affect the terms or conditions of this Agreement. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

19.5 No waiver of any right or remedy hereunder shall be effective unless provided in writing executed by the waiving Party.

19.6 The agreement survives in case either Party is acquired or goes bankrupt.

19.7 This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement shall be binding upon the delivery by each Party of an executed signature page to the other Party by facsimile or electronic transmission. If signature pages are so delivered by facsimile or electronic transmission, each Party shall also immediately deliver an executed original counterpart of this Agreement to the other Party by courier delivery service.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date

TG THERAPEUTICS, INC.	**NOVIMMUNE SA**
Name: Title	Name: Title:
Date:	Date:

[8] Confidential material redacted and filed separately with the Commission.

[9] Confidential material redacted and filed separately with the Commission.

[10] Confidential material redacted and filed separately with the Commission.

[11] Confidential material redacted and filed separately with the Commission.

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[27] Confidential material redacted and filed separately with the Commission.

[28] Confidential material redacted and filed separately with the Commission.

[29] Confidential material redacted and filed separately with the Commission.

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Exhibit G

NI-1701 Study Reports & Mapping

[30]

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[30] Confidential material redacted and filed separately with the Commission.

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 quarterly report on Form 10-Q 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 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 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: August 9, 2018

/s/ Michael S. Weiss

Michael S. Weiss
Executive Chairman, Chief Executive Officer and President
Principal Executive Officer

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 quarterly report on Form 10-Q 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 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 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: August 9, 2018

/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 quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Chief Executive 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; 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: August 9, 2018

/s/ Michael S. Weiss

Michael S. Weiss
Executive Chairman, Chief Executive Officer and President
Principal Executive Officer

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 quarterly report of TG Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018 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; 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: August 9, 2018

/s/ Sean A. Power

Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer